



About Monitor

As the sector regulator for health services in England, our job is to make the health sector work better for patients. As well as making sure that independent NHS foundation trusts are well led so that they can deliver quality care on a sustainable basis, we make sure: essential services are maintained if a provider gets into serious difficulties; the NHS payment system promotes quality and efficiency; and patients do not lose out through restrictions on their rights to make choices, through poor purchasing on their behalf, or through inappropriate anti-competitive behaviour by providers or commissioners.

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Foreword

Monitor's job as regulator is to protect and promote the interests of patients by ensuring that the whole healthcare sector works for their benefit. We recognise that providers and commissioners have challenging roles on the front line of healthcare: our philosophy is to help people do the right thing rather than punishing them for doing the wrong thing.

This guidance has been written to help you, as healthcare providers, make the best decisions for patients. It is one of a set of documents explaining how we apply competition rules, first published in March 2013 for a 12-week public consultation. We are grateful for all the support and engagement we received to help us develop our guidance, and we have acted on feedback.¹

The full set of finalised guidance comprises this document, alongside:

- how we apply the choice and competition conditions of the licence for providers of NHS healthcare services
- how the Competition Act 1998 applies to the healthcare sector.

As an extra aid we have published (and will continue to publish) hypothetical <a href="https://scenarios.google

We have previously published guidance both to <u>support NHS providers considering transactions</u>² and to assist <u>commissioners using the Procurement, Patient Choice and Competition Regulations</u>.³

To help you use this guidance most fully and identify when it might be necessary to work with us, we briefly explain what we mean by choice and competition and set out how and why we are working in this area below.

Our role in choice and competition

Choice and competition have existed in the NHS in England for many years and are powerful tools for improving the quality of care provided to patients. They enable patients and commissioners to select the providers which offer quality services that best meet the needs of patients.

¹ Please see the <u>consultation response document</u> at: <u>https://www.gov.uk/government/publications/nhs-healthcare-providers-working-with-choice-and-competition</u>

² https://www.gov.uk/government/publications/supporting-nhs-providers-considering-transactions-andmergers

https://www.gov.uk/government/publications/procurement-patient-choice-and-competition-regulations-guidance

Choice and competition are governed by specific rules which seek to make sure that:

- they operate in the best interests of patients
- procurement decisions by commissioners achieve the best results
- all providers are treated fairly
- no-one behaves anti-competitively to the disadvantage of patients.

Our role is to make sure that this all works the way it is meant to: that the rules are applied taking into account the specific circumstances of the health sector, and above all that they are applied in the best interest of patients.

We take this responsibility seriously. We will enforce the competition rules affecting healthcare services to ensure that they operate fairly in the interests of patients, and to help both NHS providers and NHS commissioners meet the needs of patients.

To achieve this, we will explain in documents like this one how any breach of these rules might have negative effects on patients, and how we expect our intervention to maintain or improve service quality or innovation, or deliver better value for money.

Introduction to this guidance

The aim of this guidance⁴ is to inform patients, healthcare providers, commissioners, patient groups and other interested parties of how we approach our powers to make market investigation references under Part 4 of the Enterprise Act 2002 (EA02).⁵ It also provides an overview of changes made by the Enterprise and Regulatory Reform Act 2013 (ERRA13)⁶ to the way market investigation references and market studies are conducted.

It is structured as follows:

· examining markets

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⁴ This guidance reflects the views of Monitor at the time of publication and may be revised from time to time to reflect changes in best practice, legislation and the results of experience, legal judgments and research. This guidance may in due course be supplemented, revised or replaced. Monitor's website will always display the latest version of the guidance. Although this guidance covers most of the points likely to be of interest to organisations and their advisers, it makes no claim to be comprehensive and cannot be cited as a definitive interpretation of the law.

⁵ References to the Competition and Markets Authority in Part 4 of EA02, except in sections 166, 171 and 174E of EA02, shall be construed as including references to Monitor – see section 73(2) of the Health and Social Care Act 2012.

