

Guidance on the Procurement, Patient Choice and Competition Regulations: consultation response



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.

Executive summary

On 20 May 2013 we launched an eight-week public consultation on Monitor's draft guidance on the Procurement, Patient Choice and Competition Regulations.¹

We received 70 written submissions from a range of stakeholders including individuals, NHS England, clinical commissioning groups, local area teams at NHS England, commissioning support units, NHS trusts, NHS foundation trusts, independent providers, charities, and various representative bodies such as NHS Clinical Commissioners, the NHS Confederation, the Foundation Trust Network and a number of Royal Colleges.

As well as seeking views in writing we also ran four workshops with commissioners on the draft guidance in London, Leeds and Birmingham. These aimed to give commissioners an overview of the regulations and the draft guidance and an opportunity to give initial feedback on the draft guidance, and to encourage commissioners to provide further feedback in writing.

We have also consulted with the Department of Health and NHS England throughout the development of the guidance.

We are grateful for the time, effort and thought that stakeholders have devoted to our consultation. As we gain practical experience of enforcing the regulations, we will consider whether it is useful to revise or update the guidance.

¹ The National Health Service (Procurement, Patient Choice and Competition) (No. 2) Regulations 2013.

1. Introduction

1.1 Monitor's role

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. 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.

We make sure that public sector providers are well led so that they can provide high quality care to local communities; that essential NHS services continue if a provider gets into difficulty; that the NHS payment system rewards quality and efficiency; that licensed providers do not behave in a way that is detrimental to the delivery of integrated care; and that commissioning of services, patient choice and competition operate in the interests of patients.

Further information on Monitor's functions is available on our website www.monitor.gov.uk

1.2 The Procurement, Patient Choice and Competition Regulations

The Procurement, Patient Choice and Competition Regulations create a framework for decision-making by commissioners. The Regulations are designed to:

- ensure that commissioners buy high quality, efficient NHS health care services that meet the needs of patients;
- protect patients' rights to make certain choices about where they receive NHS health care services; and
- prevent anti-competitive behaviour by commissioners, unless this is in patients' interests.

The Procurement, Patient Choice and Competition Regulations also give Monitor power to enforce the regulations. We are able to investigate complaints that a commissioner has breached the regulations. We can also investigate on our own initiative whether a commissioner has behaved in a way that is anti-competitive and not in patients' interests. Where we conclude that a commissioner has breached the regulations we have the power to take enforcement measures to address the breach.

1.3 Monitor's guidance on the Procurement, Patient Choice and Competition Regulations

We are required to publish guidance on compliance with the Procurement, Patient Choice and Competition Regulations and our approach to enforcement.²

The Act also required us to consult with NHS England and such other persons as we consider appropriate in preparing the guidance. Given public interest in the Procurement, Patient Choice and Competition Regulations we thought it was appropriate to run a full public consultation.

We launched an eight-week consultation on 20 May 2013. We received 70 written submissions from a range of stakeholders including individuals, NHS England, clinical commissioning groups (CCGs), local area teams at NHS England, commissioning support units (CSUs), NHS trusts, NHS foundation trusts, independent providers, charities and various representative bodies such as NHS Clinical Commissioners, the NHS Confederation, the Foundation Trust Network and a number of Royal Colleges. A list of respondents is provided in Annex 1.

As well as seeking views in writing, we also ran four workshops with commissioners in London, Leeds and Birmingham. A total of 124 people from clinical commissioning groups, NHS England local area teams and commissioning support units (and other organisations offering commissioning support services) attended these events.

We also consulted with the Department of Health and NHS England in preparing the draft guidance for consultation and have continued to work with them in finalising the guidance.

We have also sought and received the approval of the Secretary of State to publish the guidance as required under the Act.³

1.4 Outline of this document

This document gives an overview of the feedback that we received in writing and during workshops and through our on-going consultation with NHS England and the Department of Health. It sets out the common themes that emerged from our consultation. It also sets out our response to that feedback.

We are grateful to all of those that have participated in our consultation and we have considered all of the feedback that we received carefully.

Given the volume of feedback that we received, we are not able to address every point that was raised during the consultation in this document. We have therefore generally focused on addressing major themes raised by more than one respondent.

² s.78 of the Health and Social Care Act 2012.

³ s.78(3) of the Health and Social Care Act 2012.

The rest of the document is in three parts:

- **Section 2** describes general feedback that we received on the approach taken in the guidance and our response;
- **Section 3** describes feedback that we received on the draft substantive guidance and our response; and
- **Section 4** describes feedback that we received on the draft enforcement guidance and our response.

The headings in the document refer to the subject matter of the feedback.

2. General

2.1 Monitor's general functions

Feedback

A number of respondents said that the guidance should say more about how Monitor's role in enforcing the Procurement, Patient Choice and Competition Regulations fits with our other responsibilities.

Our response

Our main duty is to protect and promote the interests of patients by ensuring that the whole sector works for their benefit. To do this, we promote the provision of health care services that are economic, efficient and effective and that maintains or improves the quality of services.

We have a number of different functions to enable us to do this (see section 1.1 above). One of these functions is to enforce the Procurement, Patient Choice and Competition Regulations. This allows us to take action where commissioners are not buying high quality efficient services that meet patients' needs in accordance with the requirements of the Regulations, are not safeguarding patients' right to choose who provides their health care set out in the *NHS Constitution*, or are acting anti-competitively where this is not in patients' interests.

We have included more information about Monitor's role in the health care sector in the introduction to both sets of guidance.

2.2 Presentation

Feedback

Several respondents suggested that we could adapt the guidance in a number of ways to make it more user friendly. In particular, a number of respondents suggested that checklists and decision-trees would be helpful.

A few respondents said that the guidance should be expressed in positive language throughout in tune with the intention of helping commissioners to comply with the Procurement, Patient Choice and Competition Regulations.

One respondent also suggested that the guidance should be articulated from the perspective of commissioners by setting out the factors that commissioners should consider rather than what Monitor might look at when assessing whether a commissioner has breached the rules.

Our response

We have made some changes to the guidance to make it more accessible and user-friendly.

In particular, we have developed a checklist of key questions which flow from the regulations. These are the questions that we would generally expect commissioners to answer whenever they are procuring services in order to be confident that they are securing high quality, efficient services that meet patients' needs in line with their obligations under the regulations.

We also intend to publish a range of supplementary materials including hypothetical scenarios to help commissioners to understand how to comply with the rules, which we hope will be an accessible complement to our statutory guidance. Section 2.3 below gives more details of these.

We agree that the general tone of the guidance should be positive and articulated from the perspective of commissioners, and we have made some adjustments to reflect suggestions from respondents. In particular, we have amended the guidance to include examples of the key of factors that commissioners are likely to need to consider in complying with each of the different requirements in the regulations.

2.3 Hypothetical scenarios and other materials to support commissioners

Feedback

Many respondents welcomed the publication of the six case studies that consider how the regulations might apply to a number of hypothetical scenarios alongside the guidance. Some of these suggested that the hypothetical scenarios would be more helpful if they reached a conclusion on whether the commissioners had acted consistently with the regulations. Some suggested that it would be helpful to publish more hypothetical studies.

Several stakeholders suggested that we should supplement our guidance with other published materials to help commissioners understand how the rules apply, including real-life examples, information on the investigations that we carry out under the regulations and details of informal action that we take.

A number of respondents also suggested that we should update the guidance as our experience grows.

Our response

There are a number of existing materials to help commissioners available on our website. We refer to a number of these in the relevant parts of this response.

In addition, we intend to publish supplementary materials to help commissioners understand how to comply with the rules. In particular, we intend to publish a number of additional hypothetical examples covering issues that respondents have raised during the consultation during the coming months. Over time we also plan to publish a series of 'frequently asked questions' covering common topics on which people have sought informal advice.

We also plan to run a series of events for commissioners following the publication of the final guidance to support them in carrying out their procurement activities consistently with the regulations. Information on these events will be available on our website in due course and will also be sent directly to CCGs and local area teams at NHS England.

Monitor will also support commissioners considering how the rules apply to specific scenarios by providing informal advice. Queries can be sent to cooperationandcompetition@monitor.gov.uk

We will continue to carry out our investigations in an open and transparent way. We generally publish a range of different materials on our ongoing case work, including, for example, information about the subject matter of the investigation, information about the issues we are considering, relevant evidence and, ultimately, a reasoned decision setting out the evidence that we have relied on. To date we have opened three investigations under the regulations. Information on these investigations is available on our website.⁴

We will keep the guidance under review and will update it as appropriate as our experience of enforcing the regulations develops.

