Monitor

Making the health sector work for patients

Substantive guidance on the Procurement, Patient Choice and Competition Regulations

www.monitor.gov.uk

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 Regulations[1] 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 those 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 are intended to enable commissioners to decide for individual services what is best for patients. They adopt a principles-based approach and do not generally include prescriptive rules on how commissioners must carry out their procurement activities. It is for commissioners to decide what services to procure and how best to secure them in the interests of patients, within the framework of the regulations. Neither the regulations nor this guidance set out a preferred approach. Monitor's role is to ensure that commissioners have operated within the legal framework established by the regulations. Other than in relation to regulation 10 (anti-competitive behaviour), Monitor is only able to investigate if it has received a complaint.

The Procurement, Patient Choice and Competition Regulations also give Monitor 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] These requirements safeguard the rights of patients, set out in the *NHS Constitution,* to choose who provides their health care in certain circumstances.

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

[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).

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 for commissioners. We have tried to use straightforward language and have avoided quoting sections of the Procurement, Patient Choice and Competition Regulations and the Responsibilities and Standing Rules Regulations where possible. This means that we do not always use the exact wording from the regulations.

Monitor expects to follow the interpretation of the regulations 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 both sets of 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, choice and competition work well for patients.

This guidance is concerned with our role in ensuring that the commissioning of services, 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.

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

[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.

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]

1.2.2. What legislative requirements does the guidance cover?

This document provides guidance on how to comply with the Procurement, Patient Choice and Competition Regulations and the requirements relating to patient choice in the Responsibilities and Standing Rules Regulations.

It does not explain how to comply with other legislative requirements that commissioners may be required to comply with. However, the requirements in the Procurement, Patient Choice and Competition Regulations create a framework for decision making that will assist commissioners to comply with these other legislative requirements. They include:

- commissioners' duties under Chapters A1 and A2 of Part 2 of the National Health Service Act 2006;
- the Local Government and Public Involvement in Health Act 2007;
- the Equality Act 2010;
- the Public Contracts Regulations 2006, the Public Sector Directive (Directive 2004/18/EC) and general European Union (EU) law; and
- the Public Services (Social Value) Act 2012.

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.

[5] www.monitor.gov.uk

Guidance on how to comply with the Local Government and Public Involvement in Health Act 2007, the Equality Act 2010 and the Public Services (Social Value) Act 2012 is also available to commissioners.[6]

This document also does not provide guidance on compliance with the legislative requirements on choice and competition that **providers** are required to comply with and that Monitor enforces including:

- the competition and choice conditions in the NHS provider licence; and
- the Competition Act 1998 and the Treaty on the Functioning of the EU in so far as they apply to the health care sector.

Guidance on how to comply with those legislative requirements is available on Monitor's website.

1.2.3 Where can I find out more about Monitor's approach to enforcing the Regulations?

This document does not describe Monitor's approach to exercising its powers under the Procurement, Patient Choice and Competition Regulations, including the investigation procedures that we follow and the enforcement measures we might impose if we find that a commissioner has breached the rules.

For guidance on our approach to taking enforcement action, please see Monitor's *Enforcement guidance on the Procurement, Patient Choice and Competition Regulations*, available on our website.

1.3 Overview of the Regulations

The Procurement, Patient Choice and Competition Regulations create a framework for procuring NHS health care services that is designed to ensure that commissioners secure high-quality, efficient services that meet the needs of patients. The regulations also include requirements that are designed to protect patients' rights, set out in the *NHS Constitution,* to choose their health care provider and prohibit anti-competitive behaviour by commissioners unless this is in the interests of patients.

The regulations are structured as follows:

- Regulation 2 sets out the **objective** that commissioners must pursue whenever they procure NHS health care services. This objective is to secure the needs of patients who use the services and to improve the quality and efficiency of the

[6] Guidance on sections 116 and 116A of the Local Government and Public Involvement in Health Act 2007 is available here; guidance on the Equality Act 2010 is available here;and guidance on the Public Services (Social Value) Act 2012 is available here.

services, including though the services being provided in an integrated way (including with other health care services, health-related services or social care services).

- Regulation 3 sets out a number of **general requirements** that commissioners must comply with whenever they procure NHS health care services. Complying with these general requirements will help commissioners to achieve their overall objective in Regulation 2. Regulation 3 includes requirements:
    - to act transparently and proportionately, and to treat providers equally and in a non-discriminatory way;
    - to procure services from one or more providers that are most capable of delivering commissioners' overall objective and that provide best value for money;
    - to consider ways of improving services (including through services being provided in a more integrated way, enabling providers to compete and allowing patients to choose their provider); and
    - to maintain a record of how each contract awarded complies with commissioners' duties to exercise their functions effectively, efficiently and economically, and with a view to improving services and delivering more integrated care.
- Regulations 4 to 12 set out more specific requirements that commissioners must comply with. Complying with these requirements will help commissioners to comply with their overall objective in Regulation 2 and the general requirements in Regulation 3. Regulations 4 to 12 include:
    - requirements about where and how to publish a contract opportunity where a commissioner decides to advertise a contract;
    - a requirement to make arrangements for providers to express their interest in providing services;
    - a prohibition on awarding a contract for services where a conflict of interest affects or appears to affect the integrity of the contract award;
    - a prohibition on engaging in anti-competitive behaviour unless this is in the interests of people who use health care services;
    - a requirement to establish and apply transparent, proportionate and non-discriminatory qualification criteria;

- a requirement to ensure that those providing commissioning support and assistance act consistently with certain requirements in the regulations;
- a requirement to publish information about contracts that commissioners award; and
- various requirements to protect the rights of patients, set out in the *NHS Constitution,* to choose who provides their health care.

These rules provide a framework for commissioners when deciding what services their patients need and how to go about securing them. The framework is relevant whenever commissioners are awarding new contracts or making material variations to existing contracts.

It is for commissioners to decide, while acting within the framework of the regulations, what services to procure and how best to secure them in the interests of patients. The regulations do not require commissioners to follow a prescribed process every time they procure services.

We have set out below some of the key questions which flow from the regulations and that we would generally expect commissioners to address in order to be confident that they are securing high-quality, efficient services that meet patients' needs consistent with their overall objective under the regulations. The list of questions is not exhaustive, but covers some of the core issues that commissioners are likely to need to think about. Commissioners will need to consider what evidence they need to be able to answer these questions – what is required will depend on the circumstances.

Procuring services within the framework of the regulations: key questions commissioners should ask themselves

- What are the needs of the health care service users we are responsible for? Are those needs currently being met? Have they changed since services were last reviewed? What level of engagement with the local community, patients and patient groups, clinicians and others should we undertake?
- How good are current services? How can we improve them?
- How can we make sure that the services are provided in a more joined-up way with other services so that they are seamless from the perspective of the patient? How can we get the professionals that are responsible for different elements of a patient's care to work together more effectively for patients?
- Could services be improved by giving patients a choice of provider to go to and/or by enabling providers to compete to provide services?
- How can we identify the most capable provider or providers of the services? Is the current provider the only provider capable of providing the services?
- Are our actions transparent? Do people know what decisions we are taking and the reasons why we are taking them? Do we have appropriate records of our decisions?
- How can we make sure that providers have a fair opportunity to express their interest in providing services? What do we need to do to make sure that we do not discriminate against any providers?
- Are there any conflicts between the interests in commissioning the services and providing them? If so, how can we manage them to make sure that they do not affect or appear to affect the integrity of the award of any contract at a later point in time?
- Are our actions proportionate? Are they commensurate with the value, complexity and clinical risk associated with the provision of the services in question and consistent with our commissioning priorities?

Commissioners are required to comply with various other legislative requirements in addition to the requirements in the Procurement, Patient Choice and Competition Regulations. The regulations and these other requirements create a cohesive body of rules that are designed to ensure that commissioners act in patients' interests when carrying out their general functions. In particular, the regulations do not require commissioners to duplicate or take steps that are inconsistent with their other legal obligations.

For example, CCGs are required to prepare joint strategic needs assessments (JSNAs) with local authorities to identify the current and future health and social care needs of the population in their area.[7] They are also required to prepare joint health and wellbeing strategies (JHWSs) for meeting the needs identified in the JSNAs.[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 secure meet the needs of people who use the services, consistent with its objective under the regulations. In preparing JSNAs and JHWSs, commissioners must have regard to statutory guidance issued by the Secretary of State.[9] When considering a complaint about a procurement decision under the Procurement, Patient Choice and Competition Regulations, Monitor may, where relevant, look at the steps that the commissioner has taken in assessing the needs of its population and the services they need before deciding what services to buy. If a commissioner has acted consistently with relevant 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.

1.3.1 What services do the rules apply to?

The Procurement, Patient Choice and Competition Regulations apply to all health care services for the purposes of the NHS (including those that may also constitute adult social care services).

"Health care" includes all forms of health care, whether relating to physical or mental health.

The "NHS" for these purposes means the comprehensive health service designed to secure improvement in the physical and mental health of the people of England and in

[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 statutory guidance on JSNAs and JHWSs from the Department of Health available at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/223842/Statutory-Guidance-on-Joint-Strategic-Needs-Assessments-and-Joint-Health-and-Wellbeing-Strategies-March-2013.pdf

the prevention, diagnosis and treatment of physical and mental illness, but excludes the part of the comprehensive health service that is provided in pursuance of the public health functions of the Secretary of State or local authorities.

Pharmaceutical services (including local pharmaceutical services) under Part 7 of the National Health Service Act 2006 are expressly excluded from the scope of the regulations.

The regulations do not apply to the procurement of any other services or goods by commissioners, such as the procurement of commissioning support services.

1.3.2 Who do the rules apply to?

The Procurement, Patient Choice and Competition Regulations apply to all NHS commissioners – CCGs and NHS England. They do not apply to other organisations that may commission health care services on commissioners' behalf, or provide them with commissioning support or assistance.

Commissioners have ultimate responsibility for complying with the regulations, including where they have delegated responsibility for commissioning to a third party or relied on third party support or advice. Commissioners must therefore ensure that those third parties act in a way that enables the commissioners to comply with their own duties under the regulations. We consider some common scenarios below.

Local authorities

Local authorities are responsible for commissioning public health and social care services.

Commissioners may enter into a range of different arrangements with local authorities. These may include, for example, pooling funds with a local authority in order to commission services jointly or entering into a "lead" commissioning arrangement under which the local authority or commissioner leads the commissioning of certain services on behalf of the other.

The Procurement, Patient Choice and Competition Regulations do not apply to local authorities. However, a commissioner will need to ensure that where a local authority commissions health care services jointly with the commissioner or on the commissioner's behalf, the commissioner is able to fulfil its own obligations under the regulations. In practice, this means that the commissioner will need to ensure that the local authority acts in a way that is consistent with the regulations when it is procuring NHS health care services on a commissioner's behalf (for example, to ensure that health care services are procured from the most capable provider or providers).

Where a local authority is running a procurement process that is governed by the Public Contracts Regulations 2006 and/or general EU law and an interested party has concerns about whether the process is consistent with those rules, it should raise its concerns with the local authority. Any concerns over compliance with the Procurement, Patient Choice and Competition Regulations will only be relevant in so far as the procurement relates to NHS health care services and should be raised with the NHS commissioner.

"Prime" and "lead" provider models and sub-contracting

Commissioners may decide to award a contract for a set of related health care services to a "lead" or "prime" provider that is responsible for delivering some of the services itself and arranging for other providers to provide the remaining services. Providers may also independently decide to sub-contract the delivery of certain services to other providers.

The Procurement, Patient Choice and Competition Regulations do not apply to providers. However, a commissioner will need to be satisfied that it is complying with its obligations under the regulations if it decides to procure services through a "prime" or "lead" provider model. The commissioner will need to ensure that both the decision to adopt the model as a way of securing services and the process through which the "prime" or "lead" provider is chosen is consistent with these rules. The commissioner will need to consider what arrangements it should put in place to ensure that the way the "prime" or "lead" provider secures services from other providers enables the commissioner to be satisfied that the commissioner is compliant with the regulations.