⁶ The ERRA13 established the Competition and Markets Authority (CMA) as the UK's economy-wide competition authority with an obligation to promote competition for the benefit of consumers. On 1 April 2014, the functions of the Competition Commission and many of the functions of the Office of Fair Trading (OFT) were transferred to the CMA, and the OFT and Competition Commission were abolished.

- our approach
- undertakings in lieu of a market investigation reference
- consulting on proposed market investigation references and on accepting undertakings in lieu
- market investigations.

As we gain more experience examining markets, we expect to update this guidance from time to time.

Examining markets

We undertake a range of work to examine whether healthcare services are working well for patients, including whether choice and competition is working effectively. This includes reviews of the provision of services, ⁷ calls for evidence, ⁸ research ⁹ and market studies.

The work may lead to a range of outcomes including a clean bill of health for the market, making recommendations to the government to change regulations or public policy, taking enforcement action, accepting commitments from parties to take certain actions, or making a market investigation reference to the Competition and Markets Authority (CMA).

Market investigation references

We can make a market investigation reference when we want the CMA to conduct a detailed examination to determine whether there is an adverse effect on competition in the market(s) referred.

We have concurrent (shared) powers with the CMA to make market investigation references under Part 4 of EA02 in relation to activities concerning the provision of healthcare services in England.¹⁰ Our concurrent powers are not limited to NHS-funded services but apply to all healthcare¹¹ services in England.

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⁷ See, for example, our review of NHS walk-in centre services in England:

https://www.gov.uk/government/publications/nhs-walk-in-centre-services-in-england-review

See, for example, the call for evidence on the general practice services sector in England:
https://www.gov.uk/government/publications/nhs-walk-in-centre-services-in-england-review

See, for example, our research project on NHS adult hearing loss services in England:
https://www.gov.uk/government/consultations/nhs-adult-hearing-services-in-england-now-any-qualified-provider-is-working-for-patients and our research on how NHS commissioners are working to improve community services for patients:
https://www.gov.uk/government/publications/how-nhs-commissioners-are-working-to-improve-community-services-for-patients.

That is, in respect of healthcare services in England, either we or the CMA may make such a

¹⁰ That is, in respect of healthcare services in England, either we or the CMA may make such a reference (Section 73 of the Health and Social Care Act 2012).

¹¹ Section 64(3) of the Health and Social Care Act 2012 defines 'healthcare' as all forms of healthcare provided for individuals, whether relating to physical or mental health.

We can make a market investigation reference if we have reasonable grounds for suspecting that any feature, or combination of features, of a market in the UK prevents, restricts or distorts competition in connection with the supply or acquisition of any goods or services in the UK or part of the UK.

A feature of a market means:

- the structure of the market concerned or any aspect of that structure
- any conduct (whether or not in the market concerned) of one or more than one person who supplies or acquires goods or services in the market concerned or
- any conduct relating to the market concerned of customers or any person who supplies or acquires goods or services.¹²

Conduct in this context includes any failure to act (whether intentional or not) and any other unintentional conduct.¹³

Under Part 4 of EA02 we have investigatory powers to require parties to give evidence in person and/or to supply specified documents and information (including estimates or forecasts).¹⁴ If a person fails to comply with these requirements without reasonable excuse, we have the power to impose a penalty.¹⁵

If we consider that it would be appropriate to use these investigatory powers in connection with deciding whether to make a market investigation reference¹⁶ we must publish a market study notice.