⁴ The Cooperation and Competition Panel also published a range of materials on cases decided under the *Principles and Rules for Cooperation and Competition*, which were replaced by the Procurement, Patient Choice and Competition Regulations.

3. Substantive guidance

3.1 The principles-based approach in the guidance

Feedback

We received a variety of views on whether the guidance strikes the right balance between giving commissioners sufficient autonomy to decide what is best for patients and giving them practical instructions on how to comply with the Procurement, Patient Choice and Competition Regulations.

Some stakeholders said that the guidance should set out more specifically what commissioners should do to comply with the regulations. For example, some respondents suggested that we should stipulate a contract value threshold above which all services should be procured through a competitive tender process and that we should specify a time period within which a commissioner should publish details of a contract award, even though these things are not prescribed in the regulations.

Other stakeholders welcomed the approach in the guidance and emphasised the importance of allowing commissioners to decide on a case-by-case basis what is best for patients.

Our response

Having carefully considered the responses, we believe the guidance strikes the right balance between giving commissioners the autonomy to decide in individual cases what is best for patients and providing practical instructions for commissioners.

We also believe that our approach is consistent with the approach in the Procurement, Patient Choice and Competition Regulations. The regulations are largely principles-based. They establish a framework for decision-making that is designed to ensure that commissioners secure high quality, efficient health care services that meet the needs of patients. For the most part, the regulations do not set out prescriptive requirements about the procedures that commissioners must follow and therefore we have not done so in our guidance.

There were however particular areas where respondents suggested that it would be helpful to provide clarification or more examples. We have made a number of changes in response to these suggestions and these are set out in the sections that follow.

3.2 Other requirements that commissioners must comply with

Feedback

Several respondents said that our guidance should explain how to comply with other rules that commissioners are required to comply with when they procure services. In particular, respondents suggested the guidance should cover the Public Contracts Regulations 2006 and EU procurement law. A number of these respondents suggested that the guidance should make clear which rules take precedence. A number of respondents said that we should address the impact on commissioners of the Public Services (Social Value) Act 2012.

Some respondents also suggested that we should emphasise the role that the voluntary sector can play in helping commissioners to comply with their duties under the Public Services (Social Value) Act 2012.

Our response

The purpose of the guidance is to explain how to comply with the Procurement, Patient Choice and Competition Regulations.

However, we have also highlighted a number of other rules that commissioners must comply with when they procure services and have referred to relevant guidance available to help commissioners understand what these other rules require in our revised guidance.

None of these different legal obligations takes priority over others and commissioners must therefore ensure that they comply with all of them when carrying out their functions. The Procurement, Patient Choice and Competition Regulations and other rules that commissioners must comply with when they procure services create a cohesive body of rules that are designed to ensure that commissioners act in patients' interests. In particular, the regulations do not require commissioners to duplicate or take steps that conflict with the work that they carry out to comply with these other rules, and we make this point in our revised guidance. The regulations also establish a framework for decision-making that should help commissioners to comply the other rules that they must follow.

In addition, NHS England's forthcoming procurement guidance for commissioners will provide advice on how to comply with other rules, including EU procurement law and the Public Services (Social Value) Act 2012. This guidance will be available on NHS England's website.

Voluntary sector providers can play a role in helping commissioners to comply with their duties under the Public Services (Social Value) Act 2012. However, the Procurement, Patient Choice and Competition Regulations require commissioners to identify the providers that are best placed to meet patients' needs and deliver quality

and efficiency improvements. Commissioners will need to think about all potential providers including voluntary sector providers, existing NHS providers, independent sector providers and any others when deciding which providers can achieve the best for patients.

3.3 NHS England's best practice procurement guidance

Feedback

A number of respondents also said that we should explain the relationship between our guidance and forthcoming guidance from NHS England for commissioners. These respondents emphasised the importance of both organisations being 'joined-up' in their approach.

Our response

We are working closely with NHS England to ensure that our respective sets of guidance are aligned to form a consistent, complementary package to help commissioners.

Our guidance addresses compliance with the requirements of the Procurement, Patient Choice and Competition Regulations.

NHS England's forthcoming procurement guidance for commissioners will complement Monitor's guidance, with an emphasis on best practice.

3.4 Joint commissioning with local authorities and other arrangements

Feedback

A large number of respondents said that we should expand the guidance to explain how the Procurement, Patient Choice and Competition Regulations apply to particular examples of the different arrangements that commissioners may enter into with a range of organisations to secure services.

These respondents suggested that the guidance should specifically address, for example, joint arrangements with local authorities, the use of "prime" and "lead" provider models, sub-contracting arrangements entered into by providers and the use of commissioning support services from commissioning support units (CSUs) and other organisations.

A few respondents also suggested that we should explain how the regulations apply to personal health budgets.

Our response

The Procurement, Patient Choice and Competition Regulations apply to CCGs and to NHS England. They do not apply to other organisations.

However, 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.

We have expanded the guidance to explain in general terms what this means in practice where a commissioner jointly commissions services with a local authority, makes use of “prime” or “lead” provider models, permits sub-contracting arrangements by providers, or relies on support from a CSU or other third party. We have also included guidance on how the regulations apply to the procurement of services that are funded by personal health budgets.

3.5 Scope of commissioner behaviour subject to Monitor’s review

Feedback

One respondent queried whether the guidance could be interpreted as suggesting a role for Monitor that goes beyond the Department of Health’s policy intent for the Procurement, Patient Choice and Competition Regulations. That respondent said it was important for the guidance to be clear that Monitor does not intend to check the quality of a commissioner’s work and question the commissioner’s judgments throughout the commissioning cycle. One stakeholder suggested that the references to contract management in the guidance were not relevant to the regulations as they did not relate to procurement.

Our response

It is not our intention to scrutinise all of the steps taken by a commissioner during the commissioning cycle as a matter of course.

Regulation 2 sets commissioners an overall objective to secure high quality efficient health care services that meet the needs of patients. A number of decisions taken by a commissioner throughout the commissioning cycle (not just the decision to award a contract or not award a contract to a particular provider) may affect the quality and efficiency of the services procured and the extent to which they meet the needs of patients.

If it 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 buy 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 a commissioner.

We also recognise that commissioners are required to comply with various other legal obligations in addition to the requirements in the Procurement, Patient Choice and Competition Regulations (see section 3.2). We do not expect commissioners to duplicate or take steps that are inconsistent with their other legal obligations in order to comply with Regulation 2. 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. They are also required to prepare joint health and well being strategies (JHWSs) for meeting the needs identified in the JSNAs. The preparation of these will typically be key steps taken by a commissioner to ensure that the services that it then buys meet the needs of patients consistent with its duties under Regulation 2.

3.6 Emphasis should be on health outcomes rather than service outputs

Feedback

A number of respondents suggested that the guidance places too much emphasis on service outputs rather than health outcomes.

One respondent suggested that we might replace references to ‘health care’ services with references to ‘health’ services or make it clear that the term ‘health care’ services includes services designed to prevent ill-health and improve well being as well as treat ill-health. One respondent said that we should make it clear that commissioners should commission services with a view to improving the outcomes of the population as a whole.

Our response

The references to health care services in the guidance reflect the terminology that is used in the regulations, and which flows from the Health and Social Care Act 2012. However, this does not mean that the focus of commissioners should be on service outputs as distinct from health outcomes.

The Procurement, Patient Choice and Competition Regulations set commissioners an overarching objective to procure high quality efficient health care services that meet patients’ needs. Assessing the needs of health care users and ensuring that the services being procured will meet those needs – including the need to achieve good health outcomes – are therefore critical components of the analysis that we will expect commissioners to carry out when they are procuring services.

In addition, the National Health Service Act 2006 requires commissioners to exercise their functions with a view to improving the quality of services provided to individuals to prevent, diagnose and treat illness. NHS England is also required to exercise its functions with a view to protecting or improving public health. The National Health Service Act makes it clear that improvements in this context mean improvements in outcomes. Commissioners will need to act consistently with these duties when they decide what services to procure in their area and how to procure them.

3.7 The importance of engaging with patients and other stakeholders.

Feedback

A number of respondents suggested that we should place more emphasis throughout the guidance on the need for commissioners to engage and consult with a range of relevant stakeholders when carrying out their functions.

In particular, a number of respondents emphasised the importance of ensuring that patients' views are appropriately factored into commissioners' decision-making.

Our response

We agree that it is important for commissioners to ensure that they have taken account of the views of appropriate stakeholders (including patients) when they take decisions.

The guidance states that 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. However, in the guidance we have expanded the list of examples of potential stakeholders that it may be appropriate for commissioners to consult.