Where a provider decides to sub-contract the provision of certain services to another provider, it will not be required to comply with the regulations. However, the commissioner will need to be satisfied that the decision to allow a provider to sub-contract services, and any safeguards around the exercise of the right to sub-contract, are consistent with the commissioner's obligations under the regulations.

Personal health budgets

A personal health budget is an amount of money identified by a commissioner for the purpose of securing a person's identified health and wellbeing needs. A personal health budget is planned and agreed between the person and their local NHS team. More information on personal health budgets is available here.[10] There are three options for managing personal health budgets:

- **making a direct payment for health care** – an individual or their representative has direct control over a personal health budget and contracts directly with providers or employs assistants directly. The making of a direct payment for health

[10] http://www.personalhealthbudgets.england.nhs.uk/Topics/Toolkit/

care is governed by regulations made under sections 12A(4) and 12B(1) to (4) of the National Health Service Act 2006;[11]

- **third party budgets** – a third party has control over the budget and arranges services on behalf of the individual; or

- **notional budgets** – the commissioner procures services funded by a personal health budget on behalf of an individual.

The framework of the regulations applies to a commissioner's decision that the best way to meet the needs of a patient is to use a personal health budget in the same way as it does to any other procurement decision. The commissioner will need to be satisfied that the use of the personal health care budget and the arrangements with the patient for how it should be spent enable it to comply with its own obligations under the regulations.

An individual may want to use part or all of their personal health budget to buy a particular health care service from a specific individual or organisation (for example, to fund a carer that the patient knows and trusts and is therefore best placed to provide that care). So long as these services are clinically appropriate for the individual and have been suitably planned and agreed between the individual and the NHS team responsible for administering the personal health budget, then using the budget to fund these services (regardless of the way in which this is achieved) is unlikely to be contrary to the regulations. In practice, the way in which decisions about what services to buy and from whom are reached – through detailed discussions about the individual's specific needs and how best to secure them with the funds available between the individual (or his representative) and the NHS team responsible for the budget – should mean that they are made in a way that is consistent with the framework established by the regulations.

Commissioning support units and other advisers

Commissioners may seek advice and support from a range of organisations when they procure services, including commissioning support units (CSUs).

The Procurement, Patient Choice and Competition Regulations do not apply to CSUs and other organisations that provide commissioning support. However, a commissioner that relies on third party support and assistance will need to put in place arrangements to ensure that they act in a way that is consistent with the regulations, so that the commissioner can be satisfied that it has complied with its own obligations under the regulations.

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[11] See section 12A(5) of the National Health Service Act 2006 for the meaning of "direct payment". See also the National Health Service (Direct Payments) Regulations 2013 (SI. 2013 No.1617), as amended by the National Health Service (Direct Payments) (Amendments) Regulations 2013 (SI. 2013 No.2354).

1.3.3 Structure of guidance

Section 2 provides guidance on how to comply with the procurement objective and general requirements.

Section 3 provides guidance on the factors that commissioners should take into account in deciding whether and how to publish new contract opportunities.

Section 4 provides guidance on how to establish and apply qualification criteria.

Section 5 provides guidance on keeping records.

Section 6 provides guidance on obtaining assistance and support when commissioning services.

Section 7 provides guidance on managing conflicts of interest.

Section 8 provides guidance on the analytical framework that Monitor will apply in assessing anti-competitive behaviour.

Section 9 provides guidance on how to secure patients' rights to choose who provides their health care.

Section 2: Guidance on the procurement objective and general requirements

2.1 Introduction

This section provides guidance on the objective that commissioners must pursue and the general requirements that they must comply with when procuring (ie, obtaining) NHS health care services set out in Regulations 2 and 3 of the Procurement, Patient Choice and Competition Regulations.

2.2 Procurement: objective

Regulation 2 of the Procurement, Patient Choice and Competition Regulations requires commissioners to act with a view to achieving the following objective when procuring NHS health care services:

- securing the needs of health care service users;
- improving the quality of services; and
- improving the efficiency with which services are provided.

Commissioners must pursue this objective whenever they procure NHS health care services. Many of the decisions that a commissioner takes during the commissioning cycle will have an impact on the quality and efficiency of the health care services that the commissioner ultimately secures and the extent to which they meet the needs of the health care users for which the commissioner is responsible. These may include, for example, decisions about what services to procure, whether to procure services individually or jointly with other services, how to go about procuring them, whether to procure them from one or more providers, and how to select that provider or providers. Commissioners will need to consider whether they are acting consistently with this objective whenever they take such decisions.

There is no one-size-fits-all approach to realising this objective. By adopting a principles-based approach, the Procurement, Patient Choice and Competition Regulations set commissioners a framework within which to decide on a case-by-case basis how to secure high-quality, efficient services that meet the needs of patients.

The needs of health care service users will differ service-by-service and area-by-area, depending on a range of factors including the nature of the service and the people who need it. We recognise that commissioners must be able to be responsive to those differences. There is also often more than one way of meeting a health care need and

many different steps that commissioners can take to improve the quality and efficiency of the services they obtain.

Regulation 2 makes it clear that one way in which commissioners should seek to secure the needs of health care service users and improve the quality and efficiency of services is through health care services being delivered in an integrated way, including with other health care services, health-related services or social care services (see Section 2.3.3 for a more detailed discussion of integrated care).

In addition, Regulation 3(4) of the Procurement, Patient Choice and Competition Regulations (also considered in more detail in Section 2.3.3) requires commissioners to consider whether services can be improved by being provided in a more integrated way, by enabling providers to compete to provide services and by allowing patients a choice of provider. Although commissioners must consider whether improvements can be achieved through such means, it is for commissioners to decide the extent to which they seek to achieve improvements through these and/or other means.

Commissioners should rely on relevant evidence when considering how best to secure the needs of the population for which they are responsible and how to improve services. What is appropriate will depend on the circumstances of the case, but may include consulting publicly on proposals, engaging with patients, patient groups, carers, local clinicians (including clinicians that provide the services being procured as well as those that provide related services) and other commissioners (including local authorities), seeking the views of out-of-area experts, and referring to relevant clinical guidelines and best practice.

It is for commissioners to decide how to secure the needs of the health care service users for whom they are responsible and how to improve the quality and efficiency of services those health care service users receive, based, for example, on their JSNAs and JHWSs, and consistent with the requirements of these regulations and other legal obligations with which they must comply. Where this is relevant to a complaint, Monitor's role is to determine whether the commissioner's evaluation of needs and its assessment of what services to secure to meet those needs is consistent with its objective in Regulation 2, not to substitute our own view of what patients need or what services should be procured, for that of the commissioner. Where a commissioner has acted consistently with relevant 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.

In acting with a view to achieving the objective in Regulation 2, there are a number of factors that a commissioner is likely to need to consider. The list in the box below is not

exhaustive, but covers some of the core factors a commissioner is likely to need to consider.

Acting with a view to securing the needs of patients and improving services: examples of factors a commissioner is likely to need to consider

- What steps the commissioner should take to evaluate and identify the health care needs of the population for which it is responsible, including the extent to which it should engage with the local community, patients and patient groups, clinicians and others, to ensure that the services it procures will help to secure those needs.
- How the commissioner can make sure that all the needs of health care users are met when it procures particular services, including their needs for related services to those being procured. These may include services that patients must be able to access from the same provider on the same site when they receive the services being procured or services that can be provided across a range of different settings by different providers.
- How the commissioner can secure the needs of all health care users for which it is responsible when procuring services, including:
    - what steps it might need to take to ensure equitable access to services by different groups of health care users (such as by vulnerable and socially excluded members of the population);
    - whether particular groups of patients have specific needs and how these can be addressed (for example, whether some patients need to receive a service in a particular setting); and
    - what steps the commissioner should take to address any potential impact that a procurement decision relating to one set of services may have on the continued availability of other services that health care users need (for example, whether it is not viable for a provider to provide a particular service that patients need without also providing a related service).
- What steps the commissioner should take to monitor the quality and efficiency of existing service provision and to identify any areas where improvements are needed or could be made in advance of procuring services.
- How the health care needs of the population can best be secured (including how the commissioner can ensure the safety of services, for example, where clinicians need to carry out sufficient volumes of particular services/or a particular case mix to deliver services safely) and how the quality and efficiency of services might be improved, including through:
    - the way the services are procured (for example, through a competitive tender process or otherwise);
    - the service specification and contract design (for example, through the use of quality and efficiency indicators); and
    - ensuring that the services being procured are delivered more effectively alongside other services (whether provided by different teams in a single organisation or across multiple organisations).

2.3 Procurement: general requirements

Regulation 3 of the Procurement, Patient Choice and Competition Regulations sets out general requirements that commissioners must comply with when procuring NHS health care services.

These include a requirement:

- to act in a transparent, proportionate and non-discriminatory way;
- to procure services from one or more providers that are most capable of achieving commissioners' objective in Regulation 2 and that provide best value for money; and
- to consider appropriate ways of improving services, including through services being provided in a more integrated way, enabling providers to compete to provide services and allowing patients a choice of provider.

Commissioners must comply with these requirements whenever they procure services. Regulation 3 also makes it clear that commissioners must comply with these general requirements when taking decisions that do not in themselves result in the award of a contract to provide services (for example, when deciding which providers to enter into a framework agreement with and selecting providers to bid for potential future contracts).

Each of the general requirements in Regulation 3 is considered in more detail below.

2.3.1 Transparency, proportionality and equality

Regulation 3(2) of the Procurement, Patient Choice and Competition Regulations requires commissioners:

- to act in a transparent way;
- to act in a proportionate way; and
- to treat all providers equally and in a non-discriminatory way.

Transparency

Commissioners must ensure that they conduct all of their procurement activities openly and in a manner that enables their behaviour to be scrutinised.

Transparency is fundamental to accountability. The requirement to act transparently is also closely linked to the requirement to treat providers equally.

In complying with its general duty to act transparently, there are a number of factors that a commissioner is likely to need to consider. The list in the box below is not exhaustive, but covers some of the core factors a commissioner is likely to need to consider.

Acting transparently: examples of factors a commissioner is likely to need to consider

- Whether the commissioner is acting openly, for example by providing reasons and evidence to support its decisions.
- What information the commissioner should publish on its future procurement strategy and intentions.
- How widely the commissioner should engage with different stakeholders, such as patients, carers, patient groups, clinicians and the local community before deciding what services to procure and how to procure them.
- What steps the commissioner should take to ensure that providers are aware of its intention to procure particular services, including by publishing contract opportunities.
- What feedback the commissioner should provide to any providers that have offered to provide services as part of a tender process, but have been unsuccessful.
- The content and level of detail that the commissioner should make available to relevant third parties, including how the commissioner can make the information accessible to the audience it is intended for.
- Whether the commissioner is publishing details of the contracts it awards in a timely manner.
- Whether the commissioner is maintaining suitable records of the key decisions that it has taken (including the reasons for those decisions).

Proportionality

Commissioners' actions must be proportionate to the value, complexity and clinical risk associated with the provision of the services in question. Commissioners should therefore consider whether to adapt their activities to take account of the nature of the services being commissioned.

In complying with its general duty to act proportionately, there are a number of factors that a commissioner is likely to need to consider. The list in the box below is not exhaustive, but covers some of the core factors a commissioner is likely to need to consider.

Acting proportionately: examples of factors a commissioner is likely to need to consider

- Whether the commissioner is allocating its resources in a way that is proportionate, including by developing appropriate commissioning priorities. More resources may be appropriate where greater benefits, cost savings or quality can be gained.
- How the commissioner can ensure that its approach to procuring services is commensurate with the nature of the services being procured in the following respects:
    - the process that it will use to procure services. In deciding whether a process for the procurement of a particular service would be proportionate, a commissioner might compare, for example, the level of resources that the commissioner and potential providers have to commit to the process with the value of the services being procured;
    - the criteria that it will require providers to satisfy to supply the services, including, for example, any financial thresholds that providers must satisfy or any clinical or financial criteria against which bids will be judged as part of a competitive tender process put in place by the commissioner. Financial criteria will be proportionate, for example, if they are necessary to ensure the stability of services; and
    - the information that it will require potential providers to supply and any due diligence process that it will require providers to undergo to be eligible to provide services.

