PROCUREMENT LAWYERS' ASSOCIATION

THE PROCUREMENT AND COMPETITION REGIMES APPLICABLE TO NATIONAL HEALTH SERVICE COMMISSIONERS AND PROVIDERS IN ENGLAND

April 2016

FOREWORD

The Procurement Lawyers' Association (PLA) is an organisation which exists to bring together all procurement lawyers, whether in private practice or in-house, public or private sector and including solicitors, barristers and academics based in the UK and elsewhere.

The PLA aims to represent, promote and strengthen procurement law expertise in a number of ways, including through in-depth discussion of procurement law issues. A wide range of public bodies' activities are subject to the European Union's public procurement regime, and economic operators bidding for public contracts operate in a variety of economic markets. Reflecting this and also the breadth of discretion available to contracting authorities in administrative law terms, there is a broad variation in the approaches taken by contracting authorities to public procurement.

The PLA hopes that this publication will serve to clarify some areas of legal uncertainty in relation to the public procurement and competition rules applicable to the commissioning and provision of health care services for the National Health Service in England, and that it will assist in the development of best practice in this area.

The PLA acknowledges its gratitude to all those members who contributed their expertise and experience to the production of this publication, and hopes that readers will find it a balanced and valuable aid to understanding the law surrounding this topic.

SCOPE OF THIS PUBLICATION

This publication is arranged in three Parts, each covering a distinct area of the law applicable to procurement and provision of health services by National Health Service (NHS) commissioners and providers in England.

The systems which govern the commissioning and provision of health care services for the purposes of the NHS in Scotland, Wales and Northern Ireland are structured differently from that which exists in England. This publication accordingly only covers the procurement law regimes which apply to National Health Service commissioners and providers in England, where particular complexities are considered by procurement lawyers to exist.

As such, the areas covered by this publication (and preceded by a brief Introduction) are as follows.

Part 1: Applicable regimes:

 The relationship between EU public procurement law and the domestic regulatory regime applicable to the procurement of health care services for the purposes of the National Health Service in England;

Part 2: Remedies in NHS procurement:

• Remedies available in relation to procurement of healthcare services; and

Part 3: Competition and integration:

• The applicability of competition law to the commissioning and provision of health services to the NHS in England, and considerations around integration in the provision of such services.

Excluded areas

This publication does not consider the equivalent positions in Wales, Scotland or Northern Ireland, or in jurisdictions outside the United Kingdom.

Terminologies used throughout this publication

In this publication, references to:

- "the HSCA" are to the Health and Social Care Act 2012;
- "the Public Sector Directive" are to European Union Directive 2014/24 on public procurement, repealing Directive 2004/18;



- "the 2015 Regulations" are to the Public Contracts Regulations 2015, the domestic measures implementing the Public Sector Directive in England, Wales and Northern Ireland;
- "the 2006 Regulations" are to the Public Contracts Regulations 2006, the domestic measures which implemented in England, Wales and Northern Ireland the previous Directive on public procurement (namely Directive 2004/18);
- **the "NHS Regulations"** are to the National Health Service (Procurement, Patient Choice and Competition) (No. 2) Regulations 2013;
- a "Part" are to Part 1, Part 2 or Part 3 of this publication, as referenced above (as applicable).

For the purposes of this publication the law is correctly stated as of 18 April 2016.

1 GENERAL INTRODUCTION

Procurement by NHS commissioners in England: relevant bodies and their roles

- 1.1 The structure of the National Health Service in England was subjected to major reform by the Health and Social Care Act 2012 ("**the HSCA**"), many provisions of which came into force on 1 April 2013.
- 1.2 The HSCA introduced what is cited as "the most wide-ranging and controversial reform to the structure of the NHS since the service was established in 1948". In doing so, it implemented the reforms described in the White Paper "Equity and excellence: Liberating the NHS", which had been published in July 2010. That White Paper set out the (then) Government's aims to reduce central control in the NHS, to engage general medical practitioners (GPs) in the commissioning of health services as a matter of course², and to give patients greater choice from the provision of health care services.
- 1.3 The HSCA set up (with effect from 1 April 2013) two new types of body, each with statutory responsibility for the commissioning of health care services for the purposes of the NHS. These were:
 - 1.3.1 The National Health Service Commissioning Board (**NHS England**); and
 - 1.3.2 Clinical Commissioning Groups (**CCGs**), of which there were (and remain) more than 200 each covering a defined local geography, and each responsible for commissioning health care services for its own local population.
- 1.4 At the same time (and among other reforms), NHS strategic health authorities and primary care trusts were abolished.

Role of CCGs

- 1.5 On 1 April 2013, 212 CCGs took on statutory responsibility for commissioning the majority of NHS services, including:
 - 1.5.1 urgent and emergency care (for example, accident and emergency);
 - 1.5.2 elective hospital care (for example, outpatient services and elective surgery); and

² Schemes with similarities over the previous twenty years – "GP fundholding" from the early 1990s and "practice-based commissioning" from the mid-2000s – had been voluntary.



¹ See "The Structure of the NHS in England" – Briefing Paper Number CBP 07206, 10 March 2016, House of Commons Library (at page 5).

- 1.5.3 community health services (for example, community mental health services and health visiting).
- 1.6 At the same time, NHS England assumed responsibility for specialised commissioning, and for commissioning primary care services.
- 1.7 The NHS' "Five Year Forward View" (published by NHS England in October 2014) says that the Department of Health intends progressively to offer CCGs more influence over the total NHS budget for their local populations, including greater responsibility for commissioning primary care and specialised services.
- 1.8 The HSCA sets out the functions, duties, and governance structures for CCGs. It makes CCGs directly responsible for commissioning those NHS services which they consider appropriate to meet reasonable local needs. All GP practices are required to join the CCG for their area. In addition, CCGs must have a published constitution and be structured in a particular way (elaboration on those matters is outside the scope of this publication).

Role of NHS England

- 1.9 While CCGs now commission the majority of NHS services (including most hospital services), NHS England directly commissions certain services at a national or regional level, such as primary care services (including GP services) and specialist services.
- 1.10 NHS England is also the body responsible for ensuring that there is an effective and comprehensive system of CCGs. NHS England fulfils a national leadership role in relation to commissioning, and allocates funding for that purpose.

Procurement by NHS commissioners in England: the legal landscape

- 1.11 Part 3 of the HSCA creates a framework for choice and competition in the provision of NHS services. In particular, it allows the Department of Health to set regulations which give Monitor³, as the economic regulator for the NHS, the power to investigate and remedy anti-competitive behaviour by CCGs or by NHS England. Regulations on competition and procurement have been introduced under Section 75 of the 2012 Act: these are the NHS Regulations (they are also sometimes informally referred to as the "Section 75 regulations").
- 1.12 The legal framework set up by the HSCA is only one part of the body of laws which apply to procurement by NHS commissioners in England. EU public procurement law also applies, albeit to a generally more limited extent than it does to other types of public procurement. The legal landscape can be summarised as follows:
 - 1.12.1 EU public procurement law, namely:

³ From 1 April 2016 the role of Monitor was subsumed into that of a new organisation, NHS Improvement. For convenience, this publication continues to refer to the organisation in question as Monitor.



- a) The EU Directive on public procurement (2014/24/EU);
- b) For procurements commenced before 18 April 2016, the 2006 Regulations (as amended) regulating the procurement of health care services as "Part B" services;
- c) For procurements commenced from 18 April 2016, the 2015 Regulations applying the so-called "Light Touch Regime" embodied principally within Regulations 74 to 76 (inclusive) of the 2015 Regulations; and
- d) The Principles on the Functioning of the European Union (Treaty Principles).
- 1.12.2 A dedicated system of procurement rules (with accompanying guidance) applying specifically to the procurement of health care services for the purposes of the NHS in England, namely:
 - a) The NHS Regulations; and
 - b) Guidance supporting the NHS Regulations, published by Monitor.

1.12.3 **Competition law**, namely:

- a) Chapters 1 and 2 of the Competition Act 1998, concerned with agreements and concerted practices which prevent, distort or restrict competition, and with the abuse of dominant positions;
- b) Certain rules regulating mergers and joint ventures involving NHS Foundation Trusts, aligned with analogous rules in the Enterprise Act 2002:
- c) Competition provisions contained within the NHS Regulations; and
- d) The applicable parts of the same Guidance supporting the NHS Regulations, published by Monitor.
- 1.13 As this publication now goes on to explain, each of the above elements of the legal landscape plays a part (or may play a part) in procurement of health care services for the purposes of the NHS.

A note on the working practice of the authors

1.14 All of the authors of this publication are lawyers (solicitors and barristers) qualified in English law, and also members of the Procurement Lawyers' Association.

- 1.15 In order to facilitate the production of this publication, they divided themselves into three subgroups each subgroup having the responsibility of producing its respective Part. Following the conclusion of that work, each subgroup's output was collected and collated to form this publication.
- 1.16 Each subgroup has produced its respective Part by considering all of the legal issues which it considers relevant to the matters on which it has reported. In doing so, it is natural that each has, to an extent, developed its own style and, in doing so, may have included reference to subject-matter which has also been referred to by another subgroup in the context of that other subgroup's own Part. Whilst each subgroup has taken care to avoid duplication and inconsistency wherever possible (and whilst the final edit has sought to address any such instances), some small areas of duplication in references or coverage may remain.

PART 1

APPLICABLE REGIMES

The relationship between EU public procurement law and the domestic regulatory regime applicable to the procurement of health care services for the purposes of the NHS

1 INTRODUCTION

The scope of the 2015 Regulations as applicable to the procurement of health care services for the purposes of the NHS in England

- 1.1 Public procurement of health, social and other services by contracting authorities is regulated by the so-called "Light Touch Regime" under articles 74 to 76 of the Public Sector Directive. These articles are implemented into domestic law by Regulations 74 to 77 of the 2015 Regulations.
- 1.2 Contracting authorities include, within the health sector:
 - 1.2.1 commissioners (defined by the NHS Regulations as "relevant bodies"), that is to say CCGs and NHS England;
 - 1.2.2 all NHS trusts; and
 - 1.2.3 (insofar as they fulfil the definition of bodies governed by public law in Regulation 2 of the 2015 Regulations) NHS foundation trusts.
- 1.3 The Light Touch Regime regulates procurements with an estimated value in excess of the relevant financial threshold (EUR750,000). With effect from 1 January 2016, the sterling equivalent for the purposes of this threshold is £589,148.
- 1.4 Most public procurement of health services is England is carried out by CCGs or by NHS England. Some health services may be procured by *providers* of health care services for example, under subcontracts which relate to the services which they themselves provide, and which have been procured by NHS commissioners. The procurement of those services by NHS providers is outside the scope of this publication, and the status of providers as regards the application of public procurement law to them is not considered further.
- 2 OBLIGATIONS IN RESPECT OF HEALTH SERVICES CONTRACTS WHOSE VALUE IS EUR750,000 (£589,148) OR MORE
- 2.1 The key obligations placed on commissioners under the Light Touch Regime are described in the following sections. The Crown Commercial Service has also published statutory guidance on the new Light Touch Regime for health, social, education and certain other service contracts (updated October 2015), but that guidance is not directed specifically at contracting authorities in the NHS.

Obligation to advertise

2.2 Regulation 75 of the 2015 Regulations requires contracting authorities intending to award a public contract that is subject to the Light Touch Regime to advertise in the

- Supplement to the Official Journal of the European Union, either by means of a contract notice or of a prior information notice (PIN) as a call for competition.
- 2.3 In addition to advertising in the OJEU, contracting authorities procuring under the Light Touch Regime are required to publish an advertisement on Contracts Finder (PCR Regulation 106) where the advertisement is made by way of contract notice (although not, it seems, where it is made by way of prior information notice). However, Regulation 105 provides that the Contracts Finder requirement does not apply to the procurement of health care services within the meaning and scope of the NHS Regulations.
- 2.4 That carve-out is reversed, however, by Regulation 4(2) of the NHS Regulations which requires relevant bodies procuring contracts to which the NHS Regulations apply to place a "contract notice" (sic) on "the website maintained by the Board" (the website in question was formerly the "Supply2Health" site, but is now Contracts Finder).
- 2.5 The grounds for using the negotiated procedure without prior publication set out in Regulation 32 apply equally to the Light Touch Regime. These exceptions are explained in the section on derogations from the need to advertise health services contracts below.

Principles for awarding contracts subject to the Light Touch Regime

- 2.6 Contracting authorities are not required to follow any of the "standard" procurement procedures that apply to fully regulated procurements (Regulation 76(7)). However, they must determine in advance the process that they intend to follow.
- 2.7 Having determined the procedure, they must comply as a minimum with the EU principles of transparency and equal treatment (Regulation 76(2)).
- 2.8 In practice, the obligations above mean that the call for competition will set out the conditions for participation in the procurement (such as the criteria for selection at pre-qualification stage), the time limits for expressions of interest, submission of pre-qualification questionnaire (PQQ) responses or tender submissions, and the award procedure that the contracting authority is following (Regulation 76(3)).
- 2.9 There is also considerable case-law on the EU principles of transparency and equal treatment and this case-law continues to apply to procurements which are subject to the Light Touch Regime. For this reason, contracting authorities should continue to have regard to the Commission's Interpretative communication on the Community law applicable to contract awards not or not fully subject to the provisions of the Public Procurement Directives⁴. The General Court has confirmed⁵ that this

⁵ In Case T-258/06, Federal Republic of Germany v Commission.



⁴ Accessible at http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52006XC0801(01)&from=EN.

- Interpretative Communication accurately describes the law under the previous directives, and the authors consider that this remains the case.
- 2.10 Of particular importance in the case-law is that the principle of transparency requires contracting authorities to publish objective criteria for selecting bidders and, ultimately, the successful provider. Also, the Interpretative Communication makes clear that time limits for expressions of interest must be long enough to allow undertakings to make a meaningful assessment and prepare their offer⁶.
- 2.11 For Light Touch Regime procurements, contracting authorities have the express right under Regulation 76(8) to take into account any relevant considerations, including:
 - 2.11.1 the need to ensure quality, continuity, accessibility, affordability, availability and comprehensiveness of the services;
 - 2.11.2 the specific needs of different categories of users, including disadvantaged and vulnerable groups;
 - 2.11.3 the involvement and empowerment of users; and
 - 2.11.4 innovation.
- 2.12 In practice, these rights set out in Regulation 76(8) probably apply to all procurements, including fully regulated procurements and do not seem to add a great deal to the EU Treaty principles. Nevertheless, some contracting authorities in the health sector will find the confirmation of these rights reassuring.

Standstill obligations

- 2.13 A vital practical question is whether contracting authorities are required to notify bidders of the proposed award decision and stand still before contract signing. This is clearly required under Regulation 86 for fully regulated procurements in which a contracting authority was required to publish a contract notice in the OJEU.
- 2.14 Some commentators have suggested that there is no standstill requirement for Light Touch Regime procurements. This is on the basis that Regulation 86(5) exempts contracting authorities from the standstill obligation where the contract can be awarded without prior publication of a contract notice. The argument is that, since Light Touch Regime contracts may be advertised by way of a PIN as a call for competition instead of a contract notice, there is no obligation to publish a contract notice. Consequently, the argument is that there is no obligation to "stand still".
- 2.15 The Crown Commercial Service (CCS) has published Guidance on the standstill period, which states:

⁶ See para. 2.2.1 of the Interpretative Communication.