We have also amended the guidance to refer to the importance of consulting with patients and other stakeholders throughout a procurement process.

3.8 Service sustainability

Feedback

Many respondents stressed the importance of service sustainability and welcomed the reference to sustainability as a relevant consideration when procuring services.

Concerns over the sustainability of services were expressed in a number of different ways. Some respondents, for example, expressed concerns that some providers might cherry-pick routine elective services, leaving existing providers with more complex expensive work that is often subsidised by the routine work, making the remaining services financially unsustainable. Others suggested that services might become unsustainable if putting some services out to market left a provider with a volume of work too small to fund an acceptable consultant rota. Others suggested that there was a risk that services could become unsustainable in the long term if providers did not devote sufficient resources to education and training.

Our response

Commissioners' core objective under the Procurement, Patient Choice and Competition Regulations is to secure high quality efficient health care services that meet the needs of patients. If the effect of a procurement decision is that services that patients need are no longer sustainable, threatening service continuity, patients' needs will not be met.

Commissioners need to consider the short and long term effect of their procurement decisions, and this is reflected in the guidance. Issues concerning service sustainability are complex and commissioners will need to think them through carefully.

We are working with NHS England to ensure that the national tariff prices and rules support the reimbursement of care that is efficiently provided. This should reduce the scope for providers to cherry-pick straightforward patients only, for example.

However, if commissioners do have concerns over service sustainability, we will expect commissioners to understand which services are at risk and why. Commissioners will also need to establish whether any services at risk are meeting a need that would not otherwise be met. Where they are, we will expect commissioners to explore the different options for ensuring that those services continue to be available to patients and to pursue the option that is in the best interests of patients. In some circumstances, the best option may be to continue to procure those services from the existing provider (potentially as part of a wider service package, where, for example, one service is subsidising another). In other circumstances, patients' interests might be better met by procuring the services at risk from a different provider.

3.9 Proportionality, non-discrimination and transparency

Feedback

There was general support for the examples of factors that we might take into account in assessing whether a commissioner has complied with its duties to act transparently, proportionately and to treat providers equally. We received a number of helpful suggestions about other considerations that we should take into account.

One respondent said that it would be helpful if we could clarify whether we intend to interpret these principles in line with EU law.

Some respondents said that the duty to act proportionately must not prevent commissioners from requiring providers to meet appropriate standards and from running a sufficiently robust selection process to enable the commissioner to be satisfied that the provider will be able to meet the service specification.

In relation to the discussion of non-discrimination in the guidance, many respondents said that it was important to recognise that existing providers will by their nature work closely with commissioners when services are being redesigned.

One respondent said that we should clarify what we mean by 'objective justification' and the grounds on which commissioners can distinguish between different providers.

One respondent queried whether it was acceptable for a commissioner to take active steps to 'level the playing field' for providers, for example by building the capability of third sector providers with limited scale and commercial experience to become suppliers.

Our response

We have updated the guidance to include some more examples of factors that commissioners are likely to need to consider to ensure that they act consistently with their duties to act transparently, proportionately and to treat providers equally.

We recognise that commissioners need to strike a balance between making sure that the way that they procure services is not unduly onerous and making sure it is robust enough to satisfy them that they procure services from those providers most capable of delivering high quality efficient services that meet the needs of patients. We have updated the guidance to make this clear.

We also recognise the important role that providers can play in service redesign. However, it is important that providers are not involved in a way that gives them an unfair advantage. That said, it is possible for one provider to have a more extensive role 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 service specification, this is less likely to give rise to an unfair advantage than where a commissioner asks an existing provider to develop 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 by reference to how they are currently provided, so that they are the only provider likely to meet the specification. We have updated the guidance to reflect this.

The regulations allow commissioners to differentiate between potential providers only on the grounds of relevant differences. These are differences that relate to the ability of a provider to deliver high quality efficient health care services that meet the needs of patients.

We will base our decisions in any investigations concerning these areas on whether commissioners have acted consistently with their obligations to act transparently and proportionately and not to discriminate under the Procurement, Patient Choice and

Competition Regulations. We will have regard to relevant UK and EU law as appropriate.

There is nothing to prevent commissioners from introducing general capability building measures to level the playing field where these increase the number of available high quality efficient providers. However, commissioners will need to ensure that any steps that they take do not amount to discriminatory treatment, as would be the case, for example, if they chose to award a contract for services to a particular type of provider expressly to bring that provider onto the playing field, rather than because the provider in question was the best choice for patients in the circumstances.

3.10 Bundling

Feedback

We received a variety of views on the section on bundling in the guidance.

Some respondents thought the description in the guidance of the potential advantages and disadvantages of bundling was helpful.

A significant number of respondents suggested that purchasing bundles of different services from a single provider is a way of achieving better integrated care. They suggested that the guidance on bundling is inconsistent with the drive towards more integrated care. Some thought that unbundling services could result in services becoming clinically unsustainable or undermine training, education and research. One respondent suggested that the guidance overstates the potentially exclusionary effects of bundling, as providers offering some of the services in a bundle could always form a consortium with providers offering the other services to bid for the bundle as a whole.

Other stakeholders said that we should give more emphasis to the potentially negative effects of bundling. Some also emphasised the adverse impact that bundling might have on smaller providers, including voluntary organisations.

Our response

Having considered all the responses, we think the approach to bundling in the guidance is correct. Whether or not to bundle or unbundle services is a matter for commissioners. Bundling can have positive and negative effects depending on the circumstances. In particular, commissioning a bundle of different services from a single provider may not lead to better integrated care unless the teams delivering those different services work together effectively (for example, through multi-disciplinary meetings, joint care planning and sharing records and other updates on a patient's care). Commissioners will therefore need to take into account all relevant factors to determine whether bundling is the approach most likely to give rise to

benefits for patients in any case where bundling is an option, and procure the services separately if it is not.

3.11 Improving services: competition, choice and integrated care

Feedback

We received a variety of views on the descriptions of competition, choice and integrated care in the guidance.

Some thought that our definitions were helpful. Others suggested that this part of the guidance set out a policy rather than helping commissioners to comply with the requirements of the Procurement, Patient Choice and Competition Regulations.

Many supported our definition of integrated care. Some suggested that it could be strengthened. For example, one respondent thought that the concept of a patient care pathway did not come through strongly enough.

Some respondents said the guidance should explicitly recognise the drawbacks of competition. They suggested that competition could give rise to a number of adverse consequences including disruption (due to changes in providers), extra costs (from running competitive tenders and managing relationships with a larger number of providers), increased risk of legal challenge, reduced investment due to market uncertainty and lower quality services (because providers will reduce quality in order to cut prices and because of unmanageable volumes of patients at popular providers). In particular, many raised concerns that increased competition would lead to greater fragmentation of services. Some suggested that practical examples on how to achieve better integrated care in a way that is consistent with competition and choice would be helpful.

A smaller number of respondents said that it is important for the guidance to counter the false assumption that competition, choice and integrated care are mutually exclusive and felt that the guidance does not do enough to promote the benefits to patients of competition and choice.

Some respondents suggested that the definition of choice should be expanded beyond choice of provider to recognise other choices that patients value, such as choice of treatment.

One respondent also suggested that references to the value of co-operation, where this is in the best interests of patients, could be expanded to cover the role cooperation can play in maintaining patient safety, or ensuring service continuity and sustainability, for example.

Another respondent said that we should recognise that commissioners can choose to maintain, increase or decrease the number of providers in an area, depending on

what is in patients' best interests and suggested that the guidance implied that the latter was not an option.

A number of stakeholders said that the guidance wrongly assumes that it is only for commissioners to identify ways of improving services. Some stakeholders suggested that collaborative working driven by providers will often be the best way of improving care and, in particular, of ensuring that care is delivered in a more integrated way.

Our response

Regulation 3(4) requires commissioners to consider appropriate ways of improving services. It explicitly requires them to consider whether services can be improved through being delivered in a more integrated way, by enabling providers to compete to provide services, and by allowing patients to choose their provider. Since Monitor enforces the regulations, we believe the guidance needs to describe what we understand the terms integrated care, competition and choice mean, to help commissioners comply.

Enabling providers to compete to provide services (for example, by running a competitive tender to procure services) and/or allowing patients to choose between different providers can be ways for commissioners to improve quality and efficiency. Where providers have to perform well to persuade commissioners and/or patients (supported by their GP or consultant) to use their services, this incentivises them to maintain or improve the standard of their services. If they do not, they risk losing patients (and therefore funding).

The regulations require commissioners to consider whether competition and choice can be used to improve quality and efficiency. They do not require commissioners to increase the number of providers for competition's sake. If a commissioner concludes that patients' interests would be best served by maintaining or even reducing the number of providers of a particular service, the regulations do not prevent them from doing so.