Market study notice

Publishing a market study notice triggers statutory time limits as outlined below:

 We must complete the market study and publish a report setting out our findings and actions (if any) which will be taken as a result of the market study within 12 months of publishing the market study notice.¹⁷

¹² Section 131(2) of EA02

¹³ Section 131(3) of EA02

¹⁴ Section 174 of EA02

¹⁵ Administrative penalties may be imposed in the form of a fixed amount, by reference to a daily rate, or using a combination of the two. Maximum penalty amounts are set by order and are, as at August 2014, £30,000 (in the case of a fixed amount) and £15,000 (in the case of a daily penalty). It is a criminal offence for someone intentionally to alter, suppress or destroy any document which they have been required by notice to produce. People committing a criminal offence are liable, on summary conviction, to a fine not exceeding the statutory maximum, and on conviction on indictment, to imprisonment for a term not exceeding two years or to a fine, or to both. See the Competition and Markets Authority (Penalties) Order 2014 and 'Administrative penalties: statement of policy on the CMA's approach' (CMA4).

¹⁶ And we are proposing to carry out our functions under paragraph 14 of Schedule 8 to the Health and Social Care Act 2012 in relation to a matter for the purposes mentioned in section 130A(2) of EA02.

- Within six months of publishing a market study notice, we must publish notice
 of whether we propose to make a market investigation reference. We are
 required to consult relevant people on our proposed decision in the
 following circumstances:
 - o if we propose to make a market investigation reference or
 - if we do not propose to make a market investigation reference but we have received (non-frivolous) representations in response to a market study notice arguing that a reference should be made.

Market studies are one of several tools we use to examine whether a particular market is working well and, if not, why. We undertake a range of work that may lead to the launch of a market study or market investigation reference, or form the basis of other action by us. Such work, for example, a review of the provision of a service, economic research, or a call for evidence on a particular issue, does not itself constitute a market study. We can make a market investigation reference without conducting a market study.

We will publish information about market studies and other work that we undertake on our website.

Our approach

We will initially launch a market study or making a market investigation reference based on information coming from a wide range of sources, for example a complaint or information acquired during an informal review of a market.

In relation to healthcare services in England, the CMA and Monitor will always consult each other before:

- publishing a market study notice
- using our investigatory powers under Part 4 of EA02
- making a market investigation reference or
- accepting undertakings in lieu (undertakings in lieu are described below).

The general principle is that the relevant functions will be exercised by whichever authority is better placed to do so. In determining which authority that is, they will consider factors including the extent to which sectoral knowledge is relevant and recent experience of dealing with the markets concerned.

When determining whether the statutory criteria for a market investigation reference are met, we will have regard to the CMA's <u>Market studies and market investigations</u>:

¹⁷ Section 131B, EA02

supplemental guidance on the CMA's approach, 18 taking into account the specific characteristics of the healthcare sector. Where we do not follow this guidance, we will explain why not.

We have discretion to decide whether to make a market investigation reference where the statutory criteria appear to be met. In deciding whether to do so, we will take into account the following factors:

- the nature and the seriousness of the competition issues we believe exist in the market in question
- whether a market investigation reference would be a proportionate response to the competition issues identified
- whether we could accept undertakings in lieu¹⁹
- whether, alternatively, we have other powers to address the issues identified and
- there is a reasonable chance that appropriate remedies will be available.

ERRA13 changes the way in which market investigation references are made in certain cases. This includes a new power to make a cross-market reference; that is, refer a specific feature (or combination of features) in more than one market without also having to refer the whole of each market concerned.²⁰

Undertakings in lieu of a market investigation reference

We can accept undertakings instead of making a market investigation reference (undertakings in lieu). In doing this, we must take into account the need to achieve a solution to the adverse effect on competition.²¹ We may also have regard to the effect of any action on any relevant customer benefits²² of a feature or features of the market concerned.23

When considering whether to accept undertakings in lieu, we will have regard to the Office of Fair Trading (OFT) guidance on market investigation references which has

For example, a cross-market reference may be made where features do not fit neatly within

²³ Section 154(4) of EA02.

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¹⁸ See 'Market studies and market investigations: supplemental guidance on the CMA's approach' (CMA3).

See section 154 of EA02.

Section 154 of EA02 requires us to have regard to the need to achieve as comprehensive a solution as is reasonable and practicable to the adverse effect on competition concerned and any detrimental effect on customers so far as they result or may be expected to result from such

adverse effects. ²² In relation to the health sector, the term 'customer' means a current or future user of healthcare services (often but not always referred to as a 'patient') or a commissioner.

been adopted by the CMA,24 taking into account the specific characteristics of the health sector. Where we do not follow this guidance, we will explain why not.