"The legal position is less clear under the new rules for the Light-Touch Regime (LTR). A standstill period may not strictly be required [...] But in the light of uncertainty, CCS suggests that contracting authorities will usually wish to send a standstill notice and observe the standstill period" [emphasis added].

- 2.16 However, it is submitted that authorities ought to stand still before awarding contracts under the Light Touch Regime and that they expose themselves to a considerable risk of ineffectiveness claims and other challenges if they fail to do so. In particular, the Court of Justice case-law in the *Alcatel* and *Commission v Austria* decisions requiring a standstill period is based on articles 2(1) and 2(6) (now 2(7)) of the Remedies Directive and those articles clearly apply to Light Touch Regime procurements. It therefore seems highly unlikely that the EU legislature intended to exclude from the standstill requirement procurements by sub-central authorities or Light Touch Regime procurements. The Court of Justice regularly applies a teleological interpretation of EU law (rather than delving into literal textual analysis), and it seems likely that it would adopt a teleological interpretation in this case thus requiring the observance of a standstill.
- 3 WHERE THE NHS REGULATIONS APPLY, SHOULD COMMISSIONERS ASSUME AS A STARTING POINT THAT ADVERTISING AND COMPETITION IS LIKELY TO BE REQUIRED?

Summary

- 3.1 The Government has said that it is for commissioners to decide when to use competitive tendering as a means of improving NHS services. However, it has been remarked that:
 - 3.1.1 "there have been concerns that commissioners are unclear about when to put services out to competitive tender and that more NHS contracts are being awarded to private companies now than was previously the case. In particular, it has been alleged that the Act has extended competition law to the NHS and led to greater private sector involvement."
- 3.2 While we as yet have no guidance from the Government on the way in which (on one hand) the so-called Light Touch Regime" under the 2015 Regulations and (on the other) the NHS Regulations are expected to inter-relate from 18 April 2016:
 - 3.2.1 there are provisions in the NHS Regulations which arguably conflict with each other when it comes to the question of whether a requirement for competition (under those Regulations) should be assumed as a starting point; and

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⁷ See "The Structure of the NHS in England" – Briefing Paper Number CBP 07206, 10 March 2016, House of Commons Library (at page 17).

in any event, it is difficult to see a future for commissioning processes which involve anything short of full, OJEU-advertised competition for health services (where their value exceeds the "Light Touch Regime" threshold of £589,148), given the applicability of the Light Touch Regime to procurement by NHS commissioners from 18 April 2016.

Analysis

3.3 We take each of the above points in turn.

Arguably conflicting provisions in the NHS Regulations

- 3.4 The NHS Regulations apply to CCGs and to NHS England. They provide a bespoke set of rules for commissioners and provide a mechanism for Monitor, as the sector regulator, to investigate complaints about the procurement of healthcare services.
- 3.5 There is no financial threshold under the NHS Regulations and they therefore apply to the procurement of all contracts for healthcare services, regardless of value.
- 3.6 Their objectives are set out in **Regulations 2 and 3**. However, **Regulation 5** is also significant. In the following extracts, emphasis has been added by the authors of this publication.
- 3.7 **Regulation 2** requires that, when procuring healthcare services, commissioners:

"must act with a view to:

- (a) securing the needs of the people who use the services;
- (b) improving the quality of the services; and
- (c) improving efficiency in the provision of the services;

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

- 3.8 **Regulation 3** imposes a number of general requirements on CCGs when procuring healthcare services. **Regulation 3(2)** requires them to:
 - (a) "act in a transparent and proportionate way, and
 - (b) <u>treat providers equally and in a non-discriminatory way</u>, including by not treating a provider, or type of provider, more favourably than any other provider, in particular on the basis of ownership."
- 3.9 **Regulation 3(3)** requires CCGs to:

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"procure the services from one or more providers that:

- (a) <u>are most capable</u> of delivering the objective referred to in Regulation 2 in relation to the services; and
- (b) provide best value for money in doing so."

3.10 **Regulation 3(4)** is also important. It provides that:

"in acting with a view to improving quality and efficiency in the provision of the services, the [CCG] must consider appropriate means of making such improvements, including through:

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

3.11 **Regulation 5** provides:

- "5.—(1) A relevant body may award a new contract for the provision of health care services for the purposes of the NHS to a single provider without advertising an intention to seek offers from providers in relation to that contract where the relevant body is satisfied that the services to which the contract relates are capable of being provided only by that provider.
- (2) For the purposes of paragraph (1), a relevant body is not to be treated as having awarded a new contract—
- (a) where the rights and liabilities under a contract have been transferred to the relevant body from the Secretary of State, a Strategic Health Authority or a Primary Care Trust; or
- (b) where there is a change in the terms and conditions of a contract as a result of—
- (i) a change in the terms and conditions drafted by the Board under regulation 17 of the 2012 Regulations (terms and conditions to be drafted by the Board for inclusion in commissioning contracts), or
- (ii) new terms and conditions drafted by the Board under that regulation."

- 3.12 When reading the above Regulations together, and in the absence of any order of precedence between any of them, a level of difficulty arises in determining how they should be interpreted and, specifically, in establishing whether the it should be assumed as a starting point that the NHS Regulations require NHS commissioning to be conducted by way of full competition open to all-comers, or whether commissioners have a choice between this and a narrower, more selective approach and possibly even one involving negotiation with a single provider, identified by a commissioner as obviously the most capable.
- 3.13 In December 2013, Monitor published guidance ("**the Guidance**") to accompany the NHS Regulations and to guide commissioners in deciding how to commission health services for the purposes of the NHS. In the Guidance, reference is made to:
 - 3.13.1 the absence of any actual *requirement* on NHS commissioners to run a competition the emphasis instead being repeatedly placed on the requirement to commission services in a manner which represents the best interests of patients (echoing **Regulation 2**); and
 - 3.13.2 Monitor having no power to *force* the running of any competition.

Which provisions of the NHS Regulations point towards this?

- 3.14 The Guidance is reflective of the fact that the Regulations do indeed contain no *express requirement* for competition. However, difficulty arises from the apparent inconsistency between **Regulation 2** on the one hand, and parts of each of **Regulations 3 and 5** on the other.
- 3.15 **Regulation 3** gives rise to difficulty for a number of reasons, but principally because it contains terminology "borrowed" from EU public procurement law (which, if interpreted in accordance with EU law, would point to a requirement for competition). **Regulation 5** does so because it is worded in such a way as to infer that the only situation in which competition may be dispensed with is where there is only one possible provider.
- 3.16 We examine each of these in turn.

Regulation 3, and the use of EU terminology

3.17 The NHS Regulations require commissioners to act transparently, and to treat providers equally and in a non-discriminatory way (**Regulation 3(2)**). This clearly "borrows" certain expressions from EU public procurement law – expressions which have specific meanings in the context of that law. However, there is no clear steer as to whether those expressions are intended to have the same meaning when used in the NHS Regulations.



- 3.18 In the EU context, these expressions mean that some level of competition will be required in those instances where cross-border interest is anticipated. However, the fact that the Guidance envisages a "balanced judgement" approach (which need not necessary involve competition) supports a view that these obligations are *not* intended to have the same meaning where used in the NHS Regulations.
- 3.19 The following expressions in **Regulation 3** are also used widely in the context of EU public procurement law. In all cases, emphasis is added by the authors of this note. Commissioners are required to:
 - (a) "act in a transparent and proportionate way, and
 - (b) <u>treat providers equally and in a non-discriminatory way</u>, including by not treating a provider, or type of provider, more favourably than any other provider, in particular on the basis of ownership."
- 3.20 The question which the use of this terminology raises is whether commissioners are required to interpret these provisions in the light of the *Telaustria* case-law applicable to public procurement, as interpreted by the European Commission in relation to the question of whether cross-border interest exists in relation to the contract sought to be let⁸.
- 3.21 The Department of Health's response to the opinions of Counsel states that the No 2 Regulations do not change public procurement law, and that public procurement law continues to apply to the commissioning of services by NHS commissioners as it did prior to the introduction of the No 2 Regulations (and of the No 1 Regulations). This is, of itself, a correct assertion. However, in so being, it raises the question of whether the same meanings should be ascribed to the underlined expressions above when reading the NHS Regulations.
- 3.22 The persuasive force of the Guidance has already been seen in the recent *QSRC* case (discussed below), the first decision of the High Court based on the NHS Regulations (although not one concerned with the "competition or no competition" question with which this publication deals).
- 3.23 In the event of a decision on this question, the Guidance may therefore continue to be persuasive; the position thereafter is less clear, but it is likely that there will be a greater likelihood that any inconsistency as between the application of the NHS Regulations and EU law will be resolved in favour of the Light Touch Regime (and of competition) in the event of a decision which turned precisely on this issue.

⁸ From 18 April 2016 the "Light Touch Regime" under the 2015 Regulations applies to the procurement of health care services for the NHS where the expected contract value equals or exceeds £589,148 (EUR750,000) (2015 Regulations, Regulation 120(1)). The question of the existence of cross-border interest (and therefore of whether and how to advertise) will continue to apply in relation to such contracts whose value falls below that threshold, but such that cross-border advertisement would only be required in the event of concrete indications of cross-border interest; at or above the threshold, the requirement to advertise is automatic (2015 Regulations, Regulation 75(1)): see further below.

Regulation 5, and the potential for narrow interpretation of situations where competition is not required

- 3.24 Taking it at face value, it is possible to interpret Regulation 5 as meaning that the only situation in which non-competition is expressly sanctioned is one where there is only one provider *capable* of providing the service in question (emphasis added), such that, in any other situation, a competitive tender process must take place. In the authors' view, that interpretation does not reflect what Parliament intended.
- 3.25 If that interpretation were correct, one practical effect of it would be that commissioners are:
 - 3.25.1 no longer able to establish a so-called "NHS contract" to cover the provision of a particular service i.e. a contract between an NHS commissioner and an NHS Trust, set up without a competition and often said to have been possible from a public procurement perspective on the basis of the *Teckal* exception (or an extension of it); and
 - 3.25.2 unable to commission using methods not involving competition (or at least, not involving competitive procedures open to all-comers).
- 3.26 The effect of this would be to rule out options which, for individual commissioning decisions, might well be the most appropriate.
- 3.27 In previous written opinions on the effect of the NHS Regulations, the opinion has been expressed that the effect of Regulation 5 is, indeed, to require competition except where there is only one provider capable of providing the service in question.
- 3.28 In March 2013, the campaign group 38 Degrees sought the opinions of Leading and Junior Counsel⁹. Those opinions are in the public domain. In their opinions, Counsel addressed a number of questions arising from the NHS Regulations, including those which are discussed here. Also in March 2013, the Department of Health published a response to the opinions. That response, also in the public domain, makes the following key points on the question of the requirement (or otherwise) for competition:
 - "15. Regulation 5 specifically provides for commissioners to award a contract without a competition where there is only one provider capable of delivering their requirements. The requirements would be those specified by the commissioner and the commissioner can design those requirements according to what is necessary to meet patients' needs, improve quality and efficiency, enable patients to access services in particular locations, deliver services in an integrated way or to improve health outcomes. In many cases, there will

⁹ The opinions are available at https://secure.38degrees.org.uk/pages/38_degrees_legal_briefings_on_si_2013_500.



only be one provider capable of delivering the particular requirements of the commissioner."

3.29 It goes on to state:

- "19. The regulations do not impose compulsory competitive tendering requirements on commissioners and expressly preclude Monitor from directing a commissioner to hold a competitive tender."
- 3.30 The intention of the Department is therefore ostensibly that the starting point as to whether competition is or is not required must always be Regulation 2, rather than Regulation 5; and that commissioners may, having decided which commissioning model would operate in the best interests of their patient populations, then be at liberty to commission according to that decision. This may, in turn, lead to a finding that there was in any event only one provider capable of providing a service meeting the requirements which the commissioner had identified. Support is lent to this view by Monitor's final report following an investigation into a commissioning exercise undertaken by Northern, Eastern and Western Devon Clinical Commissioning Group for the purposes of awarding a contract for services to adults with complex care needs¹⁰, which found that the lack of a fully open competition, accessible to all-comers, did not of itself constitute a breach of the NHS Regulations¹¹.
- 3.31 Arguably, this interpretation might seem to render plausible a situation where a commissioner is able to design a requirement/specification for a service pathway with the *intention* of avoiding a competition. If we consider a situation where:
 - 3.31.1 a commissioner identified two alternative service pathways, the first of which could be provided by multiple providers and the second only by a single provider (or a single specific grouping of providers in a particular locality), but
 - 3.31.2 nothing distinguished the two pathways in terms of which of them operated in the better interests of the commissioner's local population,

then there seems to be nothing in the NHS Regulations which would operate to prevent the commissioner to select the option which avoided competition (unless the second option were precluded by Regulation 10^{12} .

3.32 However, it is submitted that the better conclusion (and the one more workable in practice) is that, when read alongside Regulations 2 and 3, Regulation 5 should be

¹² Dealt with further in Part 3, below.



¹⁰ Published in September 2015 and discussed below in Part 2.

¹¹ N.B. The report also found that the CCG was (as at the date of the report) not in a position to award a contract to its chosen provider, Royal Devon & Exeter NHS Foundation Trust, without undertaking further work to assess the value-formoney proposition put forward by the Foundation Trust.

read as setting out just one example of a situation where competition is not required (although it would have been preferable for Regulation 5 to have made this clear by express reference). Adopting this (more flexible) interpretation would seem consistent with the Guidance; in addition, it would create less of a conflict with the "Light Touch Regime" under the 2015 Regulations.

3.33 For further guidance, it is useful to look briefly at the antecedents of the NHS Regulations – namely the Principles and Rules for Co-operation and Competition (PRCC) and the National Health Service (Procurement, Patient Choice and Competition) Regulations 2013 ("the No. 1 Regulations").

The antecedents of the NHS Regulations: whether the PRCC pointed towards competition, and whether the No. 1 Regulations pointed more clearly towards the real intention behind the NHS Regulations

3.34 An explanatory note, issued by the Department of Health when the NHS Regulations came into force, sets out the key differences between the No. 1 Regulations and the NHS Regulations in relation to the matters which are discussed in this publication. The notes state as follows:

"Regulation 2 states that the 'objective' of procurement is securing the needs of patients and improving quality and efficiency. We have made it clear that providing services in an integrated way is a way of achieving that objective.

Regulation 3(5) now requires commissioners to record how their awarding of a contract complies with the duties on them to secure integration.

In Regulation 5, we have removed the words that inadvertently created the impression that there were only very narrow circumstances in which commissioners could award a contract without a competition. Monitor's guidance on the regulations will make clear that we are continuing the same approach as now under the Principles and Rules for Co-operation and Competition.

Regulation 15 has been amended to clarify, for the avoidance of doubt, that Monitor does not have the power to direct a commissioner to hold a competitive tender."

- 3.35 However, in certain key respects the position under the NHS Regulations is less clear than that under the No. 1 Regulations. Regulation 5(2) of the No. 1 Regulations set out more clearly the circumstances in which services would be capable of being provided only by that provider:
 - "(2) The services are to be determined as capable of being provided by a single provider only when—

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- (a) for technical reasons, or for reasons connected with the protection of exclusive rights, the contract may be awarded only to that provider; or
- (b) (only if it is strictly necessary) for reasons of extreme urgency brought about by events unforeseeable by, and not attributable to, the relevant body, it is not possible to award the contract to another provider within the time available to the relevant body for securing the provision of the services".
- 3.36 These provisions closely mirror what is popularly known as the "sole supplier exception" in the 2015 Regulations (and which previously existed in the 2006 Regulations).
- 3.37 The PRCC contained no provisions of the type embodied in Regulation 5 of the NHS Regulations, despite the latter being an instrument designed to place the PRCC on a statutory footing. Instead, it is fair to say that the PRCC represented a more evenly balanced set of principles, placing similar emphasis on competition (where appropriate) and on integration (where appropriate), but without the apparent anomaly seen in the NHS Regulations and discussed in this publication. As such, it is submitted that the PRCC were not capable of generating a similar degree of confusion.