Integrated care, competition and choice are not mutually exclusive. However, we recognise that there is concern across the sector that competition may lead to greater fragmentation.

There are many different ways in which commissioners can achieve the delivery of better, more integrated care for patients that are unlikely to reduce competition or choice. Measures designed to improve the links between the different services that make up a patient's care are unlikely to have any impact on competition or choice (for example, measures to manage better the transfer of patients from an acute hospital back into the community, such as improved planning of patient transfers and better discharge summaries).

Some models for integrated care may involve creating an 'integrated pathway' for all or a number of services that a patient requires. This might be structured in a number

of ways, for example, a commissioner may procure an integrated pathway from a single provider or from an “alliance” of providers. Commissioners will need to consider which models are likely to deliver better integrated care for patients on a case by case basis. In particular, they will need to consider how the links between different services can be managed to ensure that the care the patient receives from different professionals is joined up.

Commissioners will also need to consider the impact of each possible model on the extent of competition among providers and patient choice. The impact of any model on competition and choice will also depend on the way the model is implemented. For example, if a commissioner opts for an ‘integrated pathway’ model, it can still run a competitive tender process to select the provider or providers of the integrated pathway, and patients may still be able to choose between different integrated pathways or receive particular elements of their care from a provider outside the integrated pathway.

In terms of the potential disruption brought by changing providers, where a commissioner decides to change the provider of a particular service (for example, following a review of existing service provision or after running a competitive tender process), it should take steps to minimise any disruption to patient care. For example, commissioners should use contractual mechanisms to make sure the new provider can provide care seamlessly to patients from the start of the contract. These might include, for instance, requiring the existing provider to give the new provider any information it will need to provide on-going care to patients well before the new contract enters into force. Such information could include patients’ records and details of scheduled appointments.

In response to feedback, we have expanded our discussion on the relationship between choice, competition and integrated care to consider these issues in the guidance. There are also other materials available on our website that consider the interplay between competition, choice and integrated care. These include [Frequently Asked Questions](#) on integrated care and a paper on the [Implications of the Competition Rules for the Delivery of Integrated Care](#) that was published by the Cooperation and Competition Panel.⁵ We also intend to publish a number of further materials on the subject to help commissioners in the context of our work supporting the [integrated care pioneers](#). We also plan to publish some additional worked examples on integrated care in the coming months.

We recognise that many patients value being involved in decisions about their care. Regulation 3(4) explicitly requires commissioners to consider whether services can be improved by offering patients a choice of provider. We have therefore focused the

⁵ This paper considers the implications of the Principles and Rules for Cooperation and Competition (the administrative rules which the Procurement, Patient Choice and Competition Regulations replace), but the discussion on the relationship between competition, choice and integrated care may nonetheless be helpful.

discussion in our guidance on choice of provider rather than other categories of choice. However, commissioners should also consider whether giving patients more control over other aspects of their care could improve patient experience and lead to care that better meets the needs of patients.

We also recognise that co-operation between providers can lead to benefits for patients as well as more integrated delivery of care. Sharing clinical best practice, for example, may give rise to significant benefits for patients. We have focused our discussion in the guidance on the delivery of care in an integrated way rather than other forms of cooperation which may be in patients' interests because Regulation 2 and Regulation 3(4) explicitly require commissioners to consider how needs can be met and services improved through the delivery of care in an integrated way. However, commissioners should also consider encouraging other forms of cooperation between providers where this is likely to deliver significant benefits for patients.

We also recognise that providers can play a key role in driving improvements in services, including delivering more integrated care. Our discussion only focuses on the role of commissioners because the guidance is concerned with the rules that apply to commissioners.

3.12 Competitive tendering

Feedback

The guidance sets out the factors that commissioners should take into account when deciding whether to procure services by way of a competitive tender process. These prompted a range of views.

Some felt that the effect of the guidance would be that commissioners would have to tender virtually all services and that this is contrary to Ministers' assurances that commissioners are free to decide if and when to use competition. One respondent suggested that the thrust and chronology of the discussion of the procurement options open to commissioners in the guidance could be interpreted as promoting competition. A number of respondents said that the guidance should make it clear that commissioners have the autonomy to decide whether or not to tender services.

Some thought more clarity was needed on the circumstances in which services needed to be competitively tendered, for example, by reference to value thresholds. Others emphasised the importance of greater openness and transparency over contracting opportunities.

There was general support for our examples of the circumstances in which a competitive tender process may not be required.

However, some respondents thought our examples could be open to abuse. Some thought that the effect of Regulation 5(1) was that the regulations exempt commissioners from the duty to tender only where there is a single capable provider and were concerned that our examples of other circumstances where commissioners are exempt from a duty to tender may be open to legal challenge. Others questioned how providers would be able to express an interest in a contract if it is not advertised and how a commissioner would be able to establish who the most capable provider is without running a tender process. One respondent also suggested that proportionality was not a relevant basis for not running a competitive tender process.

Some respondents also suggested that the approach in the guidance was not consistent with the Public Contracts Regulations 2006 and EU procurement law.

Our response

There is no requirement in the Procurement, Patient Choice and Competition Regulations for commissioners to run a competitive tender process to procure all services and there is no assumption that virtually all services should be competitively tendered. For many services, including consultant led elective services, patients are able to choose to get health care services from any providers that satisfy a commissioner's quality criteria and are willing to provide services at the relevant tariff. These services are not procured by way of competitive tender because any provider that satisfies these criteria and is willing to provide services at the relevant tariff can offer its services to patients. This approach is consistent with the Procurement, Patient Choice and Competition Regulations.

We have amended the guidance to make it clear that for other services there is no default process that commissioners should use to buy services. We have also reorganised the text to address any perception that the chronology promotes competition.

The regulations are intended to give commissioners the autonomy to choose on a case-by-case basis how to go about securing services in order to deliver the best outcome for patients. The regulations create a framework for commissioners to establish what approach is most likely to achieve this. They do this by setting commissioners the overall objective of procuring high quality efficient services that meet patients' needs, and by requiring them to adhere to the following principles-based requirements:

- buy services from the provider (or providers) most capable of delivering that objective that offer best value for money;
- act in a proportionate, transparent and non-discriminatory way;
- ensure that arrangements exist for a provider to express its interest in providing services; and
- consider appropriate ways of improving services (including through competition and choice).

We have expanded the guidance to describe the sorts of factors that may be relevant to a commissioner's decision about whether to run a competitive tender process in practice. Which factors are relevant will depend on local circumstances but may include, for example, existing provider performance and whether there is likely to be more than one capable provider. A more detailed list of factors that may be relevant is included in the revised guidance. However, the Regulations do not set a value threshold above which services must be competitively tendered and it would not therefore be appropriate for us to introduce a threshold in the guidance.

The examples of the circumstances in which a competitive tender process may not be required are intended to support commissioners in deciding in various circumstances whether a competitive tender process is the best or only way of realising the overarching objective and satisfying the principles-based requirements in the regulations listed above. We therefore believe that the scope for these examples to be misinterpreted or applied inappropriately is limited.

Commissioners will need to ensure that any decision not to run a competitive tender process is consistent with the Public Contracts Regulations 2006 and EU law. As explained above, the Public Contracts Regulations 2006 and EU law sit alongside the Procurement, Patient Choice and Competition Regulations and are part of a consistent body of legal requirements that commissioners must comply with (see section 3.2).

3.13 New contracts

Feedback

A number of respondents said that it would be helpful if the guidance could be clearer about when amending or extending a contract will give rise to a new contract.

In particular, several respondents queried whether renewing or renegotiating existing standard NHS contracts may give rise to new contracts.

One respondent also queried whether the renewal of contracts for community services that were transferred from PCTs in connection with the 'transforming community services' programme when these expire will give rise to new contracts.

Our response

A number of requirements in the Regulations apply where a commissioner awards a contract.⁶

⁶ These include Regulation 4(2) (publishing a contract notice on supply2health where a commissioner has decided to advertise the contract); Regulation 5(1) (no requirement to advertise a contract where there is only one provider that is capable of providing the services); Regulation 6(1) (prohibition on awarding a contract where a conflict affects or appears to affect the integrity of the contract award); and Regulation 9 (maintaining and publishing records of contracts awarded).

It is difficult to define precisely when amending a contract will amount to the award of a contract. Whether or not a renegotiation or renewal of a contract amounts to a new contract will depend on the circumstances of the case.

It is possible that existing standard NHS contracts or contracts for services entered into in the context of the 'transforming community services' programme that are renegotiated or renewed may give rise to new contracts.