Prior to accepting undertakings in lieu, we must publish a notice stating, among other things, that we propose to accept the undertakings, the purpose and effect of the undertakings, and the adverse effect on competition and any resulting detrimental effect on patients identified by us that the undertakings are seeking to deal with. The notice must also mention any other facts which we consider justify the acceptance of the undertakings.²⁵ We must take into account any representation arising from the publication of the notice. Further information on the CMA's concurrent power to accept undertakings instead of making a market investigation reference is set out at paragraphs 2.20 to 2.24 of their guidance.²⁶

Consulting on proposed market investigation references and on accepting undertakings in lieu

When we propose to make a market investigation reference or to accept undertakings in lieu, we are required under EA02, ²⁷ so far as is practicable, to consult the people whose interests we consider are likely to be substantially affected by our decision. We must consult before making the decision and, so far as is practicable, we must give our reasons for our proposed decision.

Where we have published a market study notice and we are required to consult on a proposed decision about whether to make a market investigation reference or not, we will publish notice of the proposed decision within six months of the market study notice being published.

We will publish information about market investigation references and undertakings in lieu on our website https://www.gov.uk/monitor.

We have a duty, when considering whether to make a market investigation reference, to bring to the attention of the Secretary of State any case that we consider raises public interest issues relating to national security. National security is currently the only specified public interest consideration in the legislation but others may be specified in future.²⁸

See section 155(2) of EA02 which details all the points to be included in the notice.

²⁶ 'Market investigation references' (OFT511).

²⁴ 'Market investigation references' (OFT511): https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/284399/oft511.pdf

²⁷ Section 169 of EA02. The ERRA13 amended section 169 of EA02 so there is no duty to consult on decisions not to make a market investigation reference, except where there has been a request for a reference to be made during a market study.

²⁸ Section 153 of EA02. Currently the Secretary of State has the ability to intervene in market investigations to investigate defined public interest issues that are relevant to the case, while the CMA investigates the competition issues. The ERRA13 gives the Secretary of State the power to

Market investigations

Once a market investigation reference is made, the CMA's market reference group is required to investigate and decide whether any feature, or combination of features, of each relevant market prevents, restricts or distorts competition in connection with the supply or acquisition of goods or services in the UK or a part of the UK.²⁹

Where the CMA's market reference group decides there is an adverse effect on competition, it is required to decide what action should be taken by the CMA or others to remedy, mitigate or prevent the adverse effect on competition concerned or any resulting detrimental effect on customers.³⁰ These detrimental effects can take the form of higher prices, lower quality or less choice of goods or services, or less innovation in relation to goods or services in any market in the UK.³¹

The CMA's market reference group may decide on remedies, such as structural remedies (for example, divestiture of assets), behavioural remedies (such as enabling measures to open up a market or give customers more information), or making recommendations to other bodies.

The CMA is required to publish its report within 18 months of the reference,³² with a possible six-month extension in special circumstances.³³

Guidance on the substantive and procedural aspects of market investigations and possible outcomes is set out in the CMA's guidance³⁴ and in the Competition Commission's guidelines for market investigation which have been adopted by the CMA Board.

request the CMA to investigate public interest issues alongside competition issues as part of its market investigation.

²⁹ Section 134(1) of EA02

³⁰ Section 134(4) of EA02: in relation to the health sector, the term 'customer' means a current or future user of healthcare services (often but not always referred to as a 'patient') or a commissioner.

³¹ Section 134 of EA02

³² Section 144 of EA02

³³ Section 137 of EA02.

³⁴ Market studies and market investigations: supplemental guidance on the CMA's approach (CMA3). https://www.gov.uk/government/publications/market-studies-and-market-investigations-supplemental-guidance-on-the-cmas-approach



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