The Guidance: its persuasive force

3.38 The Guidance was issued in December 2013. It repeatedly suggests that the starting points for commissioners when considering whether or not to call for competition are **Regulations 2 and 3**, and not **Regulation 5**. By way of example, the following extracts from the Guidance illustrate this:

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

It is for the commissioner to decide which services to procure and how best to secure them in the interests of patients. For this reason, the regulations set out a principles-based framework to enable commissioners to decide in individual cases what is best for the people they serve.

(...)

The Procurement, Patient Choice and Competition Regulations are intended to enable commissioners to decide for individual services what is best for patients. They adopt a principles-based approach and do not generally include prescriptive rules on how commissioners must carry out their procurement activities. It is for commissioners to decide what services to

procure and how best to secure them in the interests of patients, within the framework of the regulations. Neither the regulations nor this guidance set out a preferred approach.

(...)

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

(...)

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

... How the health care needs of the population can best be secured (including how the commissioner can ensure the safety of services, for example, where clinicians need to carry out sufficient volumes of particular services/or a particular case mix to deliver services safely) and how the quality and efficiency of services might be improved, including through:

...the way the services are procured (<u>for example, through a competitive tender process or otherwise</u>);"

(...)

There is no requirement in the Procurement, Patient Choice and Competition Regulations for commissioners to publish a notice inviting offers from prospective providers to supply NHS health care services (a contract notice) before awarding a contract to provide those_services. The decision whether or not to publish a contract notice is a matter for commissioners having regard to the decision-making framework described in Section 1.3.

This decision is not an isolated decision. It will need to be taken in the context of a commissioner's decisions about what services to procure and how to go about procuring them more generally.

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

unnecessary where, <u>for example</u>, only one provider is capable of providing the services in question.

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

There will be circumstances where a decision to procure services without publishing a contract notice and/or running a competitive tendering process will be appropriate and consistent with the Procurement, Patient Choice and Competition Regulations. Three situations are considered in more detail below:

- Where there is only one provider that is capable of providing the services in question. In these circumstances, the Procurement, Patient Choice and Competition Regulations make it clear that a commissioner can award a contract to a single provider without publishing a contract notice.
- Where a commissioner <u>carries out a detailed review</u> of the provision of particular services in its local area in order to understand how those services can be improved and, as part of that review, <u>identifies the most capable provider or providers of those services</u>.
- Where the <u>benefits of publishing a contract notice would be outweighed by</u> the costs of doing so."
- 3.39 The above sections of the Guidance clearly indicate that competition is not necessarily required, even where there might be more than one capable provider of a particular service. Indeed, the Guidance contemplates not one (as per **Regulation 5**) but three situations in which a competition may be dispensed with. These apparent derogations go beyond not only the text of the No 2 Regulations, but also that of the No 1 Regulations; they clearly support a more flexible interpretation of **Regulation 5**, rather than one which supposes that the only situation in which competition can be dispensed with is where there is only one capable provider.

Does anything issued by the Department of Health therefore serve to make the position clearer?

3.40 The Department of Health's response to the opinions of Counsel (referred to above) states:

"The Opinion also asserts that commissioners will not be able to take into account wider strategic needs. This is not the case as such needs will be

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relevant to the objective set out in regulation 2 of "securing the needs of the people who use the services", including "through the services being provided in an integrated way". This means that the regulations consider integration to be a legitimate means of securing the needs of patients, improving quality and improving efficiency."

- 3.41 Whilst this response is difficult to square with a face-value interpretation of **Regulation 5**, it is consistent with the Guidance; it also lends support to the view that **Regulation 5** should not be given the narrow, face-value interpretation to which it appears to lend itself.
- 3.42 Indeed, the desire to achieve this possibility was a reason for the revocation of the No. 1 Regulations and their replacement with the NHS Regulations (and specifically the motivation behind the re-working of **Regulation 2** of the No. 2 Regulations).
- 3.43 If **Regulation 5** were absent, the position would actually be clear; there would be no scope for doubt as to whether integration (and the establishment of uncompleted contracts for health services) could in practice be achieved. It is **Regulation 5** which introduces the confusion, by ostensibly providing that the only situation in which a commissioner is entitled to dispense with a competition is where the service is *capable* of being delivered by just one provider.

QSRC Limited v NHS England

- 3.44 The recent case of *R* (on the application of QSRC Ltd) v National Health Service Commissioning Board and another [2015] EWHC 3752 is the first decision by the High Court concerning the NHS Regulations.
- 3.45 The facts of the case did not concern the specific question discussed in this publication, namely whether, on the interpretation of **Regulations 2, 3 and 5**, a particular service should or should not be commissioned using a competitive procurement procedure or not. However, it is of interest for the purposes of this publication because it largely turned on the interpretation of Monitor's 2014 guidance for commissioning the services in question "stereotactic radio surgery", or "SRS", and whether NHS England had properly followed that particular guidance when deciding not to offer a particular contract to the claimant provider rather than on a line-by-line reading of the NHS Regulations.
- 3.46 It is therefore possible that a Court would, if faced with the questions discussed in this publication (and specifically on the interpretation of **Regulation 5**), be persuaded by the force of the Guidance in making its decision. In so doing, it is possible that a Court would come down in favour of a broader, less restrictive interpretation.

Difficulty in seeing a future for non-OJEU-advertised commissioning: the application of the Light Touch Regime (LTR) to the commissioning of health care services for the NHS from 18 April 2016

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- 3.47 Whatever the merits of the arguments for and against a default requirement for competition, the implications of the opposing arguments are potentially less significant from 18 April 2016.
- 3.48 The change taking effect on that date is that the procurement of health care services for the purposes of the NHS which fall within the NHS Regulations become subject to the so-called "Light Touch Regime" under Chapter 3 of the 2015 Regulations, where the expected contract value is EUR750,000 (£589,148) or above. Previously, the pre-2015 rules governing the procurement of "Part B" services have applied to procurements for those contracts, with the result that, in relation to procurements commenced before 18 April 2016, NHS commissioners were required (by *Telaustria* principles) to assess the existence of cross-border interest and then to advertise to an extent sufficient to capture it but without the *automatic* advertising requirement which the LTR imposes where the £589,148 threshold is met.
- 3.49 In essence, the Light Touch Regime now *requires* competition where the contract value exceeds the threshold, absent a specifically available derogation (see further below). By contrast, the NHS Regulations may, but on the other hand may not, require competition in the same circumstances: their focus is on requiring commissioners to act with a view to securing the needs of service users and to improving quality and efficiency in so doing, including through integration. They must choose the provider(s) most capable of delivering the Regulation 2 objectives, and who provide best value for money in doing so. If this requires competition, so be it; on the other hand, it might not.
- 3.50 If, therefore, commissioners have no choice from April 18 2016 as to whether to advertise a contract, a clear friction exists with the "balanced judgement" approach advocated by the Guidance. In the absence of any modification to either set of rules, this may lead to ongoing confusion as to the way in which commissioners are supposed to comply with each: in other words, how, by complying with one set, commissioners do not place themselves in breach of the other. Ultimately, any dispute as to whether advertising were required or not would be likely to be resolved in favour of the 2015 Regulations (and of advertisement) by virtue of the supremacy of EU law.
- 4 DEROGATIONS FROM THE REQUIREMENT TO ADVERTISE A HEALTH SERVICES CONTRACTS UNDER REGULATIONS 74 TO 76, 2015 REGULATIONS

Which of the circumstances permitting use of the derogation at Regulation 32 of the 2015 Regulations are likely to be useful in the context of the procurement of health services for the purposes of the NHS? Might the Court of Justice continue to adopt restrictive approach to interpreting the scope of this derogation, or might there be scope for a more liberal interpretation where special sector contracts are concerned?

- 4.1 Regulation 75(1) of the 2015 Regulations provides for the publication of notices in respect of contracts for the award of social and other specific services including health care services. Whilst there is ordinarily an obligation to publish a contract notice for those contracts above the relevant threshold of£589,148, there is no requirement to do so where the "negotiated procedure without prior publication" could have been used in accordance with Regulation 32.
- 4.2 Insofar as it is relevant to public service contracts, Regulation 32 provides that the negotiated procedure without notice may be used in any of the following cases:
 - 4.2.1 Regulation 32(2)(a): Where no tenders or no requests to participate (or no suitable tenders or no suitable requests to participate) have been submitted in response to an open procedure or a restricted procedure, provided that the initial conditions of the contract are not substantially altered;
 - 4.2.2 Regulation 32(2)(b): Where the services can be supplied only by a particular economic operator for any of the following reasons:
 - a) the aim of the procurement is the creation or acquisition of a unique work of art or artistic performance;
 - b) Competition is absent for technical reasons; or
 - c) The protection of exclusive rights, including intellectual property rights.
 - 4.2.3 Regulation 32(2)(c): insofar as is strictly necessary where, for reasons of extreme urgency brought about by events unforeseeable by the contracting authority, the time limits for the open or restricted procedures or competitive procedures with negotiation cannot be complied with. The extreme urgency must not be attributable to the contracting authority (Regulation 32(4)).
 - 4.2.4 Regulations 32(7) and 32(8): relevant to public service contracts following a design contest.
- 4.3 Regulations 32(9) to 32(12): where a contracting authority wants to purchase new services which are a repetition of similar services entrusted to the economic operator by way of an original contract, provided that the services are in conformity with a basic project for which the original contract was awarded which was advertised. The basic project must indicate the extent of possible additional services and the conditions under which they will be awarded.
- 4.4 In relation to the derogation in Regulation 32(2)(a), it is just as possible in the procurement of health services, as in other types of procurement, for no suitable

tenders or requests to participate to be submitted or for there to be no tenders / requests to participate. In the authors' experience, this situation is unlikely to apply often as there is now a significant level of competition to provide many health care services, and this market is fairly sophisticated in terms of bidding against commissioners' requirements.

- 4.5 In relation to the derogation in Regulation 32(2)(b), the exceptions in points (ii) and (iii) only apply when no reasonable alternative or substitute exists and the absence of competition is not the result of an artificial narrowing down of the parameters of the procurement. Point (i) will clearly not be relevant in a health service context. The protection of exclusive rights under point (iii), including IP rights, is also unlikely to arise often.
- 4.6 Point (ii) could be relied on, for example, where there is a need to use a particular facility, the facility is controlled by an existing provider, the location is specific and it does not make practical sense to expect bidders to provide a new building. Obvious examples are A&E and associated trauma and Intensive Care Units. So far, the Department of Health and Monitor have refrained from requiring the owner of a particular hospital facility to make it generally available.
- 4.7 We can envisage circumstances where this could be relied upon in the context of the commissioning of health care services. For example, the purchase of additional services to deal with the sudden outbreak of a virus or a backlog created by an unforeseen event (the failures of another provider for example). Given the critical nature of health care services, this is perhaps more likely to apply from time to time in the health sector than in other, less critical sectors.
- 4.8 The derogation permitted by Regulations 32(9) to 32(12) may useful in the context of health services procurement, particularly in circumstances where an initial trial might be run with a view to rolling it out if successful.
- 4.9 In our view, all of the above scenarios are likely to continue to be interpreted strictly by the Courts and there is no suggestion in the Public Sector Directive or the 2015 Regulations that a more lenient approach might be taken to the health care sector. It is perhaps notable that the derogations provided for by Regulation 32 contain no derogations specific to the procurement of health services (for example, a derogation couched in terms of a "wider clinical interests" or a "cost-versus-patient-benefit" approach).
- 4.10 A further derogation in Regulations 32(7) and 32(8), applicable where the contract concerned follows a design contest, would not be relevant to health services.

Might any of the "in-house" or "public-to-public co-operation" exceptions (Regulation 12 of the 2015 Regulations) apply to the procurement of health care services?

The "in-house" exception

4.11 Regulation 12(1) to 12(3) provide as follows:

"Award of contracts to controlled persons

- 12.—(1) A public contract awarded by a contracting authority to a legal person falls outside the scope of this Part where all of the following conditions are fulfilled:—
- (a) the contracting authority exercises over the legal person concerned a control which is similar to that which it exercises over its own departments;
- (b) more than 80% of the activities of the controlled legal person are carried out in the performance of tasks entrusted to it by the controlling contracting authority or by other legal persons controlled by that contracting authority; and
- (c) there is no direct private capital participation in the controlled legal person with the exception of non-controlling and non-blocking forms of private capital participation required by national legislative provisions, in conformity with the Treaties, which do not exert a decisive influence on the controlled legal person.
- (2) A public contract also falls outside the scope of this Part where a controlled legal person which is a contracting authority awards the contract to—
- (a) its controlling contracting authority, or
- (b) another legal person controlled by the same contracting authority,

provided that there is no direct private capital participation in the legal person being awarded the contract with the exception of non-controlling and non-blocking forms of private capital participation required by national legislative provisions, in conformity with the Treaties, which do not exert a decisive influence on the legal person being awarded the contract.

- (3) A contracting authority shall be deemed to exercise over a legal person a control similar to that which it exercises over its own departments within the meaning of paragraph (1)(a) where—
- (a) it exercises a decisive influence over both strategic objectives and significant decisions of the controlled legal person, or
- (b) the control is exercised by another legal person which is itself controlled in the same way by the contracting authority,

and references to "control", "controlled" and "controlling" in paragraphs (1) to (3) shall be interpreted accordingly."

4.12 Regulations 12(4) to 12(6) provide for situations involving joint control.

Historic application of the *Teckal* exception to NHS bodies

- 4.13 It was the view of some practitioners that, prior to the coming into force of the NHS Regulations, NHS commissioners were entitled to "contract" with an NHS Trust without a competition. Historically, this was based on the premise that NHS contracts were not "contracts" satisfying the definition of "public contracts" for the purposes of the procurement rules. An alternative argument was that NHS bodies could rely on the *Teckal* exemption (which Regulation 12 now codifies).¹³
- 4.14 This view was not shared by all practitioners, and the view that NHS bodies could be seen as "one organisation" for the purposes of procurement law before the coming into force of the NHS Regulations was not, to the authors' knowledge, tested in any Court.

Current application of the "in-house" exception under Regulation 12 to NHS bodies

4.15 Two main points can be made about the application of the *Teckal* exemption (and of Regulations 12(1) to 12(3)) in a health services context. The first relates to the Commissioner/provider split between NHS bodies. The second relates to the operation of the NHS Regulations.

The Commissioner/provider split

- 4.16 In the NHS as it has been structured since 1 April 2013, NHS England is responsible for:
 - 4.16.1 providing national leadership for improving outcomes and driving up the quality of care;
 - 4.16.2 overseeing the operation of CCGs;
 - 4.16.3 allocating resources to CCGs; and
 - 4.16.4 commissioning primary care and specialist services.
- 4.17 There are currently 211 CCGs. They are responsible for commissioning most health services in England, including:

¹³ See, for example, the advice of Counsel to the campaign group 38 Degrees: https://secure.38degrees.org.uk/pages/38 degrees legal briefings on si 2013 500. The same advice is referred to above at paragraph 3.29 of this Part (above).