The Regulations do not generally set out specific procedural steps that commissioners must take whenever they award a contract. Instead they set out general principles that commissioners must follow when they are procuring services that are designed to make sure that commissioners achieve the best outcomes for patients (such as buying services from the most capable providers and acting in a transparent, proportionate and non-discriminatory way). Many of these considerations will be relevant to decisions involving the award of new contracts as well as decisions to amend existing ones.

Consequently, rather than specify precisely in the guidance the circumstances in which amending or extending a contract will amount to awarding a new contract, we set out a framework for making decisions in accordance with the regulations that commissioners can use whether they are awarding a new contract or materially amending an existing one. These include evaluating patients' needs; considering who is best placed to meet those needs; thinking about how services can be improved; being transparent; treating providers equally and taking a proportionate approach.

What this framework requires will depend on the circumstances of the case. If, for example, a commissioner wants to increase capacity temporarily, while it carries out a more thorough review of the services in question, it may be appropriate to modify the contract with the existing provider pending the outcome of that review.

3.14 Record keeping

Feedback

Most respondents that provided feedback on the guidance on keeping records and publishing information about contracts that have been awarded supported our approach.

A few said that our suggestions about the sorts of information that a record should contain and that commissioners should publish were too onerous and should be kept to minimum. Others emphasised the importance of keeping appropriate records of decisions and publishing information on contracts that have been awarded.

A number of stakeholders suggested that we should specify maximum time periods within which commissioners should publish information on the contracts that they award.

Respondents also suggested additional information that commissioners should include in their records. This included, for example, details of any engagement with patients, professionals and local communities before awarding the contract (and how their views have been taken into account) and information on quality, including, for example, details of how the performance of the provider will be assessed during the contract.

A number of respondents suggested that some of the information contained in the record should be published (not merely recorded) and in a way that will be easily understood by the public.

Our response

We recognise that it is important to strike a balance between ensuring that commissioners are transparent and accountable and that they are not overburdened with administrative requirements.

Regulation 9(2) specifies the minimum information that commissioners must publish about all the contracts that they award. What information commissioners must publish above and beyond this and the content and level of detail of the records that they keep (but do not publish) will depend on the contract in question.

This is reflected in the guidance and we have made it clear that more information is likely to be required for high value contracts than for lower value contracts, for example. We have also expanded the list of information that a record might contain to include some of the suggestions made by respondents.

Regulation 9 does not specify the time period within which information should be published. What is appropriate will depend on the circumstances of the case. However, we have made it clear in the guidance that the information should be published as soon as possible and generally before the contract is implemented.

3.15 Conflicts of interest

Feedback

Many respondents emphasised the importance of managing conflicts of interest given the role of GPs as both commissioners and providers.

There was general support for the approach in the guidance. One respondent said that we need to be pragmatic and strike a balance between the desire to achieve a purist arm's length contractual relationship and the need to encourage clinical redesign (which may appropriately involve commissioning services from GP practices). A different respondent emphasised the importance of upholding the integrity of the commissioning system and suggested that no person with a direct financial interest in a potential bidder should have any involvement beyond that afforded to all potential providers. One respondent suggested that anyone involved in commissioning services should be able to demonstrate that they have made no financial gain from the award of a contract.

Some said more detailed guidance would be helpful, including guidance for CCGs on how to commission services from GP practices in a way that is consistent with the rules. One respondent said it would be helpful to include examples of conflicts that do not involve CCGs.

We received a number of suggestions from stakeholders about interests that may give rise to a conflict. In particular, many said that the guidance should recognise that interests held by those offering commissioning support may give rise to conflicts, given that they will often be in a position to influence the decisions reached by commissioners. Respondents also suggested further examples of financial interests and personal interests that we could include in the guidance. One respondent suggested that the guidance should say that commissioners should consider whether any previous or prospective roles or relationships may give rise to a conflict of interest.

Some respondents also said that we should make it clear that conflicts can arise at early stages of the commissioning cycle, for example, during the needs assessment or initial scoping and prioritisation of services. One respondent suggested, for example, that conflicts of interest might arise where a CCG is deciding whether or not to procure services that are likely to reduce demand on existing services provided under the General Medical Services contract.

One respondent suggested that in assessing whether a conflict of interest affects or appears to affect the integrity of a contract award, Monitor should consider not only the extent of involvement of an individual in a decision, but whether a reasonable person without such a conflict of interest could be expected to have reached a similar decision. Another respondent suggested that we should take into account whether a conflict of interest has been handled in accordance with a CCG's constitution.

One respondent suggested that the guidance should address conflicts of interest that GPs may have when they refer patients to other services (such as outpatient

appointments with a consultant), as a result of financial or other interests in those other services, not only conflicts that arise in the context of commissioning.

A number of respondents, including the General Medical Council, said that it would be helpful if we could refer to the professional obligations relating to conflicts of interest that registered doctors must comply with.

Our response

We recognise that it is important that commissioners are able to redesign services according to what is in patients' best interests. In some circumstances, this may involve CCGs commissioning services from GP practices. However, it is also critical to the integrity of the commissioning system that actual and potential conflicts of interests are identified and managed appropriately. Even where a conflict does not actually affect the integrity of a contract award, a conflict that *appears* to affect the integrity of a contract award can damage a commissioner's reputation and undermine public confidence in the NHS. For this reason we propose to focus our assessment on the way the conflict was managed, rather the decision itself (and, in particular, whether the decision that is ultimately reached could have been reached by a reasonable person).

We believe that the guidance currently strikes the right balance. It is unlikely ever to be appropriate for an individual to vote on decisions relating to the procurement of services in relation to which they have a financial interest. However, it may be possible for the individual to have some involvement in the commissioning process where, for example, they have relevant clinical expertise, so long as that conflict is managed, for example, by involving other clinical experts in the process.

We have included more detail in the guidance on the circumstances in which conflicts of interest may arise and the factors that commissioners are likely to need to consider in deciding whether a conflict affects or *appears* to affect the integrity of the award of the contract based on some of the examples provided by respondents. We have also included a reference to the General Medical Council's guidance. One of the hypothetical scenarios that we published alongside the draft guidance also suggests how a CCG might approach a decision to commission services from local GP practices.

GPs play an important role in referring patients to other health care services. The role of GPs as referrers is outside the scope of regulation 6, which is concerned with conflicts between the interests in providing services and commissioning them in the context of commissioners' decisions to award contracts for services to providers (including potentially GPs). We do not therefore address GPs referring patients to providers in which they have an interest in this part of the guidance.

It is important that patients receive impartial advice from GPs about where they can receive other health care services. Commissioners have obligations under the Responsibilities and Standing Rules Regulations⁷ to ensure that patients are offered the choices set out in the *NHS Constitution* and have information to help them exercise their rights of choice. These are considered in Section 9 of our guidance. If a GP does not offer the choices set out in the *NHS Constitution* or presents misleading information about the choices available to patients, we would expect commissioners to take steps to address this.

The professional obligations enforced by the General Medical Council, with which registered doctors must comply, also include rules governing how doctors manage conflicts of interests that may arise when they make patient referrals.

3.16 Use of commissioning support

Feedback

Most respondents supported the factors that we might take into account in deciding whether a commissioner has put in place appropriate arrangements to ensure that organisations offering commissioning support and advice act consistently with the Procurement, Patient Choice and Competition Regulations. Many respondents suggested that there should be greater transparency around the use and cost of commissioning support and advice.

One respondent suggested that it is unnecessary for Monitor to regulate arrangements between commissioners and organisations providing commissioning support. It is sufficient that, as with any other public body, commissioners have ultimate responsibility for regulatory compliance whether they undertake the commissioning themselves or through a third party service.

Other respondents suggested a number of ways in which commissioners could ensure compliance with the requirements in Regulation 8. These included auditing any organisation providing support; checking that it complies with information governance rules; ensuring that the people providing advice are suitably qualified and experienced; and requiring the organisation to comply with the commissioners' policies and governance processes.

One respondent said that we should be careful not to require CCGs to duplicate the work carried out by NHS England's Business Development Unit in accrediting CSUs as suppliers of commissioning support services in 2012. They also suggested that commissioners should be able to rely on template service specifications and service

⁷ The National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012.

level agreements developed by NHS England when procuring commissioning support.

Our response

Regulation 8 is not intended to create an additional burden for commissioners. It requires commissioners to take steps to ensure that the way they use third party support and advice enables them to be satisfied that services are being procured in a way that is consistent with the requirements of the Procurement, Patient Choice and Competition Regulations.