Commissioners will need to strike a balance between making sure that their approach is not unduly onerous and ensuring that it is sufficiently robust to procure the services from those providers most capable of delivering high-quality, efficient services that meet the needs of patients.

Equality/non-discrimination

Commissioners must treat all providers equally and must not favour one provider (or type of provider including, for example, private, public, charity, voluntary and social enterprise) over another. Differential treatment between providers requires objective justification.

In complying with its general duty to treat providers equally and not to discriminate, there are a number of factors that a commissioner is likely to need to consider. The list in the box below is not exhaustive, but covers some of the core factors a commissioner is likely to need to consider.

Treating providers equally and not discriminating:
examples of factors a commissioner is likely to need to consider

- How the commissioner can ensure that no provider (including, for example, the current provider) is given a more extensive role in engaging with the commissioner on service design than other providers that would give that provider an unfair advantage. It is possible for one provider to have a more extensive role in service redesign without this being discriminatory. If, for example, an existing provider helps the commissioner to understand how services are currently provided and the commissioner uses the information to develop an appropriate specification, this is less likely to give rise to an unfair advantage than where an existing provider is asked to draft parts of the service specification. In the second scenario, a provider might gain an unfair advantage by specifying the services unduly narrowly or by specifying them with reference to how they are currently provided.

- What steps the commissioner should take to ensure that all potential providers that might be interested in providing a service being procured by the commissioner are given an adequate opportunity to express an interest in providing those services. Commissioners will need to consider what steps they need to take to identify providers that might be interested in providing the services being procured. In some circumstances, commissioners may be able to identify interested providers based on their knowledge of the market. In other circumstances, it may be necessary to advertise their intention to procure services.

- How to design the service specification so that it does not exclude a provider or category of provider unnecessarily and without objective justification.

- How to run any competitive tender process that the commissioner decides to put in place to select a provider or providers in a fair way, including, for example:

    - by adopting award criteria that are objectively justified and do not disadvantage a particular provider;

    - by applying award criteria equally to all providers and not, for example, waiving any criteria after the bidding process has started for the benefit of a particular provider;

    - by providing all potential bidders with the same information about the bidding process at the same time;

    - by requiring providers to submit their bids within the same deadline and not, for example, extending the deadline for the benefit of a particular provider; and

    - by asking providers to respond to the same or equivalent information requests, and sharing clarifications requested by one provider about the bidding process with all providers, where the questions and answers are of general relevance.

Equal treatment also requires commissioners to take into account relevant differences between providers. A difference will be relevant where it relates to the ability of a provider to deliver high-quality, efficient health care services that meet the needs of patients. For example, depending on the circumstances, a failure to take into account unresolved concerns raised by the Care Quality Commission (CQC) over the safety of particular services provided by one provider, but not by others, may amount to unequal treatment.

The National Health Service Act 2006 requires commissioners to promote health care research and to have regard to the need to promote education and training to future and existing employees involved in health care provision in England.[12] Commissioners will need to ensure that when they procure services they do so in a manner that is consistent with these statutory duties. Where a commissioner requires providers to take part in training, education and/or research as a condition of providing a service, and this is necessary to enable the commissioner to comply with these statutory duties, the unwillingness of some providers to do so will be a relevant basis on which to distinguish those providers from providers that are willing to do so (the NHS standard contract requires providers to provide continuous professional development for their employees). A commissioner that chooses to buy services only from those providers that agree to provide training and education and/or become involved in research in such circumstances will not be considered by Monitor to have breached the Regulations. However, the commissioner will need to ensure that the requirement to take part in education, training and research is transparent (see the beginning of Section 2.3.1 for guidance on the requirement to act transparently).

2.3.2 Procuring services from the providers most capable of delivering commissioners' objective and that provide best value for money

Regulation 3(3) of the Procurement, Patient Choice and Competition Regulations requires commissioners to procure NHS health care services from one or more providers that:

- are most capable of securing the needs of NHS health care service users and improving the quality of services and the efficiency with which they are provided; and
- provide best value for money in doing so.

In order to comply with this requirement, commissioners must ensure that when they enter into new contracts they do so with the most capable provider (or providers) that provides best value for money. A provider will provide best value for money where it delivers the best overall quality and price (where prices are not fixed, for example, under

[12] See s.13L, 13M, 14Y and 14Z of the National Health Service Act 2006 as amended by the 2012 Act.

the national tariff). The best value will not necessarily be delivered by the provider that supplies services at the lowest price.

Commissioners should also evaluate the performance of existing providers on an ongoing basis and should consider using the mechanisms included in the contract to address any underperformance. For example, if a provider is in breach of contract as a result of failing to satisfy quality requirements, a commissioner should consider what action it can take under the contract to address those concerns. Depending on the circumstances of the case, where underperformance continues and it appears that the provider is no longer best placed to provide the services in the interests of patients, it may be appropriate to consider terminating the arrangement where this is possible under the terms of the arrangement.

In complying with its general duty to procure services from the most capable provider or providers that deliver best value for money, a commissioner is likely to need to consider a range of factors. The list in the box below is not exhaustive, but covers some of the core factors a commissioner is likely to need to consider.

Procuring services from the most capable providers that provide best value for money: examples of factors a commissioner is likely to need to consider

- What steps the commissioner needs to take to identify existing and potential providers interested in and capable of providing the services being procured by the commissioner.
- How the commissioner can ensure that it objectively evaluates the relative ability of different potential providers to deliver the service specification and to improve quality and efficiency.
- What due diligence, if any, prospective providers should be required to undergo, as appropriate.
- The short-term and long-term impact of its commissioning decisions (including the potential effect of any procurement on the sustainability of services).
- The effect of bundling different services together where this is being considered, including, for example:
    - whether bundling may lead to better value for money through cost efficiencies resulting from providing more than one service;
    - whether bundling is clinically necessary or may give rise to clinical benefits (as a result of, for example, clinical interdependencies between different services); and
    - whether bundling will make the most capable provider or providers of a particular service ineligible to provide that service (because they do not provide all of the services in the bundle) thereby preventing patients from being able to access services from the best providers.

There may be advantages and disadvantages to bundling services in any given case. Commissioners will need to weigh these factors against one another in order to reach a decision on whether commissioning a given set of services as a bundle would be in patients' interests. If, for example, it is necessary for two services to be provided at a single site by one provider in order for one of those services to be delivered safely to patients, it will be appropriate for those services to be procured as a bundle. This will be the case even if it excludes from consideration a provider that is only able to provide one of the services. Before reaching a view that services need to be provided by a single provider, commissioners should consider whether it might be possible and in patients' interests for the services to be provided by several different providers operating from a single site.

2.3.3 Improving quality and efficiency – integrated care, choice and competition

Regulation 2 of the Procurement, Patient Choice and Competition Regulations requires commissioners to act with a view to securing the needs of NHS health care services users and to improving the quality and efficiency of services, including though the services being provided in an integrated way (including with other health care services, health-related services or social care services).

Regulation 3(4) of the Procurement, Patient Choice and Competition Regulations requires commissioners, when acting with a view to improving quality and efficiency, to consider appropriate means of making such improvements, including through:

- services being provided in a more integrated way (including with other health care services, health-related services or social care services);
- enabling providers to compete to provide services; and
- allowing patients a choice of provider.

The delivery of care in a more integrated way, competition between providers and patient choice can all play an important role in improving the quality of health care services and the efficiency with which they are provided.

We first consider in more detail what we mean by delivering care in an integrated way, by competition and choice, and then consider their role in improving quality and efficiency.

Definition of integrated care, competition and choice

Integrated care

Care and support is integrated when it is person-centred and co-ordinated. From a service user's perspective, care is delivered in an integrated way when "*I can plan my care with people who work together to understand me and my carer(s), allow me control, and bring together services to achieve the outcomes important to me*."

Many patients have complex health care needs and need to access a wide range of health, health-related and social care services. These services may be provided by one provider (such as where a person receiving inpatient treatment for cancer requires access to a range of different services from a single site such as oncology, radiology and pathology, and possibly a number of other services) or by a range of different providers in different settings (such as a person with dementia who may access services from their local GP practice, community nurses, voluntary services and social services). Patients may also need to transfer from a provider in one setting to another provider as their treatment progresses, such as where a person is discharged from a local hospital

following inpatient surgery and requires follow-up care from a community provider and their local GP.

Where care is provided to a patient by a number of teams from different disciplines (whether within a single organisation or across multiple organisations) there is a risk that the patient's care will be fragmented and that there will be gaps or delays. Physical distance between the locations at which related services are provided, and differences in working practices, culture, infrastructure and systems, can all contribute to the risk of fragmented care. There is no single model for addressing these challenges and ensuring that care is delivered in an integrated way. What unifies all models for the delivery of integrated care is that all of the different services accessed by a patient are delivered in a seamless way from the patient's perspective, regardless of whether they are provided by different professionals within an organisation or different organisations altogether.

Choice and competition

Competition and choice are closely related. Competition in the NHS typically takes one of two forms (although it can involve both):

- **Competition based on patient choice** occurs when patients can choose between more than one provider of the same or similar services. Depending on the circumstances, patients may be able to choose between different NHS organisations as well as third sector or independent providers. Patients will often be supported and advised by their GP or consultant when taking these decisions.

- **Competition for contracts to provide services** occurs when providers compete for the right to provide a particular service to patients in circumstances where a commissioner may choose one or a limited number of providers. Competition may arise, for example, where a commissioner runs a competitive tendering process to select a provider or where a commissioner is considering which providers to award contracts to in the context of a reconfiguration process.

Improving services, including the role of integrated care, competition and choice

It is for commissioners to determine ways of improving the quality and efficiency of NHS health care services, including the extent to which improvements can be achieved through services being provided in a more integrated way, by allowing patients a choice of provider and/or by enabling providers to compete for contracts to provide services.

In particular, the Procurement, Patient Choice and Competition Regulations do not require commissioners to extend patient choice beyond patients' rights to choice set out in the *NHS Constitution*, or to promote competition by increasing the number of providers of a service in an area.

For example, if a particular service (such as a community dementia service) is provided by a single provider in a local area, there is no requirement on the commissioner to introduce patient choice under the regulations (such as, by opening up the service to the

“any qualified provider model” or by entering into contracts with a small number of available providers in the area from whom patients can choose to receive treatment). When the arrangement with the existing provider comes to an end, however, the commissioner will need to ensure that the process that it adopts to choose a provider in the future is consistent with the requirements of the regulations.

Regulation 3(4) requires commissioners to consider whether introducing competition and choice, and ensuring care is delivered in a more integrated way could be used to improve quality and efficiency. Commissioners will need to be able to demonstrate that they have considered whether services might be improved through such means.

When care is delivered in an integrated way, it results in a better patient experience and may lead to improved clinical outcomes and more efficient health care (for example, by reducing duplication of patient assessments by different teams or providers, or by reducing the need for unnecessary health care interventions through better management of a patient’s long-term condition).

Competition between providers, whether to attract patients or to obtain contracts to provide services, can incentivise providers to improve both the quality of the services they provide and value for money. Competition can therefore give rise to a range of benefits for users of health care services, including improved clinical outcomes, safer health care and a better patient experience (as a result of, for example, better amenities and surroundings or through care being delivered in a more integrated way with other services).

What will work best for any given service will depend on the circumstances. For example, providers earn income for many elective services, based on the volumes of patients they treat. A provider’s income is therefore dependent on the number of patients they are able to attract. Patients may choose to go to particular providers for a range of reasons such as reputation, clinical outcomes and waiting times. Unless providers offer high-quality services, patients may choose to receive treatment at another provider. In some circumstances, extending choice may be an effective way of incentivising providers to improve the quality and efficiency of the services they provide. In other cases, extending choice may be impracticable or inappropriate.

Even where it is not practicable for a patient to exercise choice (such as for some emergency services) or where it would not be appropriate to offer patients choice, competition may still be able to play a role in improving services. Commissioners may be able to incentivise providers to offer higher-quality care and better value for money in

order to be chosen to provide services by running a competitive tendering process, for example. Commissioners can also create incentives for providers to maintain or improve quality, and value for money, where they regularly review service provision and/or competitively tender services, because of the possibility that the commissioner may terminate the contract and select another provider if service quality declines.