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- 4.17.1 planned hospital care;
- 4.17.2 rehabilitative care;
- 4.17.3 urgent and emergency care (including out of hours);
- 4.17.4 most community health services; and
- 4.17.5 mental health and learning disability services.
- 4.18 The two types of commissioning bodies, NHS England and the CCGs, do not have any remit to provide health care services themselves. They do, however, have the power to set up companies. NHS England may, under section 223 of the National Health Service Act 2006 (as amended), form a company to "provide facilities or services to persons or bodies exercising functions or otherwise providing services under this Act". CCGs have the same power although, under section 223A, the section 223 power must only be exercised for the purpose of securing improvement (a) in physical and mental health or (b) in the prevention, diagnosis and treatment of illness. It is therefore possible that NHS England (or perhaps more likely the CCGs) could set up a subsidiary company which provides or has a role in providing health care services and which could satisfy the requirements of Regulation 12.

The operation of the NHS Regulations

- 4.19 The NHS Regulations apply to CCGs and NHS England when "procuring" health care services for the purposes of the NHS. "Procuring" is not defined in the NHS Regulations. The opinion of Counsel¹⁴ was that this gives rise to a risk that the effect of the NHS Regulations could be to abolish the *Teckal* exemption as applicable to CCGs (and presumably NHS England) when commissioning health care services. Counsel submitted that one reading of "procuring" in this context is as "purchasing services from any third party, even one that satisfies the *Teckal* exemption". By contrast, another interpretation of "procuring" in this context might be to consider purchases from an entity that meets the Teckal requirements as a form of in-house provision, and therefore not a procurement at all.
- 4.20 We can envisage situations where a *provider* of health care services (such as an NHS Trust) may "subcontract" the provision of clinical services to a third party – e.g. to provide certain elective services for example. In this situation, there would seem to be no reason why the Teckal exemption could not apply given that there is no legislative restriction on NHS Trusts subcontracting the provision of health care services; the NHS Regulations do not apply to provider bodies such as NHS Trusts.

The "public-to-public cooperation" exemption



- 4.21 Under Regulation 12(7) of the 2015 Regulations, where a contract is concluded exclusively between two or more contracting authorities, it will fall outside of the scope of the 2015 Regulations (and therefore will not need to be advertised) where all of the following conditions are fulfilled:
 - 4.21.1 the contract establishes or implements a cooperation between the participating contracting authorities with the aim of ensuring that public services they have to perform are provided with a view to achieving objectives that they have in common;
 - 4.21.2 the implementation of that cooperation is governed solely by considerations relating to the public interest; and
 - 4.21.3 the participating contracting authorities perform on the open market less than 20% of the activities concerned by the cooperation.

Current application of the "public-to-public co-operation" exception under Regulation 12 to NHS bodies

4.22 Similar considerations apply as to the "in-house" exception:

The Commissioner/provider split

- 4.23 Given the fact that the CCGs and NHS England commission health care services but do not provide them themselves, it is difficult to envisage a situation whereby there could be a cooperation between two or more commissioners for the provision of health care services. It is possible, however, that two companies established under the section 223 NHS Act 2006 power could cooperate, and that this could fall within the exception.
- 4.24 There is also the question as to whether a contract between a commissioner and a provider (e.g. a CCG and a NHS Trust) could be seen as a cooperation agreement falling within the conditions in Regulation 12(7). It is doubtful however whether the first condition of "cooperation" could be fulfilled in this type of arms-length transaction: the relationship between commissioner and provider is distinct, and is based on the commissioner paying for the services and the provider providing those services. It is therefore difficult to see how the aims of the cooperation would be seen as fulfilling the same common objectives bearing in mind the objectives of commissioner and provider are, by their nature, different (albeit complementary).
- 4.25 In respect of two or more *provider* organisations, the public to public cooperation exception could be relied upon. For example, it is feasible that two NHS Trusts could pool resources with a view to providing a service to themselves and potentially to other Trusts (provided they fall under the 20% activity threshold).



The operation of the NHS Regulations

- 4.26 Reference in the NHS Regulations to the "procuring" of health care services could either be understood to rule out public-to-public cooperation or, instead, not to rule out an interpretation to the effect that a public-to-public cooperation arrangement is not a form of procurement at all and therefore does not fall within the scope of the NHS Regulations; the position in the light of the NHS Regulations is therefore somewhat uncertain.
- 4.27 The NHS Regulations do not apply to provider organisations such as NHS Trusts so it does not impose any restrictions on those.

Does Regulation 72 of the 2015 Regulations apply to modifications to contracts for the provision of health care services?

- 4.28 Regulation 72 sets out a series of circumstances in which a contracting authority may make changes to a contract or a framework agreement without triggering a requirement for a fresh procurement. Regulation 72 applies to procurements subject to the Light Touch Regime; accordingly the circumstances in question may apply to contracts for the provision of health care services for the purposes of the Public Sector Directive.
- 4.29 Those circumstances are not referred to in the NHS Regulations, and therefore there is a question as to whether a change to an existing contract (even one permitted by Regulation 72 of the 2015 Regulations) could still constitute the "procuring" of health care services for the purposes of the NHS Regulations. Regulation 5(2) of the NHS Regulations provides that a relevant body is not to be treated as having awarded a new contract:
 - "(a) where the rights and liabilities under a contract have been transferred to the relevant body from the Secretary of State, a Strategic Health Authority or a Primary Care Trust; or
 - (b) where there is a change in the terms and conditions of a contract as a result of:
 - (i) a change in the terms and conditions drafted by the Board under regulation 17 of the 2012 Regulations (terms and conditions to be drafted by the Board for inclusion in commissioning contracts), or
 - (ii) new terms and conditions drafted by the Board under that regulation."
- 4.30 It would appear therefore that the NHS Regulations set out their own range of "permitted changes" which are less wide-ranging than those contemplated by the 2015 Regulations. One possible view is therefore that amendments that are made to health care services contracts could still fall within the requirements of the NHS Regulations

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even when they fall within one of the six permitted changes set out in the 2015 Regulations. It is submitted, however, that the list of permitted changes in Regulation 5(2) of the NHS Regulations is not intended to exhaustive, and that this will not mean that every amendment to an existing contract will give rise to a new contract for the purposes of the NHS Regulations. For these purposes, it would seem sensible to at least be guided by the changes permitted by Regulation 72.

Part 2

REMEDIES

 $\label{lem:lemont} \textbf{Remedies available in relation to the procurement of healthcare services}$

1 INTRODUCTION

- 1.1 **Scope:** The scope of this Part is to consider the remedies available for breach of the rules applying to procurements for healthcare services¹⁵, including the Court regime and the regime enforced by Monitor. The focus of this Part is to look at the overall remedies which apply to procedures commenced from 18 April 2016 onwards, from which time the 2015 Regulations apply to the procurement of healthcare services. To the extent it is instructive to, we look at remedies achieved under the existing rules. The rules which apply to NHS procurement and specific competition law aspects are covered in the other Parts.
- 1.2 An important point regarding scope is that additional layers of regulation apply to CCGs and NHS England when commissioning healthcare services (including the NHS Regulations and the HSCA). Procurers of healthcare services may include local authorities or Acute or Foundation Trusts, or indeed other contracting authorities. They will be subject to the 2015 Regulations (as explained below).
- 1.3 **A rapidly changing environment:** The rules applicable to the procurement of healthcare services have been in a state of flux and subsequently so have the remedies available. Within just the last 5 years the rules can be characterised by 3 different eras:
 - 1.3.1 The first era preceded the introduction of the NHS Regulations. In that era, commissioners were bound by the provisions of the 2006 Regulations (as amended), TFEU¹⁶ principles where cross-border interest was attracted and general public law principles. Healthcare services were classified as "Part B" services and whilst it was generally thought by most practitioners that procurements for Part B services attracted the general duties of equal treatment, non-discrimination and transparency, the contrary argument was sometimes run. In any event, what is clear is that there was divergence of practice in the extent to which these opportunities were advertised.
 - 1.3.2 The second era saw the introduction of the NHS Regulations containing a very wide ranging set of obligations echoing these general principles. The NHS Regulations do not go so far as to mandate advertisement expressly.
 - 1.3.3 The third era will be the position under the 2015 Regulations applicable to procurements for healthcare services commenced from 18 April 2016 under which all healthcare services are categorised as "Social and other specific services" listed in Schedule 3. Regulation 75 requires mandatory

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The focus of this Part is to look at the remedies which have been achieved for Part B services (under the 2006 Regulations (as amended)), those services covered by the NHS Regulations and which are covered by Schedule 3 of the 2015 Regulations under the Light Touch Regime as from 18 April 2016. This includes some clinical services if they are classified as healthcare services or Light Touch Regime services. It excludes clinical services if they are classified as services other than Light Touch Regime services, or do not fall within the definition of healthcare services under the HSCA.

Treaty on the Functioning of the European Union.

advertisement for contracts for healthcare services which are above threshold¹⁷.

- 1.4 This rapidly changing regulatory environment reflects the transformation of the provision of healthcare services, reflecting the enhanced contribution of the independent sector and the commercialisation of NHS bodies.
- 1.5 This Part is broken down into 3 sections:
 - **SECTION 2:** Executive Summary
 - **SECTION 3:** Remedies available under the 2015 Regulations, including the approach of the Courts
 - **SECTION 4:** Remedies available under the NHS Regulations
 - **SECTION 5:** Alternative routes to challenge including:
 - Right to refer to the European Commission
 - Judicial Review
 - **SECTION 6:** Conclusion

2 EXECUTIVE SUMMARY

- 2.1 The remedies available to economic operators interested in the provision of healthcare services are adequate. For those bidders who are aware of a commissioner's intention to enter into a contract before the conclusion of the contract, and are therefore able to issue a claim before contract award, the available remedies equate broadly to those remedies available for fully regulated services. Post-award the position is different. This means that for those cases where an authority fails to tender at all, the remedies available will depend on whether or not the provider is aware of the proposed contract before it is entered into.
- 2.2 The Monitor regime offers an additional option for providers considering grounds of challenge for healthcare commissioning. It is not subject to the same time constraints as imposed on claims under the PCR. It offers greater powers to set aside contracts than the Courts have under the PCR. However there is less control over the process: there is no certainty that Monitor will take the complaint on and although bound by public law principles, Monitor is not bound by precedent.
- 2.3 A point germane to all procurement challenges is the effect of the recent increase in Court fees on availability and accessibility of remedies. The fee for a damages claim has recently increased from £2,480 to £10,480¹⁸ which makes the issue of proceedings

^{£589,148/€750,000} between 1 January 2016 and 21 December 2017.

For claims seeking damages in excess of £200,000 and which seek a declaration. The Ministry of Justice has consulted on raising the Court fee to a maximum of £20,000. The overwhelming response to that consultation was

a significant investment for operators, particularly SMEs. This makes a complaint to Monitor a more attractive option if legal fees are a significant deterrent. Alternatively some operators are considering whether to issue a claim just for a declaration alone, rather than also for damages. This would attract a Court fee of £480¹⁹ only. However, in the event that the suspension were lifted, it would leave the operator with no remedy.

2.4 The Court has power to award damages in claims under the PCR (and in judicial review where the claimant has a private law cause of action). It is not clear whether Monitor would award damages under the NHS Regulations or its other statutory powers.

3 REMEDIES AVAILABLE UNDER THE PUBLIC CONTRACTS REGULATIONS 2015

This section is divided into the following sub-sections:

- Paragraphs 3.1 3.4: Above threshold;
- Paragraphs 3.5 3.7: Below threshold;
- Paragraphs 3.8 3.12: Limitation, pre-action issues and FOIA;
- Paragraphs 3.13 3.14: Approach of the Courts;
- Paragraphs 3.15: Observations.
- 3.1 **Above threshold:** The Remedies provisions are contained within Part 3 of the 2015 Regulations and apply to contracts and framework agreements falling within the scope of Part 2^{20} . Provided they are not excluded under Regulations 7 12 (for example by virtue of provisions on inter-authority co-operation) above threshold procurements for healthcare services are within the scope of Part 2^{21} .
- 3.2 Part 3 of the 2015 Regulations provides for the following remedies:
 - 3.2.1 For a standstill period to be run where Regulation 86, 2015 Regulations applies (see below in relation to whether this provision applies for healthcare services).
 - 3.2.2 For an automatic suspension where Regulation 95, 2015 Regulations applies. This is a valuable remedy which does apply for healthcare service procurements. Its utility is dependent on the operator being aware of the contract award decision and is of less use where there is no announcement

that the fees should not be further increased. For now, the Ministry of Justice has responded to say that it will not increase fees further, but may revisit the issue again in the future.

This is soon to be increased to £528.

Regulation 85 of the 2015 Regulations.

Regulation 3 and 74 of the 2015 Regulations.

of the intention to enter into the contract and/or no standstill period. This is likely to be the case in situations where there is an illegal direct award. In those situations an operator would hope to be able to set aside any contract entered into, but for the reasons set out below, may be unable to do so under the 2015 Regulations.

- 3.2.3 For interim orders where Regulation 96, 2015 Regulations applies (this includes the ability to apply for a suspension of the contract award procedure under the usual provisions of Part 23 of the Civil Procedure Rules and encompasses the ability to injunct the process before the contract award decision is made).
- 3.2.4 For pre-contractual remedies where Regulation 97, 2015 Regulations applies namely:
 - (a) setting aside decisions or actions;
 - (b) ordering an authority to amend a document; and/or
 - (c) awarding damages to an economic operator which has suffered loss or damage as a consequence of breach.

These are the final orders which a Court may grant at trial, for example, in situations where an interim (automatic or otherwise) suspension has been in place until trial. The Court may quash the decision to award to a successful bidder²².

- 3.2.5 For post-contract remedies where Regulation 98, 2015 Regulations applies, namely:
 - (a) a declaration of ineffectiveness and associated civil financial penalty;
 - (b) where grounds for ineffectiveness exist, but as an alternative to ineffectiveness where Regulation 102, 2015 Regulations applies, a civil financial penalty and/or contract shortening; and/or
 - (c) damages.
- 3.2.6 Within the jurisdiction of the Courts of England and Wales, as at the time of writing of this Part, there has been no declaration of ineffectiveness. The Scottish Courts have made one finding of ineffectiveness in relation to the decision by Inverclyde Council to award a contract for street lighting under

As in Woods Building Services v Milton Keynes Council [2015] EWHC 2172 (TCC).