We do not expect commissioners to undertake unnecessary work. Where NHS England or some other body has assessed the capability of those offering commissioning support and advice or has developed tools to help commissioners to manage their relationships with CSUs or any other organisations offering support, Monitor will not expect commissioners to replicate this work where it is reasonable for them to rely on it.

3.17 Anti-competitive conduct that is not in patients' interests

Feedback

We received a variety of views on the section of the guidance addressing the prohibition on anti-competitive conduct that is not in patients' interests.

Many of those who provided feedback on this section of the guidance supported the approach. Others felt that more guidance was needed on what amounts to anti-competitive conduct and the circumstances in which anti-competitive conduct may be in patients' interests. Some of these said it would be helpful if we could clarify the relationship between the objective and general requirements set out in regulations 2 and 3 and the prohibition on anti-competitive conduct in regulation 10 and, specifically, to set out what types of conduct regulation 10 is intended to capture that regulations 2 and 3 do not.

A number of stakeholders suggested that our approach is not balanced, as commissioners have to demonstrate the benefits of anti-competitive behaviour, whereas the benefits of competition are assumed.

Two respondents suggested that we should look at what might have happened in a counterfactual situation (ie, if the conduct had not occurred) to decide whether there was a negative effect. One of these respondents suggested that, for example, although limits imposed by a commissioner on the total volume of procedures that a provider can carry out might reduce competition overall, the alternative might be that the commissioner would not have contracted with some of the providers at all.

One respondent said that we should refer to relevant case law from the Office of Fair Trading and the Competition Commission.

Our response

Regulation 10 prohibits commissioners from engaging in anti-competitive behaviour unless to do so is in the interests of patients. Commissioners must therefore demonstrate the benefits of any anti-competitive behaviour that they engage in.

We have added a new section describing the interplay between regulation 10 and the other regulations. The requirements in all 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 patients' needs. Actions by a commissioner that do not meet this objective may breach several regulations at once (including regulation 10).

In theory any action by a commissioner that restricts competition and that is not in patients' interests could be assessed under Regulation 10. However, other requirements in the Procurement, Patient Choice and Competition Regulations create a framework for making decisions about what services to procure and how to go about procuring them in the best interests of patients (in particular, Regulations 2, 3 and 4). Consequently, unless there are specific reasons for taking a different approach, we would usually investigate any complaints about such decisions by reference to these other requirements of the Procurement, Patient Choice and Competition Regulations. Such decisions include, for example, decisions about whether to procure services by way of a competitive tender process, decisions about the number of providers to enter into a contract with and issues around the equal treatment of providers during a procurement process. These examples are explored in more detail in the revised guidance.

We have also included more detail on how we assess whether behaviour is anti-competitive and not in patients' interests.

Restrictions on competition that are objectively justified will not breach the regulations. We have included new examples in the guidance of circumstances in which anti-competitive conduct may be in patients' interests. These may include, for example, restrictions on GPs referring certain categories of patients to particular providers where those providers do not offer the type of treatment that is most clinically appropriate for a patient, or preventing a provider from differentiating itself from other providers where the way in which it is seeking to do this reduces the efficacy of the treatment that patients receive. Arrangements designed to share best clinical practice between providers are also unlikely to breach Regulation 10.

3.18 Patient choice

Feedback

Most respondents that provided feedback on this section of the guidance agreed that we should set out the rules relating to choice in the Responsibilities and Standing Rules Regulations in full in the guidance. A few suggested that this was unnecessary or that the guidance provided too much detail and that signposting the relevant rules would be sufficient.

A small number thought that it was not appropriate to offer patients a choice of provider. One respondent suggested that patients are not empowered, educated or qualified to make decisions about where they receive treatment and will ultimately lose out because the effect of giving them choice will be that responsibility for the quality of their care will shift to them. This respondent suggested that patient choice is also likely to increase health inequalities. A number of respondents suggested that patients do not want to have choice.

A similar number of respondents emphasised the importance of patient choice. A number of these suggested that many people are not aware of their rights of choice and do not have the necessary information to make informed choices.

One respondent said that we should be clear about what is expected of CCGs and NHS England. This respondent suggested that there is a limit to what CCGs can do to influence whether choice is offered by GPs given that it is NHS England and not CCGs who procures primary care services.

Several respondents suggested additional factors we should consider in assessing whether commissioners have complied with their obligations. For example one respondent suggested that commissioners should use key performance indicators that are linked to evidence of choice being offered (for example, through use of choose and book).

One respondent said that we should make it clear that commissioners should only be required to act on legitimate complaints by patients that choice has not been offered.

One respondent said we needed to consider what might be better achieved through policy developed at a national level, for example, to improve the extent to which patients are aware of their rights to choice and able to exercise them meaningfully.

Our response

The right of patients to choose who provides their health care services in certain circumstances is enshrined in the NHS Constitution. Allowing patients to choose

between providers can also incentivise providers to offer high quality efficient services. This can bring benefits for patients who exercise their rights of choice and also patients who do not (but who benefit from the overall improvement in care).

In deciding whether a commissioner has complied with its obligations relating to patient choice, we will be mindful of what can be expected of individual commissioners and what might be more appropriately achieved through national developments outside the regulatory framework. We also recognise that the roles of CCGs and NHS England are different and that it is NHS England which holds contracts with GPs.

There were several helpful suggestions of factors that commissioners should take into account in complying with their duties relating to patient choice and we have added some of these to the guidance. We only expect commissioners to act on complaints that turn out to be well-founded.

Finally, since we published the draft guidance for consultation, the Responsibilities and Standing Rules have been amended⁸ to reflect the extension of choice of provider for elective referrals for mental health services from 1 April 2014.⁹ From this date, commissioners will need to make arrangements to ensure that patients are offered a choice of provider for first outpatient appointments for these services. We have updated the guidance to reflect this.

⁸ See The National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) (Amendment) Regulations 2013 (SI. 2013 No.2891) which amended the Responsibilities and Standing Rules Regulations (see in particular Regulation 4).

⁹ See the 2013/2014 Choice Mandate published in May 2013 available here: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/193567/Choice_framework_2013_-14_DH_log.pdf

4. Enforcement guidance

4.1 General

Feedback

A number of respondents told us that commissioners have limited resources and said that Monitor needs to recognise this when exercising its powers under the Procurement, Patient Choice and Competition Regulations.

Several respondents also raised concerns over vexatious complaints and suggested that the guidance should clarify how Monitor would address these.

Some respondents suggested that there is a risk that commissioners will be overly cautious because of the fear of legal challenge (in particular, the risk that a contract might be declared ineffective) and that they will therefore focus their attention on procedure rather than the interests of patients. In particular, some respondents raised concerns that commissioners will unnecessarily run competitive tenders to buy services in order to reduce the risk of challenge.

Some respondents suggested that we should limit the circumstances in which we will investigate complaints. Stakeholders suggested a number of ways in which we might do this. We might, for example, require complainants to attempt to resolve issues directly with their commissioner before bringing complaint to Monitor; specify a contract value threshold beneath which we will not or are unlikely to investigate a complaint; set a time limit within which complaints must be brought; or impose a charge for bringing a complaint that would be refunded if the complaint were upheld (the charge would be proportionate to size of complainant).

One respondent also suggested that disputes with a CCG should be raised with the relevant local area team at NHS England where it has not been possible to resolve the issue through direct engagement with the CCG before being escalated to Monitor.

Our response

We recognise that commissioners are new organisations. We also recognise that they have finite resources. We expect them to consider how best to allocate the resources that they have. This includes developing commissioning priorities that focus efforts on those areas where commissioners can achieve the most for patients. Where a commissioner has developed a robust and transparent plan for reviewing different services based on such priorities, and we receive a complaint about services that are due to be reviewed by the commissioner in the future under that

plan, we will take this into account in deciding what if any action to take. We have reflected this in our revised enforcement guidance.

Consistent with our prioritisation framework we will focus our resources on the cases where we can make the most difference for health care service users. We will not use our resources to investigate apparently vexatious complaints.

The Procurement, Patient Choice and Competition Regulations create a framework for decision-making that is designed to lead commissioners to procure high quality efficient health care services that meet the needs of patients. They do not require commissioners to follow a prescribed set of procedures every time that they acquire services. In particular, as explained at section 3.12 above the regulations do not require commissioners to procure all services through a competitive tender process or establish a competitive tender process as the default option. Compliance with the regulations should therefore lead to good procurement decisions that achieve the best outcome for patients rather than diverting attention away from what is in patients' interests.

The lapse in time before a complaint is made, the steps taken by a complainant to try to resolve a dispute at the local level and the value of a contract under dispute will all be relevant considerations when we decide whether to open a case, but no single factor is determinative.