Relationship between choice, competition and integrated care

Choice, competition and integrated care are not mutually exclusive.

Competition (including competition based on patient choice) generally occurs between providers of the same or similar services (for example, providers of physiotherapy) who compete to be chosen to provide a particular service to a patient. Delivering care in an integrated way, however, generally requires *different* services to be provided to an individual patient in a seamless way.

A person with diabetes, for example, may require a wide range of different services including hospital-based care, GP services, mental health support, social care and community care (such as physiotherapy, dietician services, optometry and podiatry).

It is possible to design models of care for patients that enable competition between providers to provide services, allow patients a choice of a provider and deliver care to individual patients in an integrated way. In other cases, the effect of a model of care on choice, competition and integrated care will require careful consideration to establish what will achieve the best overall outcome for patients.

Many measures designed to improve the links between the different services that make up a patient's care to make it more seamless (for example, between a provider of mental health services and a patient's GP) can co-exist alongside competition between providers to deliver the individual services and patient choice. Measures might include, for example:

- encouraging multi-disciplinary meetings between the different professionals involved in the patient's care;
- the development of a care plan for the patient that covers all aspects of their care;
- improving physical transfers between sites (for example, the patient's discharge from hospital into the community); and
- more effective sharing of the patient's clinical records.

Some models for integrated care may involve the creation of an "integrated pathway" for all or a number of services that a patient requires. This might be structured in a number of different ways. For example, a commissioner may procure an integrated pathway from a

single provider responsible for delivering all aspects of the patient's care, or it might appoint a "lead" or "prime" provider that is responsible for delivering some of the services itself and arranging for other providers to provide the remaining services, or it might commission services from an "alliance" of providers that will work together to provide different elements of the patient's care. The extent to which these models are likely to deliver better integrated care and their impact on competition and choice will need to be considered by the commissioner on a case-by-case basis.

In practice, even where services are provided by a single provider or alliance of providers, consideration should still be given to how links between different services can be managed to ensure that the care the patient receives (which is likely to continue to be provided by different individuals from different disciplines, often in different settings) is well co-ordinated. It is possible that certain models may give rise to advantages that might otherwise be more difficult to achieve. For example, an organisation may have a single IT infrastructure across its sites giving clinicians from that organisation involved in the patient's care real-time access to the patient's records. However, any such advantages will need to be balanced against any disadvantages, such as any potential loss of choice for the patient over who provides individual elements of their care. Ultimately, the benefits and advantages of a potential model will need to be evaluated by the commissioner to decide what is in the interests of patients.

Where a commissioner decides to change which provider provides a particular service (for example, following a competitive tendering process or a more general review of existing service provision), the process should be designed to minimise any disruption to patient care. For example, contractual mechanisms should be used to ensure that the incoming provider is able to provide care seamlessly to patients from the start of the contract.

This might include, for example:

- making sure that the new provider has access to the information that it needs from the existing provider (such as patients' records and details of scheduled appointments) sufficiently in advance; and

- putting systems in place so that the new provider is built into any integrated pathways from the start (such as multi-disciplinary meetings with other providers providing related care to patients).

Allowing providers to compete for contracts to provide services need not therefore undermine the delivery of integrated care.

In complying with its general duty to consider appropriate means of improving the quality and efficiency of services including through competition, choice and the delivery of more

integrated care, there are likely to be a number of factors for a commissioner to consider. The list in the box below is not exhaustive, but covers some of the core factors a commissioner is likely to need to consider.

Considering how to improve services (including choice, competition and integrated care): examples of factors a commissioner is likely to need to consider

- What steps the commissioner might take so that services are delivered in a more integrated way with other health, health related and social care services that patients need. These might include:
    - requiring potential providers to demonstrate how different professionals that are responsible for particular aspects of an individual patient's care will co-operate with one another (where a provider provides more than one service) and how the provider will co-operate with third party providers that are responsible for other aspects of an individual patient's care. This could include, for example, requiring providers to submit plans detailing how they will organise patients' care where it involves individuals from multiple professional disciplines, share patient records effectively and manage transfers of patients to different wards or sites, etc;
    - requirements in its contracts with providers that oblige them to ensure that the different professionals and teams that are responsible for different aspects of an individual patient's care co-operate with one another (where the provider provides more than one service) and to co-operate with third party providers that are responsible for other aspects of an individual patient's care, for example by sharing patient records;
    - performance metrics in contracts with providers that are linked to the delivery of care in a more integrated way, such as reductions in unnecessary non-elective admissions and reductions in delayed discharges of patients from one setting to another; and
    - procuring services from a single provider where it is in patients' best interests for the services to be provided to patients from a single location by a single provider.
- Whether the commissioner can improve services by allowing patients a choice of provider, for example, by entering into contracts to provide a particular service with more than one provider, in order to incentivise providers to improve both quality and efficiency, in order to attract patients.
- What steps the commissioner should take to ensure that any change to the identity of a provider does not disrupt ongoing care to patients.
- The potential impact of the award of a contract to a single or limited number of providers on the availability of credible, alternative providers of those services in the future, when existing contracts end.
- The potential impact of a procurement decision on the availability of patient choice for particular services.

3: Guidance on publishing new contract opportunities for NHS health care services

3.1 Introduction

This section provides guidance on what factors commissioners should take into account in deciding whether and, if so, how to publish contract opportunities for NHS health care services.

There is no requirement in the Procurement, Patient Choice and Competition Regulations for commissioners to publish a notice inviting offers from prospective providers to supply NHS health care services (a contract notice) before awarding a contract to provide those services. The decision whether or not to publish a contract notice is a matter for commissioners having regard to the decision-making framework described in Section 1.3. This decision is not an isolated decision. It will need to be taken in the context of a commissioner's decisions about what services to procure and how to go about procuring them more generally.

The previous section examined the objective that commissioners must pursue and the general requirements that they must comply with when procuring services (Regulations 2 and 3). This objective and these requirements are relevant to the decision whether or not to publish a contract notice. For example, publishing a contract notice may be a way for a commissioner to identify the most capable provider (or providers) and to increase transparency around its actions. Conversely, publishing a contract notice may be unnecessary where, for example, only one provider is capable of providing the services in question.

In addition, Regulations 4 and 5 of the Procurement, Patient Choice and Competition Regulations contain specific requirements that commissioners must comply with that are relevant to the question of whether or not to publish a contract notice. These are:

- Regulation 4(4), which requires commissioners to make sure arrangements exist to enable providers to express an interest in providing any NHS health care services; and
- Regulation 5(1), which provides that commissioners can award a new contract to a single provider without publishing an intention to seek offers from providers where they are satisfied that the services are capable of being provided by only that provider.

Regulation 4 also contains specific requirements that commissioners must comply with, that are relevant to the question of how to go about publishing a contract notice where a commissioner decides to do so. These are:

- Regulation 4(1), which requires NHS England to maintain a website on which commissioners can publish:
    - opportunities for providers to provide NHS health care services; and
    - records of the contracts for NHS health care services that commissioners award to providers;
- Regulation 4(2), which requires commissioners to publish a contract notice on the website maintained by NHS England where they decide to publish an intention to seek offers from providers in relation to a new contract for the provision of NHS health care services; and
- Regulation 4(3), which establishes requirements about the content of that contract notice.

3.2 Deciding whether or not to publish an intention to seek offers for new contracts

There is no default process that commissioners should use to secure services. In particular, the Procurement, Patient Choice and Competition Regulations do not establish a competitive tender process as the default mechanism that commissioners should use to buy services. Commissioners need to consider on a case-by-case basis what the most appropriate way of procuring services is, having regard to the general principles that are set out in the Procurement, Patient Choice and Competition Regulations. This guidance gives commissioners a framework for taking such decisions.

There is no requirement in the Procurement, Patient Choice and Competition Regulations for commissioners to publish a contract notice before awarding a contract to provide those services.

When deciding how to procure services, including whether or not to publish a contract notice, commissioners will need to ensure that their decision is consistent with:

- their general objective, when procuring services, to secure the needs of people who use the services and to improve quality and efficiency including through the

services being provided in an integrated way (Regulation 2 of the Procurement, Patient Choice and Competition Regulations);

- the requirement to secure that arrangements exist to enable providers to express an interest in providing any NHS health care services (Regulation 4(4) of the Procurement, Patient Choice and Competition Regulations);

- the requirement to act transparently, proportionately and not to discriminate between providers (Regulation 3(2) of the Procurement, Patient Choice and Competition Regulations);

- the requirement to commission services from those providers that are most capable of securing the needs of health care service users and improving the quality and efficiency of services, and that provide the best value for money in doing so (Regulation 3(3) of the Procurement, Patient Choice and Competition Regulations); and

- the requirement to consider appropriate means of improving NHS health care services, including through enabling providers to compete to provide services (Regulation 3(4) of the Procurement, Patient Choice and Competition Regulations).

3.2.1 Commissioners need to make a balanced judgment, depending on local circumstances

Local circumstances vary, so the decision of how to go about procuring services (including, for example, whether to publish a contract notice) is a matter for commissioners, having due regard to the requirements of the Procurement, Patient Choice and Competition Regulations set out above. Commissioners need to make an informed and balanced judgment on the mix of factors relevant to their local circumstances. What is relevant will depend on the circumstances, but may include, for example: existing provider performance; ensuring service sustainability; delivering care in a more integrated way; whether there is likely to be more than one capable provider; whether providers have expressed an interest in providing the services or are likely to be interested in providing them; whether it would be beneficial to enter into a contract with one provider, several providers or all providers of the service; how much time has passed since services were last reviewed; and the value of the contract and the costs associated with running the different procurement processes being considered. Commissioners will need to balance the short-term and long-term impact of their commissioning decisions (including the potential impact of any procurement decision on the sustainability of services).

Where a commissioner does decide to publish a contract notice as a way of procuring services, it will need to consider what steps it should take to avoid any disruption to patient care if a new provider is selected as a result of the process. Examples of the sorts of steps that a commissioner might take are set out at Section 2.3.3 of this document.

These are examples of the mix of factors that commissioners need to consider when making balanced judgments, demonstrating that commissioners should only introduce competition where it is appropriate for local circumstances and in the best interests of patients. Many of these factors (such as delivering integrated care and ensuring service sustainability) will be relevant not only to the decision about what process to use to secure services, but to broader decisions about what services to procure and from whom. This guidance provides a framework for commissioners to take into account these factors within their particular context. Decisions about what process to use should not be taken in isolation from these other decisions.

3.2.2 Circumstances in which benefits for patients may be achieved by publishing a contract notice

Regulation 3(4) requires commissioners to consider whether services can be improved by enabling providers to compete to provide services.

Publishing a contract notice may help commissioners to improve the quality and efficiency of services in a number of ways.

Publishing a contract notice can help to identify those existing and potential providers that are interested in providing a service and to compare their relative ability to secure the needs of patients and to deliver high-quality, efficient care. This, in turn, can help commissioners to select the most capable provider (or providers) that provide the best value for money for the services in question.

Running a competitive tendering process can also encourage prospective providers to offer high-quality care and better value for money in order to win the contract. If a contract is negotiated with a single provider or subset of providers from the start, that benefit for patients may be lost.

3.2.3 Circumstances in which benefits for patients may not be achieved by publishing a contract notice

The decision whether or not to publish a contract notice is a matter for commissioners having regard to the decision-making framework described in Section 3.2 above.

There will be circumstances where a decision to procure services without publishing a contract notice and/or running a competitive tendering process will be appropriate and

consistent with the Procurement, Patient Choice and Competition Regulations. Three situations are considered in more detail below:

- Where there is only one provider that is capable of providing the services in question. In these circumstances, the Procurement, Patient Choice and Competition Regulations make it clear that a commissioner can award a contract to a single provider without publishing a contract notice.
- Where a commissioner carries out a detailed review of the provision of particular services in its local area in order to understand how those services can be improved and, as part of that review, identifies the most capable provider or providers of those services.
- Where the benefits of publishing a contract notice would be outweighed by the costs of doing so.