- a framework to an entity not on that framework²³. There has been no finding of ineffectiveness in relation to healthcare services.
- 3.2.7 Where the Court does make a finding of ineffectiveness, it can decide to shorten the contract instead of setting it aside where there are general interest grounds for doing so²⁴. This may well apply in the case of contracts for healthcare services where continuity of service provision will be in the public interest. Where the Court does make a finding of ineffectiveness, it also has to impose a civil financial penalty payable to the Crown. As there is not yet an instance to set a precedent, it is not known how large this penalty might be. Regulation 102(4) provides that the penalty must be "effective, proportionate and dissuasive" and regulation 102(5) provides that the Court must take account of the seriousness of the breach, the behaviour of the contracting authority and the extent to which the contract remains in force.
- 3.3 It is however important to note that the remedies set out in paragraph 3.2.1, 3.2.5(a) and (b) above (i.e. the standstill provisions and those remedies which flow from a declaration of ineffectiveness) are unlikely to apply to procurements for healthcare services unless (in the case of the ineffectiveness remedy) a contracting authority has breached either the automatic injunction or Court order suspending the contract award procedure:
 - 3.3.1 **The first ground of ineffectiveness:** Regulation 99(2) provides that the first ground of ineffectiveness applies where the contract has been awarded without prior publication of a contract notice in any case in which Part 2 required the prior publication of a contract notice. Above threshold procurements for healthcare services can always be advertised by way of a prior information notice <u>instead of</u> a contract notice (see regulation 75(1)(b)). The first ground of ineffectiveness therefore does not apply to procurements of healthcare services, because Part 2 never requires the prior publication of a contract notice for the procurement of healthcare services.
 - 3.3.2 **The second ground of ineffectiveness:** Regulation 99(5) provides that the second ground of ineffectiveness applies where the contract has been entered into in breach of any requirement imposed by any of the following three situations:
 - (a) **Regulation 87** (the standstill period)²⁶: As there is no express obligation to hold a standstill period in procurements for healthcare services, this breach will not arise:

Lightways (Contractors) Ltd v Inverclyde Council [2015] CSOH 169.

Regulation 100.

²⁵ Regulation 102.

²⁶ Regulation 99(5)(a)(i).

• Regulation 87 provides that a contracting authority must hold a standstill period "where Regulation 86(1) applies". Regulation 86(1) applies "subject to paragraphs (5) and (6)". Regulation 86(5) provides that:

"Exemptions

- (5) A contracting authority need not comply with paragraph 1 in any of the following cases:-
- (a) where the contract or framework agreement is permitted by Part 2 to be awarded or concluded without prior publication of a contract notice..."
- As healthcare procurements can be commenced by means of a prior information notice rather than a contract notice (see paragraph 3.3.1 above) this means that there is no express requirement to run a standstill period or issue a standstill letter for healthcare procurements. This is referred to in the Crown Commercial Service's Guidance on the New Light Touch Regime for Health, Social, Education and certain other service contracts and Guidance on the Standstill Period. The Crown Commercial Service refers to the ability to begin Light Touch Regime procurements by way of a prior information notice rather than a contract notice, and suggests that the position on whether or not a standstill period must be run is therefore "unclear". The Guidance suggests that in many cases it would be advisable to run a standstill period in order to act in a transparent way in any event. The authors would agree that it is advisable to issue a standstill letter and run a standstill period as this complies with the principles of transparency and equal treatment which are applicable to Touch Regime procurements. In exceptional Light circumstances a commissioner may decide that it has grounds not to run a standstill period, but the authors would recommend that the reasons for doing so be carefully considered and documented. It is however clear on the face of the Regulations that there is no express obligation to run a standstill period for Light Touch Regime services. As Regulation 87 does not require a standstill period to be run for healthcare procurements, there can be no breach of Regulation 87 if a standstill is not held, and accordingly this second ground of ineffectiveness will not arise under Regulation 99(5)(a)(i). Practically, it is also an important distinction in terms of the opportunity for a disappointed tenderer to access meaningful pre-contract remedies.

- (b) Regulation 95 (contract-making suspended by challenge to award)²⁷: The second situation in which the second ground of ineffectiveness might apply is where the authority is in breach of this provision. This is commonly referred to as the automatic suspension and will apply to procurements for healthcare services. Were an authority to enter into a contract in defiance of the automatic suspension an economic operator would be able to access the ineffectiveness remedy provided the other conditions in Regulation 99(5) were met. This will be (it is hoped) a relatively rare occurrence.
- (c) Regulation 96(1)(b) (interim order restoring or modifying a suspension originally imposed by Regulation 95)²⁸: The third situation in which the second ground of ineffectiveness might apply is where the authority is in breach of this provision. This relates to the ability of the Court to restore or modify a requirement originally imposed by the automatic suspension provisions. If, for example, a contracting authority applied to lift the suspension, the Court may choose to maintain the suspension but order the claimant to provide a cross-undertaking in damages and an expedited trial. Were the authority to enter into the contract in defiance of the suspension being maintained, this economic operator would be able to access the ineffectiveness remedy provided the other conditions in Regulation 99(5) were met. Again, this will be (it is hoped) a relatively rare occurrence.

Note that this second ground of ineffectiveness is not available where an authority defies an injunction which an operator has obtained by virtue of applying for the same under the usual provisions of Part 23 of the Civil Procedure Rules. This is because the second ground of ineffectiveness only refers to breaches of Regulations 87 (standstill), 95 (the automatic suspension) and 96(1)(b) (interim order restoring or modifying automatic suspension). It does not apply to the other circumstances in which a Court may suspend the procedure. This means that if an economic operator applies for and obtains an injunction halting a process at PQQ stage, were the authority to proceed in defiance of the injunction, no ineffectiveness remedy would apply.

3.4 **The third ground of ineffectiveness:** Regulation 99(6) provides that the third ground of ineffectiveness applies where an above threshold contract is awarded in breach of any requirement imposed by r33(11) (award of contract based on framework agreements through re-opening of competition), or r34(21) to (24) (award of contracts under dynamic purchasing systems). Those requirements do not apply to healthcare

²⁷ Regulation 99(5)(a)(ii).

Regulation 99(5)(a)(iii).

services procurements. This is because public contracts for the services listed in Schedule 3 (i.e. Light Touch Regime services including healthcare services) are to be awarded in accordance with the provisions of Section 7, Chapter 3. Whilst authorities can shape their healthcare services procurements in a way which corresponds to procedures, techniques and features set out in Chapter 2²⁹ (which includes frameworks and DPS), authorities are not bound by those requirements in the way that they are for fully regulated services. As such, the third ground of ineffectiveness will not apply to healthcare procurements.

- 3.5 **Below Threshold:** The remedies set out above which are available in above threshold procurements as provided for in Part 3 of the 2015 Regulations are not available for below threshold procurements as those procurements are outside the scope of Part 2³⁰. There is however the possibility to found an action based on general principles: TFEU principles will apply where there is a requisite degree of cross-border interest³¹. Recital 114 of Directive 2014/24/EU states that below threshold procurements will typically not attract cross-border interest <u>unless</u> there are concrete indications to the contrary. We would suggest that contracting authorities cannot automatically conclude that a below threshold procurement does not attract cross-border interest, and that following the case of *Mansfield DC v Secretary of State for Communities and Local Government* [2014] EWHC 2167³² a failure to consider whether there is a potential cross-border interest for below threshold procurements may amount to a breach of TFEU principles.
- 3.6 Although guidance issued by the Crown Commercial Service suggests that member states only agreed to new Light Touch Regime rules on the basis that below threshold contracts would not attract cross-border interest (see below), the guidance does not give due weight to the words underlined below.

"In the negotiations, the European Commission was clear that contracts below the LTR threshold would not be of cross border interest and so would not need to be advertised in the OJEU. Member States only agreed to the new LTR rules on that basis. This is reflected in recital 114 of the Directive, which sets out that it is the services above that threshold which might have a cross border interest. In particular, the recital states that "Services to the person with values below that threshold will typically not be of interest to providers from other Member States, unless there are concrete indications to the contrary, such as Union financing for cross-border projects" extracted from the Crown Commercial Service's Guidance On The New Light Touch Regime For Health, Social, Education And Certain Other Service Contracts".

3.7 A challenge based on breach of TFEU principles would be actionable:

Regulations 3 and 85.

Concerning the claw-back of ERDF funding.

Regulation 76(7).

Telaustria Verlags GmbH and Telefonadress GmbH v Telekom Austria AG, Case C-324/98 [2000] ECR I-10745 and Commission v Ireland C-507/03.

- 3.7.1 by way of judicial review; and/or
- 3.7.2 Article 258³³ infraction proceedings; and/or
- 3.7.3 possibly a tortious claim for breach of statutory duty under the European Communities Act 1972, with a 6 year limitation period.³⁴
- 3.8 **Limitation:** Claims brought under the 2015 Regulations or under the 2006 Regulations (as amended) which do not seek a declaration of ineffectiveness must be brought within 30 days of when the economic operator knew, or ought to have known, that grounds for starting the proceedings had arisen³⁵. This period is extendable to a maximum of 3 months where the Court considers that there is a good reason for doing so³⁶. What would constitute a good reason for the exercise of discretion in this regard is not set out in the Regulations, and has not been set out by the Courts. In *Mermec UK Limited v Network Rail Infrastructure Limited* [2011] EWHC 1847 (TCC) Akenhead J said that:

"It is perhaps unhelpful to try to give some exhaustive list of the grounds upon which extensions should be granted but such grounds would include factors which prevent service of the Claim within time which are beyond the control of the claimant; these could include illness or detention of the relevant personnel" [paragraph 23(b) of the judgment].

- 3.9 There are different time limits applicable to claims for declarations of ineffectiveness and associated remedies but as set out above these are unlikely to apply to procurements for healthcare services.
- 3.10 As will be seen below there is an important point regarding limitation in relation to judicial reviews of procurement decisions. Broadly, Part 54 of the Civil Procedure Rules ordinarily allows for a 3 month limitation period for judicial review (see further Section 5 below for important detail). The limitation period in respect of judicial reviews of procurement decisions was however reduced down to 30 days by The Civil Procedure (Amendment No. 4) Rules 2013 (SI 2013/1412). It would be reasonable to assume therefore that the limitation period in judicial review of procurement decisions will be aligned with challenges brought under the 2015 Regulations. However, a recent decision creates some uncertainty on how this applies³⁷. We would suggest that the decision in *QSRC* ought to be treated with some caution in so far as it concerns limitation periods for judicial review of procurement decisions, and that the two limitation periods ought to be aligned.

Ex Article 226.

See *AG Quidnet Hounslow LLP v Mayor and Burgesses of London Borough of Hounslow* [2012] EWHC 2639 and *Phonographic Performance Ltd v DTI* [2004] 1WLR 2893. Query whether this would be a legitimate way of circumventing the 30 day limitation period in above threshold challenges.

Regulation 92(2).

Regulations 92(4) and 92(5).

See R (QSRC Ltd) v National Health Service Commissioning Board (NHS England) and anor [2015] EWHC 3752 (Admin).

- 3.11 **Pre-action issues:** Procurement claims, both within and outside the NHS, have their own unique complexities in what is an area of rapidly developing law. In recognition of this a draft pre-action protocol applicable to the Technology and Construction Court³⁸ has been developed to provide guidance to practitioners on the management of public procurement claims. Whilst the protocol is not binding, its aim is to enable the parties to settle issues between them without the need to start proceedings. To the extent it is practical and does not make it unreasonably difficult to issue and serve proceedings within the relatively short limitation period, the parties are encouraged to use the pre-action process including: a letter before claim; response, exchange / disclosure of information and to make proportionate efforts to resolve the dispute without litigation (including through the use of alternative dispute resolution).
- 3.12 Freedom of Information Act 2000 (FOIA) requests: The pre-action protocol encourages early exchange / disclosure of information in relation to a procurement disputes but, in addition to this, potential claimants (both within and outside the NHS) may use rights under FOIA as a means to obtain information. However, the timescales for responding to FOIA requests (20 working days running from the day after receipt) can be problematic as often the information requested will not materialise until after the limitation period for commencing proceedings has expired. Nevertheless, FOIA is still used widely as a means of seeking information about a procurement process. The claimant making the request will often encourage the disclosing authority to respond in advance of the statutory deadline in the interests of making efforts to resolve matters prior to the need to issue proceedings. Once proceedings have commenced, FOIA is of less use as exchange of information will normally be dealt with as part of standard disclosure or Court directed disclosure under the proceedings.

3.13 Approach of the Courts to remedies:

- 3.14 There are no reported final decisions in relation to procurements for healthcare services. This means that the Court has not (a) quashed a decision in respect of healthcare services (b) declared a contract ineffective nor (c) awarded damages. There are very few reported interim decisions in relation to procurements for healthcare services, but there are some reported interim decisions on social care services. Although these are outside the scope of this Part (as social care services are not commissioned by CCGs or NHS England), social care services are also Light Touch Regime services, often including a patient care element, and it is likely that the decisions below would be relevant to a case involving pure healthcare services.
 - <u>Solent NHS Trust v Hampshire County Council [2015] EWHC 457</u>: this case concerned a procurement for county wide integrated adult substance misuse recovery services. The claimant Trust was the incumbent provider, and issued a claim triggering the automatic suspension when it lost the re-tender process. The defendant Council applied to lift the suspension³⁹. The Court accepted that

TCC Protocol on Procedures for Public Procurement Cases (Proposed Appendix H to the TCC Guide).

Under Regulation 47H(1)(a) of the PCR 2006 (the equivalent provision to be found in Regulation 96(1)(a) of the 2015 Regulations).

the test to be applied in determining the Council's application to lift the suspension was that set out by the House of Lords (albeit as developed in further case law) in *American Cyanamid Co. v Ethicon* [1975] AC 396:

"In essence, in deciding whether or not to lift the suspension, the Court has to decide whether there is a serious question to be tried, whether Solent would be adequately compensated by an award of damages and whether on the balance of convenience the suspension should or should not remain in place. The development of the law, so far as is material, is that the Court in considering whether damages would be an adequate remedy needs to consider the question of ""whether it is just in all the circumstances that the claimant should be confined to his remedy in damages"" (per Jackson LJ in Iraci v Fallon [2011] EWCA Civ 668 at Paragraph 42)."

The defendant accepted that there was a serious issue to be tried but primarily on the basis that disclosure had yet to take place. Regarding the adequacy of damages, Akenhead J noted that Solent's claim included damages for lost profit/wasted bid costs and that this was not a case where the Court would have to carry out a complex assessment of the percentage chance of Solent winning the contract; either the claimant would have won the contract or it would not. Whilst the impact of losing the contract on the reputation of the claimant had been taken into account in other cases, in this case the Court did not accept that losing the contract would have a material effect on Solent's reputation. The Court said that the real considerations in relation to adequacy of damages arose out of two issues (1) TUPE and (2) closure of a unit known as Baytrees. In relation to the TUPE issue, Solent argued that staff transferring under TUPE to the winning bidder would have a detrimental impact on Solent's ability to deliver other services. The Court was not persuaded by Solent's evidence on this point, and nor was it persuaded of the potential impact on the Baytrees unit.

In terms of the balance of convenience, the Court concluded that this pointed clearly in favour of the suspension being lifted. Whilst the Court recognised the public interest in seeing the 2006 Regulations properly followed, that factor was not conclusive. What was more persuasive in this instance was the evidence submitted by the defendant as to the improvements which the new contract would deliver.

"I am very concerned, on the evidence, about the ""service users"" and the impact of a delayed contract on the services to be provided for their benefit. Whilst, decently, Solent has agreed in principle to continue to provide the current level of services for as long as is reasonably necessary, what is not going to be provided is the new, improved and integrated service which this proposed contract was intended to provide." [Paragraph 38]

• R (Frendoc) v Bristol Primary Care Trust [2013] (Unreported, Administrative Court): Frendoc was the incumbent provider of GP out of hours services in Bristol. It competed in the procurement to identify a new provider for Bristol, South Gloucestershire and North Somerset to whom the service would transfer in time for the implementation of the new NHS 111 service in order that it could be integrated with that service. The procurement was won by BrisDoc whereas Frendoc failed to reach the second stage of evaluation and was notified of its exclusion from the process in May 2012.