In general we will expect a complainant to have attempted to resolve its concerns with the relevant commissioner directly before bringing a complaint to us. However, there may be circumstances where this is not practicable, not necessary or not appropriate and we will consider each case on its facts. We have changed the guidance to reflect this.

We would also generally expect complainants to notify the local area team at NHS England where they think that a CCG is or has been in breach of the regulations and it has not been possible to resolve the dispute through direct engagement with the relevant CCG. However, complainants are free to raise their concerns with us at the same time that they notify the local area team at NHS England of their concerns.

We do not propose to charge complainants to bring complaints.

4.2 Prioritisation

Feedback

Most respondents that provided feedback on our proposed prioritisation framework supported it.

Some respondents suggested that the framework gives us wide discretion and could lead to arbitrary decisions. Another respondent said that we should not have the discretion to close a case.

One respondent was not convinced of the fairness of taking enforcement action primarily to deter other commissioners from breaching the Procurement, Patient Choice and Competition Regulations.

Various stakeholders suggested additional factors that we should take into account in deciding whether to open an investigation. These included an accumulation of historic low impact breaches by the commissioner, the impact of the conduct in question on the local health economy and whether the matter has attracted major public interest.

One respondent suggested that complainants should be able to get an early view from Monitor about whether a complaint is likely to meet Monitor's prioritisation criteria, given the resources that are required to prepare a fully reasoned complaint.

Our response

We believe that the level of discretion in our prioritisation framework is appropriate. It also reflects the approach of other regulators.

Our overarching consideration will be the expected difference we can make for health care service users. Where there is major public interest in a potential case, this may amplify the potential benefit to patients of our work on it, for example, by helping to increase awareness and understanding across the sector of the regulations and what they require of commissioners. An accumulation of low impact breaches over time will also be relevant to our assessment of potential indirect benefits to patients. In particular, in the event that we find a breach, taking action might reduce the likelihood of that commissioner failing to comply again in the future. Our assessment of the impact of the alleged breach on the local health economy will only be relevant in so far as it affects our assessment of the expected benefit of taking action for patients.

We believe it is appropriate to have the discretion to close cases if appropriate. We have limited resources and should be able to divert resources to other areas where we think we can achieve a greater impact for patients.

We also believe it is appropriate to consider the general deterrent effect that any enforcement measures that we might impose would have if we find that there has been a breach.

4.3 Informal and formal action

Feedback

There was widespread support for the availability of informal action as an alternative to a formal investigation. Most of these respondents also supported our approach to deciding whether or not to take informal or formal action. Some said informal action should be the default. We also received suggestions about other forms of informal action that we might take in addition to those listed in the draft guidance.

Some did not think that any of the considerations set out in the guidance were more important than others in deciding whether to take formal or informal action. Some respondents suggested that Monitor should decide what weight to attach to them on a case-by-case basis. Others thought that some considerations were more important than others, but there was no consensus or consistent theme concerning which factors are the most important, although impact on patients and staff was mentioned by a number of respondents.

One respondent suggested that complainants should be able to make representations on decisions over whether to take formal or informal action.

Many respondents emphasised the importance of ensuring that informal action is taken seriously. Respondents suggested, for example, that we should record serial occurrences and act on trends, include examples of what will lead to an escalation from informal to formal action, and set out timescales for commissioners to make improvements to ensure that informal action is taken seriously.

Some respondents said it would be helpful if the guidance explained how Monitor will approach and identify whether other regulators have concerns about a commissioner in the context of deciding whether to take formal or informal action.

Our response

Informal action may be an effective alternative to a formal investigation in some circumstances. We think it is appropriate to decide whether to take formal or informal action based on what is in the interests of health care users on a case-by-case

basis. Depending on the circumstances, some considerations may be more important than others.

Although we may seek views from a complainant on whether we should pursue formal or informal action, we will reach a final decision on what action to take based on what is in the best overall interests of patients in line with our main duty.

We agree that it is important that informal action is taken seriously. Where we choose to take informal action we will continue to have regard to our prioritisation criteria and, where we think that better outcomes would be achieved through a formal investigation, we may escalate from informal to formal action. We have made this clear in the guidance. This might be the case, for example, where a commissioner fails to implement agreed changes within agreed timeframes.

We received helpful suggestions about different types of informal action that we might take in addition to those set out in the guidance. For example, one respondent suggested that informal action could involve an audit of a commissioner's processes. Informal action can cover wide range of action. In choosing the most effective response to a potential issue, we will consider proposals from the parties concerned in deciding what action is likely to create the greatest potential benefit to health care service users and is proportionate.

4.4 Making declarations of ineffectiveness and issuing directions

Feedback

A number of respondents expressed general concern about the effect of enforcement measures and, in particular, any declaration that a contract is ineffective. They suggested that it would be helpful to have more guidance on the circumstances in which Monitor may make a declaration of ineffectiveness and the consequences.

A number of stakeholders said that we needed to consider the impact of potential enforcement measures on service continuity and the viability of the local health economy.

We are only able to make a declaration of ineffectiveness where a breach is sufficiently serious. Most respondents agreed with the factors that we proposed to consider when assessing seriousness. Many said that none of the considerations that we proposed to take into account were more important than others. Others disagreed. In particular, a number of respondents said the impact of a breach on health care users was the most important consideration in assessing seriousness.

The majority of respondents also agreed with the factors that we proposed to consider more generally when deciding what enforcement measures to impose. Some suggested that the guidance should place more emphasis on the impact of breaches on providers in deciding what enforcement action to take. Others said that it was good that the emphasis is on the effect on patients.

The guidance states that we will consider the likely effect of enforcement measures on third parties that have acted in good faith (such as providers) in deciding what, if any, enforcement measures to impose. One respondent suggested in this context that providers should understand the legal framework that they operate in.

The Department of Health also indicated that it was not the intention that Monitor would be able to require the payment of compensation as a means of mitigating the effect of a breach of the regulations (Monitor has the power to issue a direction to mitigate the effects of a breach under Regulation 15(b)).

Our response

We have included more guidance on what a declaration of ineffectiveness means in practice. We have also deleted reference to the possibility of directing a commissioner to pay compensation to remedy a breach of the regulations. Complainants will continue to be able to seek compensation through the courts.

In deciding what, if any, enforcement measures to adopt, we will consider the potential impact of enforcement measures, including, in particular, their impact on the continued availability of services for patients. We have amended the guidance to make this clear.

We agree that the impact that a breach has on patients is important in deciding whether to impose enforcement measures and what enforcement measures to impose. However, we also think we should consider the other factors set out in the guidance to reach a decision that takes into account all relevant considerations. We consider that the emphasis on patients, not providers, is right given our main duty to protect and promote the interests of patients under the Act.

We agree that providers should be expected to know the legal framework in which they and commissioners operate. Where a provider knew or should have known that the commissioner had awarded a contract in breach of the Procurement, Patient Choice and Competition Regulations, we will take this into account in assessing good faith and deciding what enforcement measure, if any, would be appropriate. We have updated the guidance accordingly.

4.5 Accepting undertakings

Feedback

Most respondents supported the use of undertakings as an alternative to continuing an investigation, so long as they are taken seriously. One respondent said that we should set out circumstances in which undertakings would never be appropriate.

Some suggested that it would be helpful if the guidance explained what will happen if a commissioner does not comply with undertakings. One respondent suggested that we should require commissioners to report on compliance with undertakings and that Monitor should maintain a record of all undertakings given. One respondent suggested that a commissioner's ability to comply with an undertaking should be independently assessed before it is accepted.

Our response

We believe that the appropriateness of undertakings will depend on the circumstances of the case. We do not therefore list circumstances in the guidance where undertakings would never be considered an acceptable way of resolving a case.

We agree that it is important that undertakings are taken seriously. We will consider the ability of a commissioner to comply with an undertaking when we decide whether to accept it. It may or may not be necessary to have this independently tested. We will keep records of undertakings and expect to require commissioners to report on compliance. This is reflected in our guidance.

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

4.6 General case procedures

Feedback

Most respondents supported our proposed case procedures.

Many suggested that it would be helpful if the guidance provided more information on the timing of the different stages of an investigation. Most suggested that timings should be short given the potential impact of uncertainty on patients and services. In particular, a number of stakeholders said that we should bear in mind the time limits for bringing legal proceedings under the Public Contracts Regulations 2006 in deciding the timetable for our investigations.

One respondent said that it was important that our requests for information are relevant and proportionate. The respondent also said that Monitor would need to consider how it handles confidential information that it receives, including when it will be appropriate to disclose that information to third parties.