Acute elective care and other services where any qualified provider can provide services to patients

Different considerations will apply where patients are able to choose between any providers that satisfy a commissioner's quality criteria and are willing to provide services at the national or local tariff. For example, the *NHS Constitution* sets out the right for patients to choose, subject to certain exceptions, which provider to go to when they are referred for a first outpatient appointment for a service led by a consultant.

Where a commissioner does not restrict the total number of providers that appear on a list from which patients can choose to go to for a particular health care service, it will not need to run a competitive process to select providers (because subject to satisfying the commissioner's requirements on quality and price, all interested providers will be able to offer their services to patients). The commissioner will, however, need to ensure that the process through which a provider is able to become eligible to provide services is consistent with the framework established by the regulations. For example, consistent with Regulation 7, the commissioner will need to establish and apply transparent, proportionate and non-discriminatory qualification criteria and, where the health care service is a first outpatient appointment for elective care led by a consultant, the commissioner cannot refuse to add a provider to the list of providers from which patients can choose to go if the provider satisfies that criteria (see Section 4 for details). It will also need to be satisfied that the way it handles requests by providers to become accredited is consistent with the requirements of the regulations (including, for example its overall objective to procure high-quality, efficient services that meet patients' needs, the requirement to procure services from those providers most capable of delivering this objective and the requirement to act transparently, proportionately and to treat providers equally).

Once a provider has been qualified to offer its services to patients, a commissioner should not run a new process to re-qualify the provider when its contract with the provider comes to an end, unless there are specific reasons for doing so (for example, because the commissioner has already raised concerns as part of the contract management process that the provider is not meeting required quality standards, or because the commissioner has decided to change the quality criteria). If, for example, a provider of acute elective care wants to continue to offer services at the relevant tariff and the commissioner is satisfied that the provider continues to meet the necessary quality standards, it should simply extend or renew the contract.

(i) Single capable provider

Regulation 5(1) of the Procurement, Patient Choice and Competition Regulations provides that a commissioner may award a new contract without publishing a contract notice where the commissioner is satisfied that the services in question are capable of being provided only by that provider.

There may be a range of circumstances where only one provider is capable of providing NHS health care services being procured by a commissioner. This may be the case, for example, where the commissioner concludes that:

- only one provider has (or is able to develop) the necessary infrastructure and/or capacity to provide the services in question, such as where only one provider is capable of supplying A&E services in a particular area or where only one provider is capable of providing specialised services;

- it is necessary for services to be co-located in order to ensure patient safety as a result of clinical interdependencies between the services in question and there is only one provider that is able to provide all of the services (or that could develop the capacity to do so). The commissioner should consider, before arriving at this conclusion, whether it would be possible for some of the services to be provided by different providers from the same location;

- it is not viable for providers to provide one service without also providing another service (for example, because of the need to ensure a sustainable staff rota) and there is only one provider that is capable of providing both services (or of developing the capacity to do so); and

- there is only one provider that can meet an immediate, temporary clinical need. Such a need is only likely to arise in exceptional circumstances, for example, on clinical safety grounds such as where services have been suspended following regulatory intervention or in response to a major incident.

A commissioner should consider what steps it should take and what evidence it should rely on to satisfy itself that there is only one capable provider in assessing whether Regulation 5(1) is applicable.

In addition, Regulation 5(2) provides that a commissioner will not be treated as having awarded a new contract for the purposes of Regulation 5(1) in the circumstances described below. Where these circumstances apply, a commissioner will not be required to publish a contract notice:

- The first is where the rights and liabilities under a contract are transferred to a commissioner by the Secretary of State, a strategic health authority or a

primary care trust. This is intended to help to deliver a smooth transition from the commissioning of services by these organisations to the commissioning of services by CCGs and NHS England.

- The second is where NHS England changes the terms and conditions of commissioning contracts entered into by CCGs pursuant to Regulation 17 of the Responsibilities and Standing Rules Regulations. Any changes to terms and conditions that CCGs are mandated to make to their contracts by NHS England pursuant to this Regulation will not give rise to new contracts.

(ii) General review of service provision

A commissioner may decide to carry out a detailed review of the provision of particular services (for example, A&E services) in its local area in order to understand how those services can be improved in the interests of patients. The review may involve extensive public consultation and engagement with existing and potential providers and other stakeholders. Reviewing available services and providers in this way is good commissioning practice and something that commissioners should consider doing as a matter of course.

In the context of this review, the commissioner may be able to identify with reasonable certainty those providers that are capable of providing the services (or that are capable of developing the capacity/infrastructure to do so) and to determine which provider (or providers) are most capable of securing the needs of health care service users and of improving services, and represent best value for money. In these circumstances, it may be appropriate to negotiate directly with the providers in question.

Such a process should not be designed in order to avoid running a more formal process. The commissioner should also consider whether additional benefits could be gained through a more formal procurement process.

The commissioner will also need to ensure that its engagement with each of the prospective providers is consistent with its obligation to act transparently and to treat providers equally under the Procurement, Patient Choice and Competition Regulations. In particular, the commissioner will need to ensure that potential providers have a reasonable opportunity to express their interest in providing the services in question.

(iii) Proportionality

Commissioners are required under Regulation 3(2)(a) of the Procurement, Patient Choice and Competition Regulations to act in a proportionate way whenever they carry out any procurement activity.

In order to comply with Regulation 3(2), the process put in place by a commissioner to secure services must therefore be commensurate with the nature of the services being procured, including their value and the clinical risk associated with their provision.

The cost and complexity of running a competitive tendering process (including publishing a contract notice) can vary substantially. Tendering processes should be adapted to be commensurate to the value, complexity and clinical risk associated with the provision of the services in question. In some circumstances, the costs of running a competitive tendering process may be greater than the benefits of doing so. This may be the case, for example, where the contract is of low value and low clinical risk and designed to meet a short-term need for additional services.

However, commissioners will need to consider on a case-by-case basis whether the costs of a competitive process would outweigh the benefits that could be achieved, or whether the process could be adapted so that it both secures the benefits of a contested process and is proportionate to the nature of the services being procured.

Commissioners will also need to ensure that their actions are consistent with the requirement to act transparently and treat providers equally. For example, a commissioner might consider announcing its intention to award a contract without running a competitive tendering process on its website and https://www.supply2health.nhs.uk/, which would allow other providers to have a reasonable opportunity to express their interest in providing the services. In the event that the commissioner receives expressions of interest, it would need to consider what steps it should take to ensure that its engagement with providers is consistent with the requirement not to discriminate between providers. Depending on the circumstances of the case, this may or may not include running a competitive tendering process.

3.3 Content of contract notice

Where a commissioner decides to publish an intention to seek offers from providers in relation to a new contract for the provision of NHS health care services, Regulation 4(3) requires the commissioner to publish a contract notice containing:

- a description of the services to be provided; and
- the criteria against which any bids for the contract will be evaluated.

When publishing a contract notice, commissioners will also need to bear in mind the requirement in Regulation 3(2) of the Procurement, Patient Choice and Competition Regulations to act in a transparent way and to treat all providers equally. This will affect the level of detail commissioners should include on the services being commissioned and the criteria against which bids will be assessed and whether any additional information should be included in the contract notice. The information in the contract notice should be sufficient to enable providers to decide whether they are interested in providing the services in question and to make an offer to provide the services. Relevant information may include, for example, the place of delivery, the approximate value of the contract, the duration of the contract, any conditions to participation in the bidding process including any pre-qualification criteria and the procedure for awarding the contract.

3.4 Form of advertisement

Where a commissioner decides to publish an intention to seek offers from providers in relation to a new contract for the provision of NHS health care services, it must publish a contract notice on the website maintained by NHS England for this purpose, which is currently https://www.supply2health.nhs.uk/

4: Guidance on the qualification of providers

4.1 Introduction

This section provides guidance on how to establish and apply qualification criteria when choosing a provider.

Under Regulation 7 of the Procurement, Patient Choice and Competition Regulations, commissioners are required to establish and apply transparent, proportionate and non-discriminatory criteria when deciding which providers qualify for any of the following:

- to be included on a list from which a patient is offered a choice of provider (consistent with their rights set out in the *NHS Constitution*) for their first outpatient appointment with a consultant or a member of a consultant's team;
- to be included in a list from which a patient is otherwise offered a choice of provider (where a commissioner has decided to introduce choice for other services);
- to enter into a framework agreement with the commissioner; or
- to bid for future contracts.

Regulation 7 also prevents commissioners from refusing to qualify providers that meet the criteria they have set, except in limited circumstances.

Regulation 7 does not apply to the use of award criteria in the context of a competitive tendering process, which is governed by the objective in Regulation 2 and the general requirements in Regulation 3 of the Procurement, Patient Choice and Competition Regulations. However, many of the same considerations set out in this section will apply to establishing and applying award criteria in a manner that is consistent with Regulations 2 and 3.

Regulation 7 does not apply to the extent that providers are required to satisfy relevant criteria by virtue of other legislation.

4.2 Transparency

The qualification criteria established by a commissioner must be clear so that providers understand what requirements they must satisfy in order to qualify and what information they must provide to the commissioner as part of the qualification process.

In complying with its duty to establish and apply transparent qualification criteria, there are a number of factors that a commissioner is likely to need to consider. The list in the

box below is not exhaustive, but covers some of the core factors a commissioner is likely to need to consider.

Establishing and applying transparent criteria: examples of factors a commissioner is likely to need to consider

- Whether the commissioner is describing qualification criteria clearly and in sufficient detail to potential providers.
- Whether all the criteria that the commissioner intends to take into account when deciding whether providers qualify are being disclosed to providers in advance of the qualification process.

4.3 Non-discrimination

The qualification criteria established by a commissioner must not favour a particular provider or category of provider without objective justification. Once established, the criteria must be applied equally to all potential providers.

In complying with its duty to establish and apply non-discriminatory qualification criteria, there are a number of factors that a commissioner is likely to need to consider. The list in the box below is not exhaustive, but covers some of the core factors a commissioner is likely to need to consider.

Establishing and applying non-discriminatory criteria: examples of factors a commissioner is likely to need to consider

- Whether the criteria that the commissioner plans to adopt are objectively justified and do not favour one provider or category of provider over others unfairly (for example, criteria may be discriminatory where they take into account a provider's previous experience with the commissioner but not its previous experience with other commissioners).
- What due diligence it would be appropriate for the commissioner to carry out to ensure, for example, that providers that say they can provide equivalent or higher-quality care for less money are able to do so.
- If it is considering doing so, whether waiving certain criteria part way through its decision-making process would advantage a particular provider without objective justification.

4.4 Proportionality

The qualification criteria set by commissioners must be proportionate to the value, complexity and risk associated with the provision of the services in question. What is proportionate will also depend on what decision is being taken.

For example, where the criteria are intended to determine which providers qualify to be included on a list from which patients can choose their provider, the criteria might be more onerous than where they are designed to select the providers that will be eligible to bid for potential future contracts (and who will therefore have to go through a further selection process before being able to provide services to patients).

In complying with its duty to establish and apply proportionate qualification criteria, there are a number of factors that a commissioner is likely to need to consider. The list in the box below is not exhaustive, but covers some of the core factors a commissioner is likely to need to consider.

Establishing and applying proportionate criteria: examples of factors a commissioner is likely to need to consider

- Whether the financial or clinical criteria that the commissioner is proposing to apply are proportionate, given the nature of the services in question.
- Whether any due diligence process that the commissioner plans to require providers to undergo is commensurate with the services to be provided.

4.5 Rejection of qualifying providers

Under Regulation 7(3), commissioners must not refuse to include a provider on a list from which a patient is offered a choice for a first outpatient appointment with a consultant or a member of a consultant's team where the provider has satisfied the qualification criteria established by the commissioner.

Regulations 7(4), (5) and (6) recognise that commissioners may limit the total number of providers included on a list from which a patient is otherwise offered choice, the number of providers to enter into a framework agreement with and the number of providers that are eligible to bid for future contracts covered by the pre-qualification stage. Where a limit on the number of providers is exceeded, the commissioner will be entitled to refuse to qualify a provider for these purposes even if the provider has satisfied the relevant qualification criteria.