The application for judicial review was issued in March 2013, only two weeks before the services were due to transfer to BrisDoc. The grounds of claim focussed on an allegation that the PCT had acted irrationally in allegedly failing properly to investigate anonymous complaints that had been made against BrisDoc's practices and on alleged failure to discharge the public sector equality duty under s.149 of the Equality Act 2010. The Claimant sought an injunction preventing the transfer of services to BrisDoc.

At the point the application for judicial review was issued, Frendoc was out of time to issue a claim challenging the procurement process itself either under the 2006 Regulations or by way of judicial review. The issued claim sought the same remedy that would have been granted if a claim had been issued prior to contract award under the 2006 Regulations; namely, an injunction to prevent the services transferring. The claim was in time because it challenged events that took place much later than the procurement or the contract award decision.

The applications for judicial review and for the injunction were refused with the Court ordering indemnity costs in the Claimant's favour. Services were therefore able to transfer on the expected date. The Court was not convinced of the harm to patients arising as a result of the alleged poor practice by BrisDoc or of the failure by the PCT to carry out a reasonable investigation of the allegations.

• Bristol Missing Link Ltd v Bristol City Council [2015] EWHC 876 (TCC): the Claimant had for the previous 16 years under a rolling contract awarded by the Council provided services to women in Bristol who had suffered domestic violence. On the re-procurement of the service, the Claimant came second, losing out to the winning bidder, Refuge. BML perceived several errors in the evaluation of tenders and so issued a claim under the 2006 Regulations which triggered the automatic suspension and prevented the Council from signing the contract. The Council immediately applied to lift the suspension and, as in Solent (above), the Court considered this application applying the test set down in American Cyanamid Co v Ethicon [1975] AC 396.

Unlike in *Solent*, the Court declined to lift the automatic suspension. The Court was very dismissive of the Council's earlier refusal to disclose documents relating to the evaluation of tenders on which it now sought to rely

in asserting that there would be harm to service users if the contract were not permitted to be signed. The Court found that the low hurdle in establishing that there was a serious issue to be tried was met in light of the unexplained moderation downwards of scores and where relevant documents had not been disclosed.

With regard to whether damages were an adequate remedy, the Court considered it relevant that the Claimant was a not for profit entity. As such, it found that damages, which are usually calculated on a loss of profit basis, would not adequately compensate BML for any breach and were not therefore an adequate remedy. It was also relevant that BML's evidence was that its business as a whole would suffer catastrophic harm as a result of the loss of this critical contract that could not be compensated by damages.

On the balance of convenience, the Court found that the Council had failed to evidence that the implementation of the new contract and the Refuge service would bestow substantial advantages on the current service users such that delay in this implementation would cause them harm:

"Finally on this topic, I should say that Mr Williams QC relied heavily on the decision of Akenhead J in Solent, which he said was very similar to the present case, and where the suspension was lifted because of the balance of convenience. In truth, although there are some superficial similarities between the cases (the provision of social care services by 'not for profit' organisations), there were three important differences. One was the fact that Solent bid on the basis of a 5% profit margin, which was not what happened here. Secondly, the judge rejected Solent's case as to the other consequences if the suspension was lifted (damage to reputation and so on) whereas, on the facts here, I have found in favour of BMLL and the (different) consequences for them. But thirdly, and for this purpose most importantly of all, I note that at paragraphs 4 and 5 of his judgment in **Solent**, Akenhead J spent some time demonstrating the considerable advantages of the new contract, compared to the services which were currently being supplied. On the facts of this case, and for the reasons that I have given, the opposite applies here. That is a further explanation for the different result. "

The Court therefore ordered that the suspension should remain in place.

• <u>Counted 4 Community Interest Company v Sunderland City Council [2015] (Unreported, TCC): Counted 4 was the current provider of the clinical aspect of substance misuse services to the Council under an existing contract. It bid for the Council's procurement of substance misuse treatment and harm reduction services but the contract was awarded to the previous contract holder, an NHS trust. Counted 4 brought proceedings and the Council applied</u>

for the automatic suspension of the award under Regulation 96(1) of the 2015 Regulations to be lifted.

Carr J held that there was a serious issue to be tried. Although Counted 4's claim to damages was readily calculable, if the suspension were to be lifted then the workforce would be lost and it would take years to develop skills that were not available in the wider market. There was a public interest in the local authority complying with EU legislation. The current service did not create such a risk to the users of the service that the public interest outweighed the prejudice to Counted 4 if the suspension were lifted. Consequently the automatic suspension should not be lifted, but it should rather continue until trial on the terms of the limited undertaking Counted 4 had offered.

- Newcastle Upon Tyne Hospital NHS Foundation Trust v Newcastle PCT [2012] EWHC 2093 (QB). In November 2011 Newcastle-upon-Tyne Hospital NHS Foundation Trust tendered for contracts to provide diabetic retinopathy screening services (DRS Contracts) to the four defendant Primary Care Trusts in the North East of England (the PCTs). The Hospital challenged on the basis that it alleged that the PCTs had failed to observe their duties under Regulation 4(3) of the PCRs to "treat economic operators equally and in a non-discriminatory way" and to "act in a transparent way". The Court granted an application, under Regulation 47H of the 2006 Regulations (as amended), to lift the automatic suspension of a procurement process imposed by Regulation 47G. The balance of convenience favoured lifting the suspension because it would not be just to put the defendant in a position where it had no choice but to award an interim contract to an unsuccessful bidder, who was the existing service provider, when it did not consider that to be the proper course.
- <u>R (QSRC Ltd) v National Health Service Commissioning Board (NHS England)</u> and anor [2015] EWHC 3752 (Admin): See further below in relation to the remedy of judicial review and in relation to the Monitor regime enforced under the NHS Regulations.
- 3.15 **Observations:** The ability to trigger the automatic suspension is an important remedy for operators. It forces the authority to pause and consider the objections (and often the authority will provide disclosure during this time). The Courts will not always lift the suspension, although what is in the patients' best interests will likely be determinative of the issue. If the suspension is lifted, operators will be left with a claim in damages and settlement may be reached before trial.
- 3.16 Being afforded the opportunity to issue a claim before contract award is an important remedy, but operators cannot do so if they are not aware of the intention to conclude the contract in question. Post-contract award there is unlikely to be any remedy of ineffectiveness, but there will be a potential claim in damages. Access to an effective remedy is therefore likely to be enhanced where a process of advertising and standstill is run. Under the 2015 Regulations some form of call for competition will need to be made in respect of above threshold health service contracts and therefore this is likely

to improve the ability for operators to access pre-contract remedies for health service procurements. However the 2015 Regulations do afford extensive flexibility to authorities in how the tender process is run, and what factors an authority can take into account in setting criteria and making its award. For example, under r76(8) authorities can take into account "any relevant considerations" in awarding health service contracts, including continuity of service, needs of user groups, and innovation. Although there is no express obligation to run a standstill period arguably an authority ought to do so to comply with general transparency principles which apply to Light Touch Regime contracts (unless there are exceptional circumstances). Where an operator can establish manifest error, lack of transparency or unequal treatment (of the kind found by the Court in *Woods Building Services v Milton Keynes Council* [2015] EWHC 2011 (TCC)), a Court may be willing to set aside the contract award decision, although notably, as that decision makes clear, a Court will be reluctant to make a specific order mandating an authority to enter into a contract unless exceptional circumstances exist.

4 REMEDIES AVAILABLE UNDER THE NHS REGULATIONS

This section is divided into the following sub-sections:

- Paragraphs 4.1 4.6: The remedy in outline and inter-relationship with the 2006/2015 Regulations and judicial review;
- Paragraphs 4.7 4.10: Monitor's powers;
- Paragraphs 4.11 4.13: Monitor's approach in actions to date.
- 4.1 Overview of making a complaint to Monitor, and inter-relationship with PCR and JR remedies: Section 75 of the HSCA provides that regulations may be made imposing requirements on the National Health Service Commissioning Board (NHS England) and clinical commissioning groups for the purpose of securing that, in commissioning health care services for the purposes of the NHS, they (amongst other things) adhere to good practice in relation to procurement. The regulations made under Section 75 of the HSCA are the NHS Regulations. Whilst Section 75(3) enabled the NHS Regulations to impose requirements relating to competitive tendering, it should be noted that the NHS Regulations do not contain an express requirement that contracts for health care services be tendered. Instead the NHS Regulations contain a wide set of obligations relating to how commissioners should act when procuring those services. Given the extent of those obligations (for example, the duties of transparency and equal treatment arguably require advertisement in many cases), in practice it may be rare for a commissioner to be able to comply with the NHS Regulations without holding a competitive tender process, other than when it satisfies the conditions set out in NHS Regulation 5 (ability to award to a provider without a competition where the commissioner is satisfied that the services are capable of being provided only by that provider). 40 Further, does this express

See paragraph 1.3.2 above.

exemption in Regulation 5 imply a duty to advertise where the exemption does not apply?

- 4.2 There is debate among practitioners about the extent to which the NHS Regulations mandate advertisement and in particular whether the duties of transparency and equal treatment imply any duty to advertise. However, it remains the case that the NHS Regulations contain no express requirement that all contracts must be tendered, and indeed the statutory guidance issued by Monitor says categorically that it is for commissioners to decide whether to put a contract out to tender⁴¹.
- 4.3 Monitor may investigate a complaint that a commissioner has breached the NHS Regulations, and can investigate on its own initiative whether a commissioner has acted in accordance with Regulation 10 thereof (anti-competitive behaviour). In terms of whether there is any other remedy for breach of the NHS Regulations, a breach of a statutory duty would amount to an actionable statutory tort in relation to which an award of damages could be made (with a limitation period of 6 years). Clearly this would provide a much longer limitation period than ordinarily associated with Breach of the NHS Regulations would also expose procurement challenges. commissioners to claims in judicial review⁴². In R (QSRC Ltd) v National Health Service Commissioning Board (NHS England) and anor [2015] EWHC 3752 (Admin) the Court judicially reviewed the decision of NHS England not to grant a gamma knife services provider an interim contract on grounds including that the commissioner was in breach of r3(2) of the NHS Regulations by not acting in a transparent and proportionate way, and in treating some providers of gamma knife services more favourably than others. In the event the Court found that the commissioner had not breached r3(2) as alleged but the case demonstrates the principle that breach of the NHS Regulations will be amenable to judicial review.
- 4.4 One reason why a complainant may prefer a judicial review to taking a complaint to Monitor might be that there is no guarantee that Monitor will investigate a complaint made to it. Under its prioritisation framework (as set out in its Enforcement Guidance on the NHS Regulations published in December 2013) Monitor takes a number of factors into account in determining how to respond to a complaint (i.e. whether to take formal action, informal action or no action at all). Those factors include the likely benefits to health service users of Monitor taking action, whether local resolution is possible, whether another regulator is taking action anyway, how widespread the practice complained of is, and whether further breaches are likely. In contrast, a claimant who brings a judicial review challenge knows that the Court will, at the very least, consider whether the claim should be granted permission to proceed.
- 4.5 One advantage of pursuing a complaint to Monitor rather than through the Courts is that there are no fees for bringing the complaint, other than the management time and any legal fees incurred should the complainant choose to instruct lawyers. In contrast,

See Section 3.2 ("There is no requirement in the Procurement, Patient Choice and Competition Regulations for commissioners to publish a contract notice before awarding a contract to provide those services").

Section 76(7) of the HSCA states that a failure to comply with a requirement imposed by regulations under Section 75 is actionable, except in so far as the regulations restrict the right to bring such an action.

Court fees are associated with bringing a judicial review⁴³ and an operator is likely to wish to instruct lawyers given the procedural requirements of a judicial review. As such, the overall cost of challenging through the Courts is likely to be far greater than that of complaining to Monitor.

- 4.6 As in R (QSRC Ltd) v National Health Service Commissioning Board (NHS England) and anor (above) a complainant may even be able to, in the first instance, complain to Monitor and then, depending on the overall outcome or final decision following Monitor's reaction, judicially review any final decision of the commissioner (providing the claim is within time). Similarly, following a final decision of Monitor, a commissioner who then breaches the PCR in implementing that decision could be amenable to a PCR challenge (providing the claim is within time). Complying with a Monitor direction would not afford a commissioner complete protection against either type of challenge. There is also of course the potential to judicially review any Monitor decision. In terms of trying Court action before going to Monitor, whilst with judicial review an operator can try the Court first and then access the Monitor regime, the same duality of remedy does not exist with claims brought under the PCR. R17 of the NHS Regulations provides that a person who has brought an action under the PCR may not also bring an action under section 76(7) of the HSCA⁴⁴. Regulation 13(3) of the NHS Regulations provides that Monitor may not investigate a complaint where the complainant has also brought an action under the PCR.
- 4.7 **Monitor's powers:** Whilst an operator has greater control over the conduct of the litigation if it challenges under the PCR, Monitor does have extensive powers under the NHS Regulations, and will adopt a more inquisitorial approach when it takes on a complaint. It is likely to investigate the overall impact on the provision of health care services in a way which the Court will be unwilling to do.
- 4.8 Monitor has powers to investigate complaints that a CCG or NHS England has failed to comply with the regulations or initiate its own investigation into whether a CCG has failed to comply with the competition provision of the regulations.
- 4.9 Monitor can provide the following remedies:
 - 4.9.1 Declaration of ineffectiveness⁴⁵ in relation to an arrangement or to a term or condition of an arrangement. In both cases the declaration of ineffectiveness does not affect the validity of anything done pursuant to the arrangement or the term or condition, any right acquired or liability incurred or any proceedings or remedy in respect of such right or liability. This ability to set aside a contract already entered into goes wider than the powers of the Courts in such situations under the PCR.

ation 14, 1415 Regulations.

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Currently £155 on issue of the Claim Form and an additional £700 on permission.

²⁰¹⁵ Regulations Sch.6(2) para.21. Regulation 14, NHS Regulations.

- 4.9.2 Directions⁴⁶ to put in place measures to prevent failures to comply with the regulations; measures to mitigate the effects of failures; vary or withdraw an ITT to prevent or remedy a failure; to vary an arrangement made in order to remedy a failure, and to vary an arrangement for the purposes of preventing failure to comply with the competition provision. Whilst the power to give directions is a wide ranging power, Monitor may not require a CCG or NHS England to hold a competitive tender.
- 4.9.3 Undertakings⁴⁷ accept undertakings to prevent or mitigate specific failures in the same way as the directions.
- 4.10 In its Enforcement Guidance Monitor notes that its informal action can include providing guidance, issuing advisory letters or issuing a warning letter. The timings of investigations carried out to date suggest that Court action may result in a speedier outcome (depending on Court's availability, where the claim is issued, and whether the claim is expedited). For example in the Devon investigation (see below) the complaint was first made on 18 December 2014 and the final decision was made in August 2015.

4.11 Action taken by Monitor to date:

- 4.11.1 **First Investigation:** Monitor's first investigation was into how cancer surgery services were purchased in Greater Manchester by NHS England.
- 4.11.2 The investigation was initiated in August 2013 after two complaints by NHS Foundation Trusts, one in March 2013 by University Hospital of South Manchester NHS FT, and one in June 2013 by Stockport NHS FT. The complaints related to the procurement which began in January 2013 in relation to the reconfiguration of cancer surgery services. They specifically related to the involvement of the Greater Manchester Cancer Services Provider Board (and the process for managing conflicts of interest) and the criteria for proposals requested by the Provider Board including university teaching hospital status and joint provider bids. Monitor investigated whether NHS England had acted consistently with the NHS Regulations and in particular with the requirements to secure the needs of patients and procure services from the most capable provider.
- 4.11.3 No contract has been awarded in this procurement and NHS England subsequently confirmed that the procurement had been discontinued, leading Monitor to close its investigation in January 2014. Monitor's guidance alongside the case closure decision notice seems to lean towards criticism of the procurement process in that it confirms that the criteria used in this case may not be appropriate and that a provider board should only have an advisory, rather than decision making, role. If NHS England had

Regulation 15, NHS Regulations.