Some respondents said that there was a risk of inconsistency with taking a case-by-case approach to our case procedures (for example, whether to seek views on proposed enforcement action).

Our response

We recognise the importance of certainty and concluding investigations quickly, but we need to balance this with the need to ensure that our decisions are robust and evidence based.

How long an investigation lasts will vary depending on a number of factors including the complexity of the issues raised and how quickly we are able to gather the information that we require to reach a finding.

We will publish an anticipated timetable at the outset of each case. We are mindful that complainants have time limits within which they can bring legal proceedings under the Public Contracts Regulations 2006 and start an action for judicial review.

Our investigations will be carried out in a manner that is proportionate, in line with our duties under the Act. We also handle any confidential information that we receive in accordance with the law.

We are aware of the importance of taking a consistent approach across all of our investigations and we will be mindful of this in reaching decisions in individual cases. However, we believe it is important to have the flexibility to adapt our procedures to take account of the particular circumstances of a case.¹⁰

4.7 Representations from the commissioner and third parties

Feedback

Many of those who provided feedback on this part of the guidance, supported our intention to send commissioners a 'notice of intent' setting out the enforcement measures we intend to take and the grounds for taking them before sending commissioners a 'final notice'.

¹⁰ In practice we expect that we will almost always seek views on proposed enforcement action – including, for example, proposed undertakings, provisional findings and notices of intent.

However, a few questioned the value of doing so if our investigation is thorough and thought it would add unnecessary delay.

One respondent suggested that others affected by the investigation should also be notified.

Respondents also emphasised that we need to be transparent about whose views we seek. One respondent suggested that commissioners should be able to input on whose views are sought.

Some said it was important for third parties and commissioners to be able to make representations before the stage when a 'notice of intent' is issued.

Our response

Sending a 'notice of intent' and giving the commissioner under investigation the opportunity to make representations is an important aspect of due process.

We expect that commissioners and third parties will be involved from an early stage in our investigation, but the 'notice of intent' is a formal step that gives the commissioner the opportunity to comment on our provisional findings and any enforcement measures that we propose to impose.

Our main aim in seeking views will be to ensure that our provisional findings are accurate and that the enforcement measures that we propose to impose are the most appropriate to address the problem that we have provisionally identified. This will inform our decision on who to seek views from. Depending on the circumstances we may seek views from the complainant, patients, clinical experts and/or other third parties. The commissioner under investigation may wish to make suggestions about who we should approach and we will take these suggestions into account, but ultimately we will decide who to seek views from, based on the considerations listed above.

The final notice will set out the evidence on which our decision is based including, if relevant, details of whose views we have relied on.

4.8 Publishing final notices

Feedback

Most respondents agreed that we should publish final notices. One respondent suggested that the decision whether to publish the final notice should be subject to a public interest test. One stakeholder said that commissioners should be able to make

representations on whether the final notice should be published. Others said it should be checked for accuracy first and that commercially sensitive information should be redacted from the public version.

Our response

We think there are significant benefits to publishing final notices. Doing so may help improve the sector's understanding of how the regulations apply in particular situations and may deter breaches of the rules by other commissioners. Publishing reasoned decisions also increases the transparency of our activities. We therefore intend to publish all final notices.

We will check the accuracy of the final notice before we publish it where we consider that this is necessary, and will redact any commercially sensitive information in every case.

4.9 Decision making

Feedback

Most respondents supported our approach to decision-making.

Some respondents said that we should make clear what expertise we intend to rely on. Several respondents emphasised the importance of ensuring that we have appropriate clinical input into our decisions. One said that it was important that decisions are not taken by unaccountable management consultants.

One respondent said that in order to ensure consistency between the 'notice of intent' and the 'final notice', the decision-making committee for the final notice should also approve the notice of intent and the provisional findings within it.

One respondent suggested that the guidance should also set out the decision-making procedure for closing cases.

Our response

The guidance sets out how Monitor will take its decisions.

We will draw on a range of relevant expertise when reaching decisions, as appropriate.

Monitor's new Medical Director and clinical advisers within Monitor will provide clinical input. Our Clinical Reference Group also provides expert clinical advice during all our investigations under the Procurement, Patient Choice and Competition

Regulations. Where the Group does not contain the relevant expertise required for a particular case, Monitor will use the Group's members to help us identify appropriate additional expertise. More information on the Clinical Reference Group is available [here](#).

We are also advised by the independent Cooperation and Competition Panel. The Cooperation and Competition Panel consists of the Chair and a number of part-time panellists drawn from various backgrounds, including law, economics, business and healthcare. Further information about the Cooperation and Competition Panel is available [here](#).

Decisions to close a case before issuing a “notice of intent” will be made by the senior member of staff responsible for the decision to open a case and issue a notice of intent. We have updated the guidance accordingly.

The decision to issue a ‘final notice’ will be made by a final decision-making committee, comprising a number of Monitor’s staff. The final decision-making committee will not approve the ‘notice of intent’ before it is issued. Most of the people on the committee will not have had any major involvement in the case before deciding whether to issue a ‘final notice’, so they bring a ‘fresh pair of eyes’ to the case. However, the members of staff involved in preparing the notice of intent will participate in committee’s discussions on the final decision. The final decision-makers will also be kept informed of progress on the case as it advances, so they are familiar with it when it comes to the final decision.

Annex 1: List of respondents to consultation¹¹

1. 38 degrees (Eastern Cheshire)
2. @ne Associates
3. Barchester Healthcare
4. Bevan Brittan LLP
5. British Association of Dermatologists
6. British Dental Association
7. British Medical Association
8. British Society of Hearing Aid Audiologists
9. Cambridge University Hospitals NHS Foundation Trust
10. Capsticks Solicitors LLP
11. Chartered Society of Physiotherapy
12. Chelsea and Westminster NHS Foundation Trust (on behalf of The Royal Marsden NHS Foundation Trust)
13. County Durham and Darlington NHS Foundation Trust
14. Derby Hospitals NHS Foundation Trust
15. Dorset Orthopaedic Company Limited
16. Foundation Trust Network
17. General Medical Council
18. Great Western Hospitals NHS Foundation Trust
19. Help the Hospices
20. InHealth Group Limited
21. Lay Advisory Group of the College of Emergency Medicine
22. Marie Curie Cancer Care
23. Mills & Reeve LLP¹²
24. Moorfields Eye Hospital NHS Foundation Trust
25. NHS Arden Commissioning Support Unit
26. NHS Central Midlands Commissioning Support Unit
27. NHS Clinical Commissioners
28. NHS Commercial Solutions
29. NHS Confederation
30. NHS Dorset Clinical Commissioning Group
31. NHS East Midlands Commissioning Organisations
32. NHS East and North Hertfordshire Clinical Commissioning Group
33. NHS Eastern Cheshire Clinical Commissioning Group

¹¹ Respondents that made a written submission in response to our consultation. One respondent asked us to keep their identity confidential. A number of individuals also responded to our consultation.

¹² On behalf of NHS Dudley Clinical Commissioning Group; NHS Herefordshire Clinical Commissioning Group; NHS Mansfield and Ashfield Clinical Commissioning Group; NHS Redbridge Clinical Commissioning Group; NHS South Worcestershire Clinical Commissioning Group; NHS Staffordshire and Lancashire Commissioning Support Unit; and NHS Walsall Clinical Commissioning Group.

34. NHS England
35. NHS Kernow Clinical Commissioning Group
36. NHS North and East London Commissioning Support Unit
37. NHS North East Lincolnshire Clinical Commissioning Group
38. NHS North of England Commissioning Support Unit
39. NHS Nottingham City Clinical Commissioning Group
40. NHS Partners Network of NHS Confederation
41. NHS Rotherham Clinical Commissioning Group
42. NHS South London Commissioning Support Unit
43. NHS South West Commissioning Support Unit
44. NHS Voluntary Sector Providers Forum
45. Nottingham West Health Concern
46. Office of Health Economics
47. Recruitment and Employment Confederation
48. Royal College of Anaesthetists/ Faculty of Pain Medicine
49. Royal College of General Practitioners
50. Royal College of Midwives
51. Royal College of Nursing
52. Royal College of Physicians of Edinburgh
53. Royal College of Radiologists
54. Royal College of Surgeons
55. Royal College of Surgeons of Edinburgh
56. Salford Royal NHS Foundation Trust
57. South Essex Partnership University NHS Foundation Trust
58. Specialised Healthcare Alliance
59. West Suffolk NHS Foundation Trust
60. UK Faculty of Public Health
61. UNISON
62. Unite the Union
63. University Hospitals of Leicester NHS Trust



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