However, commissioners will need to ensure that any decision to limit the maximum number of providers is consistent with other requirements in the Procurement, Patient

Choice and Competition Regulations, including the duty to consider appropriate ways of improving quality and efficiency, including through allowing patients a choice of provider and enabling providers to compete to provide services (Regulation 3(4)) and the requirement to treat providers equally (Regulation 3(2)). Whether it is appropriate to limit the number of providers will depend on the circumstances of the case. It may be appropriate, for example, to limit the number of providers that a patient is able to choose to receive treatment from where there is evidence that higher caseload volumes result in better patient outcomes.

Under Regulations 7(4), (5) and (6), commissioners must not refuse to qualify providers that satisfy the criteria set by the commissioner for any other reasons.

Section 5: Guidance on record keeping

5.1 Introduction

This section provides guidance for commissioners on record keeping.

The Procurement, Patient Choice and Competition Regulations include a number of specific obligations about keeping records. Commissioners must:

- publish details of all contracts they award (Regulation 9(1) of the Procurement, Patient Choice and Competition Regulations);
- record how any conflicts of interest have been managed (Regulation 6(2) of the Procurement, Patient Choice and Competition Regulations); and
- maintain details of how a contract award complies with their duties relating to effectiveness, efficiency and improvement in the quality of services and the delivery of services in an integrated way in the National Health Service Act 2006 (Regulation 3(5) of the Procurement, Patient Choice and Competition Regulations).

These requirements are considered in further detail below (the requirement to record how any conflicts of interest have been managed is considered in further detail in Section 7).

More generally, commissioners must ensure that their record keeping is consistent with the requirement to act transparently in Regulation 3(2) of the Procurement, Patient Choice and Competition Regulations.

5.2 Publication of contract awards

Regulation 9(1) of the Procurement, Patient Choice and Competition Regulations requires commissioners to maintain and publish a record of all the contracts that they award on the website maintained by NHS England for this purpose. This is currently https://www.supply2health.nhs.uk/

This obligation applies to the award of any contract for NHS health care services.

Regulation 9(2) specifies certain information that this record must contain. This includes:

- the name of the provider to whom the contract has been awarded and the address of its registered office or principal place of business;
- a description of the services to be provided;

- the total amount to be paid under the contract, or where the total amount is not known, the amounts payable to the provider. For example, where services are remunerated on the basis of activity levels and the total level of activity is not known in advance, it may be appropriate for the commissioner to publish details of how payments are calculated under the terms of the contracts with providers;
- the dates between which the services will be provided; and
- a description of the process adopted for selecting the provider.

The Procurement, Patient Choice and Competition Regulations do not specify a time frame within which this information must be published. However, this should be as soon as possible and generally before the contract is implemented, consistent with the general duty of transparency.

Commissioners will also need to consider what steps they need to take to update this record to ensure its ongoing accuracy. This may include, for example, updating the record from time to time with details of the actual amounts paid to providers where payments are based on levels of activity.

5.3 Record of compliance with duties relating to effectiveness, efficiency and quality and the delivery of integrated care in the 2006 Act

Commissioners are required to exercise their functions effectively, efficiently and economically, and with a view to securing a continuous improvement in the quality of services for the prevention, diagnosis or treatment of illness.[13]

NHS England is additionally required to exercise its functions with a view to securing the continuous improvement in the quality of services for the protection or improvement of public health.[14]

Commissioners are also required to exercise their functions with a view to securing that health services are provided in an integrated way, including with health-related services or social care services, where they consider this would:

- improve the quality of health services (including outcomes);
- reduce inequalities between persons in their ability to access those services; or

[13] s.14Q and 14R (for CCGs) and s.13D and 13E (for NHS England) of the National Health Service Act 2006.
[14] s.13E of the National Health Service Act 2006.

- reduce inequalities between persons with respect to the outcomes achieved for them by the provision of those services.[15]

Regulation 3(5) of the Procurement, Patient Choice and Competition Regulations requires commissioners to maintain a record of how a contract award complies with these duties. The content and level of detail of this record will vary depending on the circumstances of the case. For example, more information is likely to be required for high value contracts than for lower value contracts. See box below.

[15] s.13N (for NHS England) and s.14Z1 (for CCGs) of the National Health Service Act 2006.

Examples of what information a record might contain

Commissioners should consider whether their record should include the following:

- the reasons for procuring the services in question;
- details of any engagement with patients, community groups, carers and other third parties before awarding the contract and how their views have been taken into account by the commissioner;
- the reasons for specifying the services in a particular way;
- the rationale for procuring a number of different services as a bundle and the composition of that bundle, if applicable;
- an analysis of how the services will be delivered in a way that is co-ordinated from the perspective of patients alongside other health care, health-related and social care services;
- details of the due diligence applied to the provider to whom the contract was awarded;
- the rationale for key terms of the contract, for example, quality requirements that the provider must satisfy, how performance will be assessed during the contract, the consequences of breaches, and the duration of the contract;
- the reasons for the procurement route chosen, for example, the reasons for any decision to procure the services through a single tender, through a formal competitive tender process, on an Any Qualified Provider (AQP) basis or otherwise;
- the basis on which the commissioner decided how to choose a provider including, for example, the decision on how to score bids in the context of a competitive tendering process;
- the reason for choosing to award the contract to the provider in question; and
- details of any analysis carried out by the commissioner of other potential providers.

Regulation 3(5) requires commissioners to record information about how the award of a contract complies with their duties under the National Health Service Act 2006. Commissioners will need to consider what information to publish in line with their general duty to act transparently.

Section 6: Guidance on assistance and support for commissioning

6.1 Introduction

This section provides guidance for commissioners on obtaining assistance and support when commissioning NHS health care services.

Regulation 8 of the Procurement, Patient Choice and Competition Regulations requires commissioners to ensure that any person that provides them with commissioning assistance or support in the exercise of their procurement functions acts in accordance with the requirements in Regulations 2, 3, 4(2) to (4), 5 to 7, 9 and 10 of the Procurement, Patient Choice and Competition Regulations.

6.2 Ensuring that contractors comply with the Regulations

Commissioners may decide to obtain support and assistance when carrying out their commissioning functions, including from new NHS commissioning support units (CSUs) or other sources of commissioning support, such as the independent or voluntary sectors. Support and assistance may be obtained for a range of different commissioning functions, such as service redesign, contract negotiation and information analysis.

Commissioners retain overall responsibility for ensuring that any procurement activity is consistent with the Procurement, Patient Choice and Competition Regulations, regardless of whether that activity is carried out by the commissioner or by any other person on the commissioner's behalf. However, it is up to commissioners to decide what, if any, external support and assistance to use. Regulation 8 requires commissioners to take steps to ensure that the person acts in accordance with the relevant requirements in the regulations.

In complying with its duty to ensure that any person providing it with commissioning support acts consistently with the relevant requirements of the regulations, there are a number of factors that a commissioner is likely to need to consider. The list in the box below is not exhaustive, but covers some of the core factors a commissioner is likely to need to consider.

Ensuring that contractors comply with the regulations: examples of factors a commissioner is likely to need to consider

- What steps it might be appropriate for the commissioner to take to evaluate the capability of the person providing support and assistance to provide services in accordance with the relevant regulations. What is appropriate will depend on the circumstances of the case, but may include requiring the person to demonstrate how the support they provide will be compatible with the regulations before entering into a contract with them.
- What measures it might be appropriate for the commissioner to put in place to ensure that the person acts in accordance with the relevant requirements in the regulations once their support services have been commissioned. What is appropriate will depend on the circumstances of the case, but may include:
    - requiring the person to report regularly on how their activities are compliant with the relevant requirements; and
    - including provisions in the contract with the person that give the commissioner the right to take remedial action if the person fails to comply with the relevant requirements (and invoking those provisions, as appropriate).

Section 7: Guidance on managing conflicts of interest

7.1 Introduction

This section provides guidance for commissioners on handling conflicts of interest.

Regulation 6(1) of the Procurement, Patient Choice and Competition Regulations prohibits commissioners from awarding a contract for NHS health care services where conflicts, or potential conflicts, between the interests involved in commissioning such services and the interests in providing them affect, or appear to affect, the integrity of the award of that contract.

Regulation 6(2) requires commissioners to maintain a record of how any conflicts that have arisen have been managed.

s.14O of the National Health Service Act 2006 includes further requirements relating to conflicts of interest. Guidance on how to comply with these requirements (including managing conflicts of interest) has been published by NHS England and is available on NHS England's website.

Members of commissioning organisations that are registered doctors will also need to ensure that they comply with their professional obligations, including those relating to conflicts of interest. These are described in the General Medical Council's guidance, *Good Medical Practice* and *Financial and commercial arrangements and conflicts of interest.* These are available on the General Medical Council's website.[16]

7.2 What is a conflict?

Broadly, a conflict of interest is a situation where an individual's ability to exercise judgment or act in one role is/could be impaired or influenced by that individual's involvement in another role.

For the purposes of Regulation 6, a conflict will arise where an individual's ability to exercise judgment or act in their role in the **commissioning of services** is impaired or influenced by their interests in the **provision of those services**.

[16] www.gmc-uk.org

7.3 What constitutes an interest?

Regulation 6 of the Procurement, Patient Choice and Competition Regulations makes it clear that an interest includes an interest of:

- a member of the commissioner;
- a member of the governing body of the commissioner;
- a member of the commissioner's committees or sub-committees, or committees or sub-committees of its governing body; or
- an employee.

Other interests that might give rise to a conflict include the interests of any individuals or organisations providing commissioning support to the commissioner, such as CSUs, who may be in a position to influence the decisions reached by the commissioner as a result of their role.

7.4 What interests in the provision of services may conflict with the interests in commissioning them?

A range of interests in the provision of services may give rise to a conflict with the interests in commissioning them, including:

- **Direct financial interest** - for example, a member of a CCG or NHS England who has a financial interest in a provider that is interested in providing the services being commissioned or that has an interest in other competing providers not being awarded a contract to provide those services. Financial interests will include, for example, being a shareholder, director, partner or employee of a provider, acting as a consultant for a provider, being in receipt of a grant from a provider and having a pension that is funded by a provider (where the value of this might be affected by the success or failure of the provider).
- **Indirect financial interest** - for example, a member of a CCG or NHS England whose spouse has a financial interest in a provider that may be affected by a decision to reconfigure services. Whether an interest held by another person gives rise to a conflict of interests will depend on the nature of the relationship between that person and the member of the CCG or NHS England. Depending on the circumstances, interests held by a range of individuals could give rise to a conflict including, for example, the interests of a parent, child, sibling, friend or business partner.

- **Non-financial or personal interests** - for example, a member of a CCG or NHS England whose reputation or standing as a practitioner may be affected by a decision to award a contract for services or who is an advocate or representative for a particular group of patients.
- **Professional duties or responsibilities.** For example, a member of a CCG who has an interest in the award of a contract for services because of the interests of a particular patient at that member's practice.

Commissioners will also need to consider whether any previous or prospective roles or relationships may give rise to a conflict of interest. A conflict of interest may arise, for example, where a person has an expectation of future work or employment with a provider that is bidding for a contract.

7.5 Conflicts that affect or appear to affect the integrity of an award

Even if a conflict of interest does not actually affect the integrity of a contract award, a conflict of interest that appears to do so can damage a commissioner's reputation and public confidence in the NHS. Regulation 6 of the Procurement, Patient Choice and Competition Regulations therefore also prohibits commissioners from awarding contracts in these circumstances.

As well as affecting the decision to award a contract and to which provider, a conflict of interest may affect a variety of decisions made by a commissioner during the commissioning cycle in a way that affects, or appears to affect, the integrity of a contract award decision taken at a later point in time. For example, conflicts of interest might affect the prioritisation of services to be procured, the assessment of patients' needs, the decision about what services to procure, the service specification/design, the determination of qualification criteria, as well as the award decision itself.

Conflicts might arise in many different situations. A conflict of interest might arise, for example where the spouse of a staff member of a local area team at NHS England is employed by a provider that is bidding for a contract. A conflict could also arise where a CCG is deciding whether to procure particular services from GP practices in the area or from a wider pool of providers, or where it is deciding whether to commission services that would reduce demand for services provided by GP practices under the NHS General Medical Services contract.