⁴⁷ Regulation 16, NHS Regulations.

not decided to discontinue would Monitor have taken enforcement action to the same effect?

- 4.11.4 **Second Investigation:** This investigation was launched in June 2013 and related to a complaint from Thornbury Radiosurgery Centre about radiosurgery procurement in Yorkshire and Humber.
- 4.11.5 Thornbury complained to Monitor about the conduct of NHS England's predecessor in choosing not to designate Thornbury (which would have allowed it to provide services on a national basis and in response to individual requests) and in refusing to provide information about particular decisions. The complaint also related to NHS England's own conduct in negotiating a contract with Thornbury (following NHS restructuring and the associated transfer of commissioning responsibilities), in particular NHS England's decision to prevent Thornbury from accepting NHS direct referrals. The issues raised by Thornbury included breaches of the NHS Regulations relating to commissioning from providers who are best placed to deliver the needs of their patients; procuring services in a transparent and non-discriminatory manner; and fostering patient choice.
- 4.11.6 In the event, the contract was concluded before Monitor reached a decision on the investigation and the case was subsequently closed in February 2014. Monitor guidance issued after the case was closed covered prioritisation and commissioning, using evidence in decision-making, acting transparently and publishing details of all contracts awarded. The content implies that enforcement action might have been taken in this investigation but for the contract being agreed.
- 4.11.7 **A Third investigation** has been undertaken into the way elective hospital services were purchased in Blackpool. This investigation was opened in October 2013 following a complaint made by Spire and Monitor completed its investigation in September 2014.
- 4.11.8 The investigation found that Blackpool Clinical Commissioning Group and Fylde and Wyre Clinical Commissioning Group (the CCGs) had not ensured that patients were being offered choice and that patient choice was being publicised and promoted. In particular the investigation concluded that the CCGs had not made arrangements to ensure that patients requiring an elective referral were offered a choice of any clinically appropriate provider for their first outpatient appointment. This was a breach of the NHS Responsibilities and Standing Rules Regulations. 48

National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012. Monitor's enforcement powers under the Procurement, Patient Choice and Competition Regulations also apply in relation to breaches of regulations 39 and 42 of the Responsibilities and Standing Rules Regulations.



- 4.11.9 Following consultation, Monitor decided to accept undertakings from the CCGs to take steps to address the issues identified. This included actions such as promoting patient choice on the CCGs' websites, on GPs' websites and in GPs' premises, producing promotional materials and conducting other promotional activities. This decision was published in March 2015.
- 4.11.10 **A fourth investigation** was launched in January 2015 into the commissioning of community services for adults with complex needs in eastern Devon. The investigation was concluded in August 2015 and Monitor found no breach of the NHS Regulations.
- 4.11.11 The background to the complaint was that the CCG decided to undertake a "most capable provider" assessment. The CCG had not formally OJEU advertised the opportunity, but there was considerable publicity surrounding the tender process and expressions of interest were received from independent sector providers. Only two formal responses submitted. The incumbent Trust was not assessed to be the most capable provider and complained to Monitor that the decision and the process used to reach that decision gave rise to breaches of the NHS Regulations (that the process did not identify the most capable provider who offered best value for money and that the CCGs failed to act transparently and discriminated in favour of another local trust). In particular, whilst the CCG had assessed the providers in terms of how they would deliver value for money, no assessment of price itself was carried out. The complainant Trust asserted that this made it impossible for the CCG to assure itself of the quality, efficiency and value for money of service provision.
- 4.11.12 Monitor concluded that the fact that prospective providers were invited to propose solutions to address the CCG's objectives which the CCG would use to select a preferred provider with which to do further work, was not a breach. However, the CCG had not entered a contract with the preferred provider at the time of the final report (due diligence was ongoing) and Monitor made it clear that the CCG would need to understand the scope of services to be provided, how they would be delivered, and how much it would cost to deliver these services in order to assure itself and the public that it had commissioned services from the provider that would best enable it to secure the needs of patients, improve the quality and efficiency of services, and deliver best value for money in doing so.
- 4.11.13 **Finally, a fifth investigation** was launched on 30 July 2015 into the commissioning of elective care services in North East London and the proposed pricing arrangements for those services. In its first report Monitor has "identified potential issues". Private healthcare firm Care UK had complained that commissioners have:
 - not followed due process in agreeing to sub-tariff prices;

- failed, through their process, to identify the provider most capable of meeting patient needs and improving the quality and efficiency of the services; and
- discriminated against it by not running a competitive tender for other services.
- 4.11.14 Three London CCGs had initially awarded the five-year, £55m contract to run services at the North East London Treatment Centre to Barking, Havering and Redbridge University Hospitals Trust. The Centre is on the site of the King George Hospital run by the Trust and provides ear, nose and throat services, gastroenterology, general surgery, ophthalmology, trauma and orthopaedics. It was set up as an independent sector treatment centre in 2006.
- 4.11.15 **The timings** of investigations demonstrate that this is a lengthy process. Even in instances where there was no decision on the substance of the complaints, the investigations took six months. In the one instance where undertakings were given, the investigation took almost a year and the remedies, consultation and decision making a further six months.
- 4.11.16 The investigation process is very much governed by Monitor, who issues requests for documents, interviews and meetings as and when it sees fit.

4.12 **Guidance issued by Monitor:**

- 4.12.1 In December 2013 Monitor issued guidance for commissioners of NHS services on how to purchase high quality healthcare services in line with the NHS Regulations. This includes substantive guidance, a briefing note, hypothetical case scenarios and enforcement guidance.
- 4.12.2 Monitor issued further guidance on the commissioning of specialised services as a result of the Thornbury investigation in April 2014 which the Court described in QSRC (ibid) as not being prescriptive and needing to be read in context.
- 4.12.3 The Monitor guidance is likely to be persuasive in terms of complaints to Monitor, particularly where the complaint is aligned to case studies contained within the guidance. It is also of relevance and has been considered in proceedings brought before the Courts (for example in *QSRC* (ibid)).

4.13 **Approach of Monitor**

4.13.1 In the experience of the authors, Monitor takes a more investigatory role than would the Court. Whereas the Court would confine itself to deciding issues of law on the basis of facts solely as presented to it, Monitor will

raise questions of its own accord with the parties, requesting responses both in writing and requesting meetings as fact-finding investigations. Monitor has the remit to consider a more holistic impact of a particular procurement (or non-procurement) on the wider health locality, or indeed nationally.

- 4.13.2 As a result, the Monitor investigations can become fairly protracted and time-consuming, requiring considering input from both all parties involved, and comparable if not more lengthy than Court proceedings.
- 4.13.3 There is no precedent to anticipate the outcome of a Monitor investigation in the same way that the parties can anticipate the outcome of a claim issued through the Courts.
- A party who objects to a final Monitor decision would have the ability to 4.13.4 challenge that decision by way of judicial review (as to which see further below).

5 ALTERNATIVE ROUTES TO CHALLENGE

This section is divided into the following sub-sections:

- Paragraphs 5.1 5.2: Complaint to the European Commission; and
- Paragraphs 5.3 5.18: Judicial Review.
- 5.1 Complaint to the European Commission: If a possible infringement of EU law is identified by the Commission or reported in a complaint, the Commission attempts to quickly resolve the underlying problem with the Member State concerned by means of a structured dialogue. Where the Commission considers it necessary to do so, it can launch a formal infringement procedure consisting of the following escalation steps⁴⁹:
 - Letter of formal notice
 - Reasoned opinion
 - Referral to CJEU
 - Judgment by CJEU

Sanctions include the ability of the CJEU to impose a lump sum and/or penalty payment.

5.2 It is also open to national Courts to refer specific questions on the interpretation of EU law to the CJEU. There have been no recent CJEU cases regarding healthcare services arising from actions of the UK, but there have been healthcare cases arising

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Taken from the European Commission's website.

from other member states. In *Grupo Hospitalario*⁵⁰ the CJEU considered a referral from the Bilbao Court to the decision of the Basque government to specify that a contract for healthcare services (elective surgery) had to be performed within the municipality of Bilbao. The CJEU held that the restriction was discriminatory and breached equal treatment principles.

- 5.3 **Judicial Review:** Judicial review is based on a breach of public law principles, and as such may overlap with the grounds being pursued under the 2006 Regulations, the 2015 Regulations, and/or TFEU principles. In practice, many procurement challenges will plead all 3 of the above. There is an important procedural distinction for Claimants in deciding whether or not to bring a claim as a judicial review or under the 2006 Regulations or 2015 Regulations. Claims for judicial review are classified as Part 8 Claims by the Civil Procedure Rules and are governed by Part 54 of the Civil Procedure Rules. Amongst other aspects, claims for judicial review:
 - 5.3.1 Are subject to a separate permission stage to weed out frivolous, vexatious or hopeless claims; and
 - 5.3.2 Are subject to different procedure regarding evidence and disclosure. The majority of documents in support of the Claim must be provided at the time the Claim Form is issued, or when the Statement of Facts and Grounds is filed which is much earlier than in standard Part 7 claims. Oral evidence is rare in Part 8 claims but common in Part 7 claims. Whilst the duty of candour applies, standard disclosure does not apply in Part 8 claims.
 - 5.3.3 Judicial review claims must be issued in the Administrative Court (although we understand that the Court is currently considering a proposal that any procurement challenge issued as a judicial review be transferred to the Technology and Construction Court).
- 5.4 **Standing:** One advantage of judicial review is that it is open to a wider group of claimants than just economic operators (to whom claims under the 2006 or 2015 Regulations are limited) (see for example *R* (*Chandler*) *v* Secretary of State for Children, Schools and Families [2009] EWHC 219 (Admin) at first instance and [2009] EWCA Civ 1011). It should be noted, however, that the standing test in a judicial review for breach of PCR is stricter than that for JR generally (see Chandler and also *R* (*Unison*) *v* NHS Wiltshire Primary Care Trust [2012] EWHC 624 (Admin)).⁵¹

Grupo Hospitalario Quiron (Judgment) [2015] C-552/13..

In <u>Chandler</u>, Arden LJ said at §77: "We incline to the view that an individual who has a sufficient interest in compliance with the public procurement regime in the sense that he is <u>affected in some identifiable way</u>, but is not himself an economic operator who could pursue remedies under Regulation 47, can bring judicial review proceedings... He may have such an interest if he can show that performance of the competitive tendering procedure in the directive or of the obligation under the Treaty <u>might</u> have led to a different outcome that would have had a <u>direct impact on him</u>. We can <u>also</u> envisage cases where the <u>gravity of a departure from public law obligations</u> may justify the grant of a public law remedy in any event." The Court in Unison cited this passage, and

- 5.5 **Alternative remedy**: Claims for judicial review are normally barred where there is a suitable alternative remedy. This means that generally, an "economic operator" which has standing to bring a claim under the PCR is not able to pursue its challenge by way of judicial review. This is because, where a statutory scheme of relief is provided, then judicial review should be withheld to protect the integrity of the statutory scheme (see R (Cookson and Clegg) v Ministry of Defence [2005] EWCA Civ 811 at paragraph 20). Manifestly, this reasoning is inapplicable both to a "third party" challenger which does not have standing to bring a claim under the PCR; and to a challenge to a tender process which is not subject to the PCR. Moreover, even an economic operator with standing under the PCR will be able to pursue a claim for judicial review if it can persuade the Court that, in the particular circumstances of its challenge, judicial review is a more appropriate remedy than a PCR claim (R (Hossack) v Legal Services Commission [2011] EWCA Civ 788 at §38 et seq.). Such an argument is likely to succeed where there is a public law cause of action and/or the relief sought is available only in judicial review.
- Insufficient public law element: a procurement decision is additionally not amenable to judicial review if it does not entail a sufficient public law element. What precisely this means is a difficult question. Not all actions of "public" bodies are subject to Part 54 judicial review; judicial review may be invoked only against actions in pursuit of public functions and subject to public law duties. Purely commercial actions fall to be challenged in private law proceedings: e.g. Mass Energy Ltd v Birmingham CC [1994] EnvLR 298. It is often said, citing R (Menai Collect Ltd) v DCA [2006] EWHC 727 (Admin) and R (Gamesa Energy) v National Assembly for Wales [2006] EWHC 2167 (Admin), that there is in general an insufficient public law element when a public body procures a contract. However, this is an over-simplification; the particular context may mean that a sufficient public law element is present in a procurement process.
 - 5.6.1 The added public element may come if there is some statutory underpinning for a procurement decision. However, there is a range of judicial opinions on what this means.
 - (a) At one extreme, there is the view of the Court of Appeal in *Mass Energy Ltd v Birmingham CC* [1994] EnvLR 298 that the proper role of judicial review is limited to policing the obligations actually imposed by the statute, and does not extend to the generality of public law principles.
 - (b) At the other extreme, there is the view of Elias J in *R* (*Molinaro*) *v Kensington & Chelsea RLBC* [2002] LGR 336 that if a contract is entered into pursuant to a statutory power, that is itself sufficient to engage the full panoply of public law.

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- held that following Mass Energy, there was "a distinction between statutory fault in not following statutory rules...on the one hand; and actions of what might be called a normal commercial nature in awarding the contract itself", the latter not being open to challenge. But he added that public law should not be excluded entirely from the contract-awarding process, even if there were no statutory breaches involved. In his view, there could be a public law challenge to a tendering decision where, for example, there was "bribery, corruption or the implementation of a policy unlawful in itself, whether because it was ultra vires or for other reasons."
- (d) In *Menai Collect* itself, McCombe J's approach was to distinguish between misconduct in the course of a tender procedure which was so serious as to amount to an abuse of power; and less serious flaws in the process which would not. In the absence of a breach of statutory obligations, judicial review would be available only in respect of the former. Similarly, in *Gamesa Energy*, the Court said that mere irrationality should not normally be a sufficient basis for the Court to interfere in procurement decisions, which are commercial in nature.
- (e) However, in *R* (*A*) *v* Chief Constable of *B* Constabulary [2012] EWHC 2141 (Admin) the Court took a more lenient approach to judicial review challenges, holding that the fact that an authority is exercising a statutory function is sufficient to justify a tendering decision being subject in principle to judicial review if it has not acted fairly and has abused its powers. The Court held that, even when the public procurement regime does not apply, contracting authorities should ensure that any procedure that they adopt when tendering for a contract is a rational and fair one and takes account of any legitimate expectations that the authority may have caused to arise.
- The added public element may also come from the subject-matter. However, it is not clear how far this requires consideration of goods or services to be supplied under the contract, and how far from the manner in which the contract award process is conducted. The contrast may be drawn between *R v Lord Chancellor's Department ex p. Hibbit & Saunders* [1993] COD 326 (award of contract for Court shorthand writing not reviewable) and *R v Legal Aid Board ex p. Donn & Co* [1996] 3 All ER 1 (award of contract to act as solicitors in legally aided group action reviewable).

In essence, therefore, a claimant who wishes to pursue a judicial review of a procurement decision will have to show that judicial review is more appropriate than a challenge under the PCR, for example because judicial review offers a remedy which would not be available via a challenge under

the PCR⁵², or because the claimant would not have standing to bring a PCR claim.