Depending on the circumstances of the case, there may be a number of different ways of managing a conflict or potential conflict of interest in order to prevent that conflict affecting or appearing to affect the integrity of the award of the contract.

It will often be straightforward to exclude a conflicted individual from taking part in decisions or activities where that individual's involvement might affect or appear to affect the integrity of the award of a contract. The commissioner will need to consider whether in the circumstances of the case it would be appropriate to exclude the individual from involvement in any meetings or activities in the lead up to the award of a contract in relation to which the individual is conflicted, or whether it would be appropriate for the individual concerned to attend meetings and take part in discussions, having declared an interest, but not to take part in any decision-making (not having a vote in relation to relevant decisions). It is difficult to envisage circumstances where it would be appropriate for an individual with a material conflict of interest to vote on relevant decisions.

Where it is not practicable to manage a conflict by simply excluding the individual concerned from taking part in relevant decisions or activities, for example because of the number of conflicted individuals, the commissioner will need to consider alternative ways of managing the conflict. For example, depending on the circumstances of the case, it may be possible for a CCG to manage a conflict affecting a substantial proportion of its members by:

- involving third parties who are not conflicted in the decision-making by the CCG, such as out-of-area GPs, other clinicians with relevant experience, individuals from a health and wellbeing board or independent lay persons; or
- inviting third parties who are not conflicted to review decisions throughout the process to provide ongoing scrutiny, for example the health and wellbeing board or another CCG.

Whether a conflict of interests affects or appears to affect the integrity of a contract award (such that the commissioner may not award the contract) will depend on the circumstances of the case. The list of factors in the box below is not exhaustive, but covers some of the core factors that a commissioner is likely to need to consider in deciding whether it is appropriate to award a contract. See box below.

Conflicts that affect or appear to affect the integrity of a contract award: examples of factors that a commissioner is likely to need to consider in deciding whether or not it can award a contract

- The nature of the individual's interest in the provision of services, including whether the interest is direct or indirect, financial or personal, and the magnitude of any interest.
- Whether and how the interest is declared, including at what stage in the process and to whom.
- The extent of the individual's involvement in the procurement process, including, for example, whether the individual has had a significant influence on service design/specification, has played a key role in setting award criteria, has been involved in deliberations about which provider or providers to award the contract to and/or has voted on the decision to award the contract.
- What steps have been taken to manage the actual or potential conflict (or example, via an external review of the decisions taken throughout the procurement process, including whether a conflict of a member of a CCG has been dealt with in accordance with the CCG's constitution).

7.6 Recording how conflicts have been managed

Regulation 6 of the Procurement, Patient Choice and Competition Regulations also requires commissioners to maintain a record of how any conflicts that have arisen have been managed.

Commissioners will need to include all relevant information to demonstrate that the conflict was appropriately managed. See box below.

Examples of what information a record might contain

Commissioners might include the following information in a record of how a conflict of interest has been managed:

- details of the individual who was conflicted and their role/position within the commissioner;
- the nature of their interest in the provision of services;
- when the individual's interest in the provision of the services being commissioned was declared and how;
- details of the steps taken to manage the conflict; and
- the individual's involvement in the procurement process, including, for example, the individual's involvement in the decision to reconfigure services and service design, attendance at meetings to discuss the proposed contract and involvement in the decision to award the contract.

Section 8: Guidance on assessing anti-competitive behaviour

8.1 Introduction

This section provides guidance to commissioners on the circumstances in which behaviour may be anti-competitive and contrary to the Procurement, Patient Choice and Competition Regulations.

Regulation 10(1) of the Procurement, Patient Choice and Competition Regulations prohibits commissioners from engaging in anti-competitive behaviour when commissioning services unless it is in the interests of NHS health care service users.

Regulation 10(2) clarifies that an arrangement for the provision of NHS health care services must not include any term or condition restricting competition that is not necessary for the attainment of intended outcomes which are beneficial for people who use such services or the objective in Regulation 2. This is because where restrictions of competition are not necessary to achieve such benefits, they are unlikely to be in the interests of health care service users.

8.2 What sort of behaviour is covered

The prohibition on anti-competitive behaviour applies to all types of behaviour that commissioners might engage in when commissioning NHS health care services, including agreements (for example, with a provider and/or another commissioner) as well as other action that the commissioner engages in alone. It is not necessary for an agreement to be legally binding for Regulation 10 to apply – informal agreements and understandings are also subject to the prohibition.

8.3 When will behaviour be anti-competitive and not in the interests of users of health care services?

Where a commissioner's conduct is in the interests of patients, its behaviour will not be inconsistent with the prohibition on anti-competitive behaviour in Regulation 10.

In assessing whether or not anti-competitive behaviour is in the interests of health care service users, Monitor will first consider the impact of the behaviour on competition.

We will assess whether the behaviour affects competition in a way that gives rise to an adverse effect for patients by removing or materially reducing the incentives on providers to provide high-quality services, provide value for money and/or improve services.

If it does, we will consider whether it also gives rise to benefits that could not be achieved without the restriction on competition.

Monitor will then consider whether any benefits outweigh any adverse effects from the loss of competition in order to establish whether the behaviour is in the overall interests of patients.

This analysis is described in more detail below.

Assessing the effect on competition

Monitor will consider whether the behaviour affects competition in a way that removes or materially reduces the incentives on providers to provide high-quality services, provide value for money and/or improve services. In carrying out this assessment we may consider, among other relevant factors:

- the nature of the restriction on competition (for example, whether the behaviour limits the extent to which particular providers compete or eliminates competition between them altogether);
- the number of providers of a particular health care service that are affected by the commissioner's conduct and their importance as suppliers of that service. For example, anti-competitive conduct is likely to have more impact where it affects competition between all the major providers of a service in an area than where it only affects competition between a sub-set of providers in the area that jointly only provide a small proportion of those services;
- the extent to which those providers affected by the conduct are close alternatives. Monitor may consider GP referral patterns, the geographic proximity of the providers and any evidence of patients switching between different providers in the past in making this assessment. For example, conduct that restricts competition between the two main providers of a service in a city centre is likely to have a greater impact than conduct that affects competition between providers that are in different cities and only compete to a limited extent; and
- the expected duration of the conduct or its effects. The longer the duration of the anti-competitive conduct or its effects, the greater its likely impact.

Assessing benefits

Monitor will also consider whether the behaviour gives rise to any material benefits to users of NHS health care services, such that the behaviour would be considered to be in the interests of health care service users.

Regulation 10(1) of the Procurement, Patient Choice and Competition Regulations includes the following non-exhaustive list of ways in which benefits might arise from anti-competitive behaviour:

- by the services being provided in an integrated way (including with other health care services, health-related services or social care services); and
- by co-operation between providers in order to improve the quality of services.

Benefits can arise in a number of different ways. In addition to improvements in quality through co-operation and the delivery of care in an integrated way, benefits may arise as a result of improvements in efficiency that lead to better value for money. Behaviour may result in better value for money for a number of different reasons, for example, through a reduction in duplicated patient assessments, etc.

Improvements in quality may consist of clinical or non-clinical improvements:

- **clinical benefits** may include a variety of improvements that lead to better patient outcomes (for example, by increasing the number of patients treated by a provider where higher patient volumes result in better outcomes); and
- **non-clinical benefits** may include a range of improvements such as better patient experience, better access for patients (for example, longer and/or more convenient opening hours, improved surroundings or better amenities).

Monitor will expect commissioners to be able to identify and describe the benefits to health care service users that arise from any anti-competitive conduct and to provide any relevant supporting evidence. In deciding what value should be attributed to claimed benefits, Monitor will consider all relevant factors including, for example:

- the materiality of the benefits submitted, including the nature and the extent of the benefit for patients and the number of patients that benefit from the conduct;
- the period of time over which the benefits will be realised. The quicker that the benefits will be realised the greater the weight that will be given to them; and
- the robustness of the analysis and evidence that supports the claimed benefits (in considering clinical benefits, Monitor will have particular regard to supporting research and evidence about clinical improvements).

Any restrictions on competition must be necessary to achieve the benefits, if those benefits are to be taken into account when considering whether the restriction is in the overall interests of patients.

Monitor will therefore consider the extent to which any benefits claimed could be realised without the restriction on competition.

A restriction on competition may be necessary to the attainment of the benefits claimed where the benefits can be achieved more quickly or more cost effectively as a result of the restriction on competition. In these circumstances, Monitor will consider the extent to which achieving the benefits more quickly or cost-effectively outweighs the cost resulting from the reduction in competition as part of its cost/benefit analysis (see next section).

Assessing whether the restriction on competition is in patients' interests

Monitor will then consider whether the benefits of the anti-competitive behaviour outweigh any reduction in competition.

If the benefits outweigh the reduction in competition, and those benefits could not be attained without the restriction on competition, the behaviour will be in the interests of users of health care services. If the reduction in competition is not outweighed by the benefits, or if the restrictions on competition are not necessary to achieve the benefits, the behaviour will not be in the interests of users of health care services.

This is not a mathematical exercise, but a qualitative assessment. Relevant benefits might outweigh the restriction on competition when, for example, as a result of a commissioner's actions there is a reduction of competition between a small number of providers, but a significant number of other providers of the relevant services remain and the clinical benefits of the initiative are significant and well evidenced.

Examples of conduct that may be anti-competitive and not in patients' interests

In deciding whether a commissioner has engaged in anti-competitive behaviour that is not in the interests of NHS health care service users, Monitor may consider, for example, whether a commissioner:

- has **prevented a provider from entering or caused it to exit the market**, for example, by agreeing with a provider and/or another commissioner not to contract with a new or existing provider without any objective justification. A commissioner will not have breached Regulation 10 where, consistent with the other requirements of the Procurement, Patient Choice and Competition Regulations, it decides not to award a contract to a provider because there are other providers that are more capable of meeting patients' needs and providing high-quality, efficient services and this results in the provider not being able to enter the market or exiting it;

- has **limited the extent to which existing providers are able to compete to attract patients**. This might be the case, for example, if the commissioner limits the total number of patients a provider can treat or the income a provider can earn, or restricts the providers to whom a provider can refer patients for further treatment, without objective justification. Requiring a provider to refer certain categories of patients to particular providers and not others may be objectively justified, for example, where the other providers do not provide the type of treatment that is most clinically appropriate for those categories of patients;

- has **restricted the ability of existing providers to differentiate themselves to attract patients**. This might be the case, for example, if the commissioner imposes minimum waiting times that providers must have or restricts the opening hours of providers without objective justification. A restriction may be objectively justified, for example, where a provider is seeking to differentiate itself in a way that affects the safety of patients or reduces the efficacy of treatment that patients receive; and

- has **reduced the incentives on existing providers to compete**, for example, by disclosing commercially sensitive information belonging to one provider to a different provider without objective justification. This could include, for example, disclosing that a provider intends to stop providing certain services, reduce its capacity or limit its investment in research or technology or revealing that the provider does not intend to bid for a contract that the commissioner has just put out to tender. Disclosing a provider's intention to stop providing services or reduce capacity might be objectively justified, for example, if it is necessary to make arrangements to transfer patients who are part way through treatment to the other provider to ensure their continuity of care. Arrangements to share best practice, including best clinical practice, between providers are unlikely to breach Regulation 10.

As explained above, Regulation 10(2) clarifies that an arrangement for the provision of NHS health care services must not include any term or condition restricting competition that is not necessary for the attainment of relevant benefits. Any term or condition restricting competition that is necessary to achieve benefits (including, for example, with respect to its duration and the range of services to which it applies) will not breach Regulation 10(2).

8.4 Relationship between Regulation 10 and other Regulations

The requirements in the Procurement, Patient Choice and Competition Regulations (including Regulation 10) are designed to ensure that commissioners secure high-quality, efficient health care services that meet the needs of patients. Actions by a commissioner that do not meet this objective may breach several Regulations at once (including Regulation 10).

In theory it is possible that any action by a commissioner that will impact on competition between providers could be assessed under Regulation 10.

However, as explained in Section 1 (see Section 1.3), the Procurement, Patient Choice and Competition Regulations create a framework for decision-making that requires commissioners to take into consideration a number of different factors when deciding what services to procure and how to procure them.

Where a commissioner has taken a procurement decision in accordance with this framework, it is unlikely that conduct that flows from that decision would breach Regulation 10 (because competition and patients' interests will have been taken into account in reaching the decision, consistent with Regulation 3(4)).

Consequently, unless there are specific reasons for taking a different approach, Monitor will usually review decisions about what services to procure and the process through which they are procured by reference to the other requirements in the Procurement, Patient Choice and Competition Regulations rather than Regulation 10.

In general, we will review conduct under Regulation 10 where a commissioner has engaged in other types of behaviour that restricts competition that is not in patients' interests (as illustrated in the examples above).

Examples of the types of procurement decisions we are unlikely to investigate under Regulation 10

Decisions about whether to procure services by way of a competitive tendering process.

Deciding whether to run a competitive tendering process is a matter that will need to be determined by reference to a number of other Regulations that regulate the way commissioners procure services: Regulation 2 (general objective to secure the needs of patients and improve services); regulation 3(2) (duty to act transparently and proportionately and to treat providers equally); regulation 3(3) (duty to procure services from the most capable provider or providers); regulation 3(4) (b) and (c) (duty to consider whether services can be improved by enabling providers to compete to provide services and/or by allowing patients a choice of provider) and regulation 4(4) (requirement to put in place arrangements so that providers can express an interest in providing services). So long as a commissioner has complied with these other requirements, it is unlikely that we would also investigate a commissioner's conduct by reference to Regulation 10.

Decisions about the number of providers to enter into a contract with.

Regulation 3(4) specifically requires commissioners to consider whether they can improve service quality and efficiency by enabling providers to compete and by allowing patients a choice of provider. Whenever they consider how many providers to enter into contracts with, commissioners will need to consider the impact of their decision on quality and efficiency. So long as a commissioner has done so, it is unlikely that we would also investigate the commissioner's conduct by reference to Regulation 10.

Treating providers equally during a procurement process

Commissioners are specifically prohibited from discriminating between providers under Regulation 3(2) when procuring services. So long as the commissioner has complied with Regulation 3(2), it is unlikely that we would also investigate the commissioner's conduct by reference to Regulation 10.

Section 9: Guidance on securing patients' rights to choose their provider

9.1 Introduction

This section provides guidance on the requirements that commissioners must comply with on patient choice.

Commissioners are required to comply with a number of requirements relating to patient choice under the Procurement, Patient Choice and Competition Regulations. The Procurement, Patient Choice and Competition Regulations also give Monitor the power to take action to prevent and/or remedy breaches by commissioners of certain requirements relating to patient choice in the Responsibilities and Standing Rules Regulations. They include:

- a requirement to consider appropriate means of improving services, including through allowing patients a choice of provider (Regulation 3(4) of the Procurement, Patient Choice and Competition Regulations);
- a prohibition on NHS England from placing certain restrictions on the ability of a person to choose their primary health care provider (Regulation 11 of the Procurement, Patient Choice and Competition Regulations);
- a requirement to put in place arrangements to ensure that patients are offered certain choices when they need elective care (Regulations 39 and 43 of the Responsibilities and Standing Rules Regulations);
- a requirement to put in place arrangements to ensure that patients are offered a choice of alternative providers in certain circumstances where they will not receive treatment within maximum waiting times (Regulation 12 of the Procurement, Patient Choice and Competition Regulations); and
- a requirement to put in place arrangements to publicise and promote certain information about choice (Regulation 42 of the Responsibilities and Standing Rules Regulations).

The rest of this section considers these requirements in more detail (Section 2 includes further detail on compliance with the requirement in Regulation 3(4) of the Procurement, Patient Choice and Competition Regulations).

9.2 Patient choice and primary care

The *NHS Constitution* sets out health care service users' right to choose their GP practice and to be registered by that practice unless there are reasonable grounds for refusal. The

constitution also gives patients the right to express a preference for seeing a particular doctor within their GP practice and requires the practice to try to comply.

Regulation 11 of the Procurement, Patient Choice and Competition Regulations is designed to protect these rights of choice by prohibiting NHS England from restricting the ability of a person:

- to apply for inclusion in the list of patients of a primary care provider of that person's choice; and
- to express a preference to receive treatment from a particular medical practitioner (or class of medical practitioner) at the primary care provider either generally or in relation to any particular condition.

This requirement does not prevent NHS England from including in its contracts with primary care providers provisions that allow providers to refuse to include a person in their patient list or to refuse a request to receive treatment from a particular practitioner at the practice in accordance with Part 2 of Schedule 6 to the National Health Service (General Medical Services Contracts) Regulations 2004; Part 2 of Schedule 5 to the National Health Service (Personal Medical Services Agreements) Regulations 2004 or arrangements made under section 83(2) of the National Health Service Act 2006.

9.3 Patient choice and elective care

9.3.1 Elective care: first outpatient appointment

The *NHS Constitution* sets out the right for patients to choose the organisation that provides their treatment when they are referred for a first outpatient appointment for a service led by a consultant, subject to certain exceptions.

Part 8 of the Responsibilities and Standing Rules Regulations underpins this right. Regulation 39 requires commissioners, subject to certain exceptions, to make arrangements to ensure that patients are offered the following choices:

- where a patient requires an elective referral, for a first outpatient appointment with a consultant or a member of a consultant's team, the choice of:
    - any clinically appropriate provider that has a contract with a commissioner; and
    - any clinically appropriate named consultant-led team employed or engaged by that provider; and

- where a patient requires an elective referral for mental health services, for a first outpatient appointment with a health care professional or member of a health care professional's team, the choice of:
    - any clinically appropriate, named health care professional-led team that is employed or engaged by the provider to which the patient is referred.

Regulation 39 also requires a commissioner to make sure that arrangements exist so that a patient is offered these choices when the commissioner is notified that the patient was not offered choice on initial referral.

These requirements do not apply to certain categories of services or to certain categories of patients (Regulation 41):

- **Excluded services**: the obligation to offer choice does not apply to any service where it is necessary to provide urgent care and does not apply, in respect of a first outpatient appointment with a consultant or a member of a consultant's team, to cancer services subject to a two-week maximum waiting time, maternity services or mental health services.

- **Excluded patients**: the obligation to offer choice does not apply to any person detained under the Mental Health Act 1983, detained or on temporary release from prison or serving as a member of the armed forces.

Regulation 43 of the Responsibilities and Standing Rules Regulations makes transitional provisions for patients who required an elective referral before 1 April 2013, but who had not received treatment and had not been offered a choice of provider by that date.

These transitional provisions require commissioners to ensure that such patients are offered a choice of any clinically appropriate provider for their first outpatient appointment with a consultant or a member of a consultant's team in accordance with the Primary Care Trusts (Choice of Secondary Care Provider) Directions 2009 (Directions). The Directions formed the legal basis for the right to choice in the *NHS Constitution* in respect of a first outpatient appointment before being replaced by the Responsibilities and Standing Rules Regulations.

From 1 April 2014, commissioners will also need to make arrangements to ensure that where a patient requires an elective referral for mental health services, the patient is offered the following choices in respect of their first outpatient appointment:

- the choice of any clinically appropriate provider that has a contract with a commissioner; and

- the choice of any clinically appropriate team led by a named consultant (for an appointment with a consultant or a member of a consultant's team) or team led by a named health care professional (for an appointment that is not with a consultant or a member of a consultant's team) that is employed or engaged by that provider.[17]

9.3.2 Elective care: maximum waiting times

The *NHS Constitution* sets out the right for patients to access services within maximum waiting times and for the NHS to take all reasonable steps to offer a range of suitable alternative providers if this is not possible. Regulation 12 of the Procurement, Patient Choice and Competition Regulations is designed to protect this right of choice where maximum waiting times are not going to be met.

Regulation 12 requires commissioners to offer patients choice in accordance with Regulation 48(4) of the Standing Rules and Responsibilities Regulations.

Regulation 48 applies where a patient who has been referred for elective care will not have commenced treatment within 18 weeks of a referral being received by the provider to whom the patient is referred. Under Regulation 48 of the Responsibilities and Standing Rules Regulations, commissioners are required to take all reasonable steps to ensure that the patient is offered an appointment with a clinically appropriate alternative provider with whom a commissioner has a contract to start treatment earlier.

If there is more than one suitable alternative provider for these purposes, Regulation 48(4) of the Standing Rules and Responsibilities Regulations requires the commissioner to take all reasonable steps to ensure that the patient is offered a choice of appointment with more than one provider.

There are a number of exceptions to the duty to offer a patient an appointment with an alternative provider and to offer a choice of alternative providers where more than one suitable provider exists.[18] These apply where:

- the patient did not attend their appointment with the provider in circumstances where the date for the appointment was reasonable, the patient was aware of the consequences of missing the appointment and the patient had not sought to re-arrange the appointment;

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[17] See The National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) (Amendment) Regulations 2013 (SI. 2013 No.2891) which amend the Responsibilities and Standing Rules Regulations (see in particular Regulation 4).
[18] See Regulation 49 of the Responsibilities and Standing Rules Regulations.

- the patient did not attend a re-arranged appointment with the provider in circumstances where the patient had re-arranged the appointment, the original date for the appointment was reasonable and the patient was aware of the consequences of missing the appointment;
- the patient has chosen to delay starting treatment until after the maximum 18-week waiting period has expired in circumstances where the patient was offered a reasonable appointment date within the 18-week period and decided that they did not want an appointment within that period;
- the patient has decided not to start treatment;
- the patient is not able to start treatment for reasons unrelated to the provider or the commissioner and in circumstances where the patient was offered a reasonable appointment date within the maximum 18-week waiting period, and was unable to make any appointment dates within that period;
- a consultant, a member of a consultant's team or a person providing interface services has determined that it is in the best clinical interests of the patient not to start treatment within the maximum 18-week waiting period, that the patient does not need treatment, or that the patient should be referred back to a primary care provider before any treatment is started;
- a consultant, a member of a consultant's team or a person providing interface services has determined that the patient requires a period of monitoring;
- the patient is placed on the national transplant waiting list; or
- the patient is referred for maternity services.

9.3.3 Elective care: duty to promote information about choice

The *NHS Constitution* sets out a requirement for patients to be given information to support their right to choice.

Regulation 42 of the Responsibilities and Standing Rules Regulations underpins this right by requiring commissioners to make arrangements to ensure that the availability of choice is publicised and promoted to patients.

This includes a requirement to make arrangements for publicising and promoting awareness of information about health care providers, consultant-led teams and teams led by health care professionals providing mental health services to enable patients to exercise their rights to choice under Regulation 39 of the Responsibilities and Standing Rules Regulations in a meaningful way.

Commissioners are also required to make arrangements for publicising details and promoting awareness of where that information may be found.

Safeguarding rights to choice under the NHS constitution: factors a commissioner is likely to need to consider

In complying with the various obligations enforceable by the Procurement, Patient Choice and Competition Regulations relating to patient choice, commissioners are likely to need to consider a range of factors. The following list is not exhaustive:

- whether the contracts that the commissioner enters into with providers responsible for making elective referrals impose positive obligations on providers to offer patients the relevant choices safeguarded by these regulations;
- what arrangements the commissioner should put in place to ensure that health care service users are aware of their rights of choice;
- the extent to which it would be appropriate for the commissioner to monitor the extent to which patients are offered choice by providers in practice. This might include, for example, reviewing the extent to which "choose and book" is used by providers and the choices that are made available to patients through "choose and book";
- what arrangements the commissioner should put in place to ensure that patients have information about providers, consultant-led teams and mental health professional-led teams and to ensure that this information is helpful and not misleading so that patients are able to exercise choice meaningfully; and
- what steps the commissioner should take to respond to any evidence (whether as a result of complaints, patient surveys or otherwise) that patients for whom it is responsible are not being offered the choices that are protected by these regulations. The commissioner will need to consider, for example, what arrangements it needs to put in place so that when a patient notifies it that it has not been offered choice on initial referral for an outpatient appointment, as required under the regulations, the patient is subsequently offered choice.

See also Section 2, which describes some of the factors that commissioners are likely to need to take into account when considering how they can improve services, including by allowing patients a choice of provider consistent with their duty under Regulation 3(4).

Monitor

Making the health sector work for patients

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