5.7 Grounds for judicial review include:

- 5.7.1 illegality Public Services (Social Value) Act 2012 (Concordia Bus Finland Oy Ab (formerly Stagecoach Finland Oy Ab) v (1) HelsinginKaupunki (2) HKL—Bussiliikenne (2002) (C-513/99)), Equality Act 2013 e.g. the Queen on the application of RB v Devon CC [2012] EWHC 3597 (Admin), HRA 1998;
- 5.7.2 irrationality;
- 5.7.3 procedural unfairness e.g. non-compliance with CCG decision making processes, e.g. Bristol CCG application for JR, C&P CCG letter before action; and
- 5.7.4 breach of legitimate expectation (*Bullmore & Anor v West Hertfordshire Hospitals NHS Trust* [2007] EWHC 1636 (Admin), *Enfield Borough Council*, *R (on the application of) v Secretary of State for Health & Ors* [2009] EWHC 743 (Admin)).
- 5.8 Examples relating to healthcare services commissioning include *R* (*RB*) *v* Devon Primary Care Trust and Devon County Council [2012] EWHC 3597 (Admin). This challenge was made by the mother of children using social care services in Devon and concerned the Defendants' decision to appoint Virgin Care Limited as the preferred bidder for a contract to provide integrated children's services. The claim was issued on the grounds that the Defendants had failed to follow their own equality policies and that they were in breach of the public sector equality duty under Section 149 of the Equality Act 2010.
- 5.9 A procurement process had been run alongside a lengthy and thorough consultation process. This involved engagement sessions with children and young people, parents, stakeholders and staff. Their views were directly fed into the overarching service specification and evaluation criteria used in the procurement. Two Equality Impact Assessments were prepared during the process: the first assessed there as being no impact on people with protected characteristics on the basis that there would be no change to the services following the transfer (and simply a change of provider). That EIA was not presented to the Defendants' decision-making bodies at the meetings to approve the identification of Virgin Care as preferred bidder. A second, more detailed, EIA was later prepared and was presented to the decision-making bodies when the decision of intent to award the contract to Virgin Care was made. That decision was not subject to challenge. The claim therefore concerned an earlier

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For example, this could be a challenge to a system-wide failing (rather than limited to a single procurement) such as that which was the subject of challenge in the Legal Aid Agency Duty Solicitor Tender litigation (see *R* (*Fair Crime Contract Alliance*) *v the Lord Chancellor*) for which permission was granted despite the existence of a multiplicity of parallel procurement challenges.

- decision to appoint Virgin Care as preferred bidder, despite the fact that a subsequent decision had been taken (and was unchallenged) of intent to award the contract to Virgin Care.
- 5.10 The Court found that the 11 July decision had engaged the public sector equality duty and that, by failing to present an EIA to the decision-makers, the Defendants were in breach of that duty. In arriving at its judgment, the Court distinguished the facts from the facts in *R* (*Greenwich Community Law Centre*) *v Greenwich London Borough Council* [2012] EWCA Civ 496 (which is authority for the principle that a change from one provider to another without more will not usually engage equality considerations) on the basis that the structure, whereby children's health and social care services are integrated, is unique to England such that there are no alternative providers with experience of running integrated services in this way. As such, the Court found, the transfer of the services to the new provider was a far more fundamental change than the change contemplated in Greenwich with the potential to affect the supply of services to vulnerable users in Devon, many of whom have protected characteristics. The decision to appoint Virgin Care as preferred bidder was therefore held to be unlawful.
- 5.11 Importantly, the Court refused to quash the decision in the interests of good public administration and reduced the Claimant's cost award, commenting that "this was a case in which it was always unlikely that a quashing order would be made". The Court noted that the Claimant had been unable to show that she or her children would suffer any detriment as a result of the transfer to Virgin Care, and indeed commented that she might even benefit under the arrangement. In contrast the Court noted that if a quashing order were made, the detriment to the children of Devon was obvious.
- 5.12 In *Keep Wythenshawe Special Ltd v NHS Central Manchester CCG* [2016] EWHC 17 (Admin), the claimants, KWS, represented the interests of consultants at Wythenshawe Hospital. The defendant organisations had responsibility for commissioning healthcare services in Greater Manchester. KWS applied for judicial review of the defendants' Healthier Together reform programme for the provision of healthcare services within Greater Manchester, on grounds relating to consultation, legitimate expectation and rationality or perversity. The Court held, dismissing the application, that the bodies responsible for commissioning healthcare services had fulfilled their obligation under s.14Z2(2) NHS Act 2006 to involve patients and their carers in decisions relating to care and treatment, and had complied with the *Sedley* criteria when carrying out a public consultation.
- 5.13 Remedies available in judicial review may include a quashing order in respect of a decision to award or even enter into a contract although it is often a high hurdle to persuade a Court to grant relief even where a breach is made out (as to which see further below). Damages in judicial review are not available alone (i.e. they can only be claimed alongside one of the above remedies) and are only available in circumstances where a private law right co-exists with the public law cause of action.

- 5.14 **Limitation:** Under Part 54 of the Civil Procedure Rules (which governs applications for judicial review) a claim form seeking judicial review must be filed "promptly" and in any event not later than 3 months after the grounds to make the claim first arose. Where the claim involves considerations of EU law, this requirements for promptness will not apply following the decision in *Uniplex (UK) Ltd v NHS Business Services Authority* [2010] 2 CMLR 47. The need to act promptly continues to apply to cases which do not involve EU law: see *R (Berky) v Newport City Council* [2012] Env. L.R.35.
- 5.15 The position therefore existed whereby a Part 8 judicial review of a decision founded on breach of TFEU principles (or indeed pleading breach of the 2006 or 2015 Regulations) enjoyed a longer limitation period than that afforded to a claim brought as a Part 7 claim. In order to align the two limitation periods, The Civil Procedure (Amendment No. 4) Rules 2013 (SI 2013/1412) has inserted into Part 54 of the Civil Procedure Rules a requirement that where the application for judicial review relates to a decision governed by the 2006 Regulations (now updated to the 2015 Regulations⁵³), the claim form must be filed within the time within which an economic operator would have been required by the PCR to start any proceedings in respect of that decision.
- 5.16 The limitation period ought to be the same at first glance, although a recent decision does cast some doubt on this and suggest that not all complaints which appear to be procurement complaints will be considered as being governed by the 2006 or 2015 Regulations. In R (QSRC Ltd) v National Health Service Commissioning Board (NHS England) and anor [2015] EWHC 3752 (Admin) the Court found that the 30-day limitation period did not apply as the decision in question was not "governed" by the 2006 Regulations. The rationale for this appears to be that the contracting authority, NHS England, had not sought offers regarding a proposed public supply contract. As NHS England had not sought offers in relation to a public contract the decision was held not to be governed by the 2006 Regulations. Extending this logic would mean that an illegal direct award would never be "governed" by the Regulations, such that the remedy of ineffectiveness would not apply to an illegal direct award. discussed above, whilst ineffectiveness may be rare in any event for illegal direct awards in respect of healthcare services contracts, the logic applied in QSRC is not specific to healthcare services and by extension would apply to any type of public contract, such that ineffectiveness would never apply where there is an illegal direct award. This is not the intention nor the plain meaning of the PCR, and it is respectfully suggested that the Judge is wrong on this point. Under the Civil Procedure (Amendment No. 4) Rules 2013⁵⁴, the definition of a decision "governed" by the PCR means:

"any decision the legality of which is or may be affected by a duty owed to an economic operator by virtue of regulations 89 or 90 of those Regulations".

Schedule 6, Regulation 11 of the 2015 Regulations.

And the subsequent consequential amendment (see footnote 24).

- Plainly a decision to ignore the obligation to seek offers in relation to a public contract would be so affected and would therefore be governed by the Regulations.
- 5.17 **Choice of Court:** A judicial review will be heard in the Administrative Court and is conducted under Part 54 of the Civil Procedure Rules as a Part 8 claim with different procedural rules, disclosure and evidential rules. A separate permission stage is necessary in judicial review, there is more limited disclosure and live oral evidence is rare.
- 5.18 **Reservation of alternative options with judicial review:** Monitor may not consider a complaint which has been brought already as a challenge under the 2006 or 2015 Regulations. A similar exclusion does not apply to judicial review cases so in theory a claimant who loses a judicial review challenge could still apply to Monitor (although it is to be queried whether Monitor would take on such a complaint under its prioritisation framework under which it decides whether or not to investigate complaints).

6 CONCLUSION

- 6.1 The commissioning of healthcare services is regulated by numerous layers of Treaty principles, national legislation, guidance and public law principles. Commissioners must work their way through not just the PCR but also the NHS Regulations, consider also any requirements under the Public Services (Social Value) Act 2012, the Equality Act 2010 and other duties of consultation arising under the HSCA when carrying out their commissioning intentions. These multiple layers of regulation afford challengers (whether members of the public or economic operators) a choice of remedies.
- 6.2 The relatively short limitation periods offered by the PCR and judicial review may constrain that type of action (as will the permission stage required for a judicial review to proceed), but commissioners face longer term threats of challenge and investigation via Monitor investigations and/or complaints to the Commission.
- 6.3 The multiplicity of regimes creates a confusing landscape for commissioners and challengers alike. Some form of future integration between the various regimes would seem welcome and a more effective use of resources.
- 6.4 In the meantime, the advent of compulsory advertising under the PCR for above threshold Light Touch Regime contracts ought to at least provide operators with the certainty that opportunities (save in exceptional circumstances) should be put out to tender. Given the relative transparency of commissioning plans, there ought to be a reasonable opportunity for operators to obtain pre-contract remedies such as the automatic suspension if they learn of a proposed direct award.
- 6.5 Post-contract, there is very little precedent to determine what approach the Court would take to awarding remedies. Under the PCR, there is little prospect of setting aside a contract for healthcare services, although the Courts can exercise this power

via judicial review. Bringing challenges via the Courts provides the challenger with greater control to direct the litigation, although at a price given the Court fees involved. Making a complaint to Monitor has the advantage of no limitation period, the range of remedial steps Monitor can order (including setting aside a contract) but the challenger will cede control of the challenge to Monitor who adopts an investigatory role.

Part 3

COMPETITION AND INTEGRATION

The applicability of competition law to the commissioning and provision of health services to the NHS in England

1 INTRODUCTION

- 1.1 This Part considers five questions:
 - (a) When does competition law apply to NHS services?
 - (b) What changes does the HSCA make to the application of competition law to NHS services?
 - (c) What is integrated care and is there a special competition regime for the NHS which permits or requires integration?
 - (d) How does merger control apply to mergers between NHS bodies?
 - (e) How does the HSCA ensure a level playing field for NHS services?

UK Competition Law

1.2 Section 2 and 18 of the Competition Act 1998 provide (in relation to agreements and conduct affecting UK markets):

Section 2 ("the Chapter One Prohibition")

- (1) ...agreements between undertakings, decisions by associations of undertakings or concerted practices which—
- (a) may affect trade within the United Kingdom, and
- (b) have as their object or effect the prevention, restriction or distortion of competition within the United Kingdom,

are prohibited unless they are exempt in accordance with the provisions of this Part.

- (2) Subsection (1) applies, in particular, to agreements, decisions or practices which—
- (a) directly or indirectly fix purchase or selling prices or any other trading conditions;
- (b) limit or control production, markets, technical development or investment;
- (c) share markets or sources of supply;

- (d) apply dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;
- (e) make the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts

Section 18 ("the Chapter Two Prohibition")

- (1) ... any conduct on the part of one or more undertakings which amounts to the abuse of a dominant position in a market is prohibited if it may affect trade within the United Kingdom.⁵⁵
- (2) Conduct may, in particular, constitute such an abuse if it consists in—
 (a) directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions;
- (b) limiting production, markets or technical development to the prejudice of consumers;
- (c) applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;
- (d) making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of the contracts."
- 1.3 There are specific provisions in Section 3 of the Competition Act 1998 for exclusions to be adopted by the Secretary of State where, for example, there are separate competition regimes. However, no such exclusion has been adopted in relation to NHS services. Similarly, there is provision for individual or block exemptions in relation to certain activity. While these exemptions may be relevant to consider in examining the competition law implications of NHS related agreements, there is no specific block exemption for NHS service agreements.
- 1.4 There are a number of ways in which competition law could potentially apply in the NHS, including in relation to procurements.⁵⁶

The test of dominance is based on the ability to exercise market power in the relevant geographical and product market (to act without regard to customers and competitors), but there is a general presumption of dominance where market share is greater than 40%.

See Monitor's Guidance: The application of the Competition Act 1998 to the healthcare sector: guidance for providers. More detailed papers on anti-competitive scenarios and conduct were published by Monitor's predecessor, the Cooperation and Competition Panel under the previous regime (when the non-statutory Principles 67

- (a) Anti-competitive agreements affecting the bidding process, which may range from simple information sharing between bidders or their subcontractors through to collusion or bid rigging, 57 which can subvert the competitive process. The competition authorities have in the past been most engaged with these practices in the NHS where they have involved private providers or private services. 58
- (b) The design and conduct of a tender process itself could amount to an abuse of a dominant position (see *Arriva the Shires Ltd v London Luton Airport Operations Ltd* [2014] EWHC 64 (Ch)).
- (c) Other competition law infringements could consist of market sharing arrangements between providers (*e.g.* agreements between neighbouring GP practices not to poach each other's patients) or even long term exclusivity deals (*e.g.* preferential referral arrangements in return for a share of the equity in a provider).
- (d) There are many types of cooperation (or 'integration') arrangements which are subject to competition scrutiny, but may be entirely consistent with competition law principles. It is sometimes wrongly assumed that integration or cooperation often found in the NHS due to the obvious patient benefits derived from cooperation between various providers on often complex care pathways or required due to clinical interdependencies is anathema to competition law. This is not correct and a cost/benefit type analysis is carried out to assess whether the consumer or industry benefits of an arrangement outweigh any adverse competitive effects, further to applicable exemption criteria. The issue of integrated care is further considered below.
- 1.5 There are also equivalent European Union ("EU") competition law prohibitions (on which the UK rules are based) which apply where the agreement or conduct affects trade between member states of the EU. This question of when competition law does apply to the conduct and agreements of NHS commissioners or providers is addressed below.

and Rules of Cooperation and Competition: "PRCC") were in force. See for example working papers of 22 March 2013: The Implications of Competition Rules for the Unilateral Conduct of Providers of NHS funded services and The Implications of Competition Rules for Agreements involving Providers of NHS funded services.

Note that certain serious competition infringements may also infringe the cartel offence under the Enterprise Act 2002 and give rise to risk of penal sanctions.

See Press Release 16 August 2012, OFT welcomes action by NHS Trusts to ensure compliance with competition law, where the OFT noted that All public bodies, including NHS Hospital Trusts, are subject to the Competition Act 1998 when engaged in the commercial supply of goods or services, such as paid treatments for private patients. Eight NHS Hospital Trusts gave voluntary assurances to the OFT that they would no longer exchange commercially sensitive information about their Private Patient Unit (PPU) prices, to ensure they comply with competition law. The OFT stated: "Where public sector providers compete with the private and voluntary sectors, the OFT is committed to ensuring that there is a level playing field for all so that effective competition encourages suppliers to offer lower prices, better quality and an improved range of goods or services.'

State aid and other state measures

1.6 The competition rules can also apply to the emanations of state. In particular, specific EU competition rules apply to the grant of state subsidy or other advantage which distorts competition and affects trade between member states of the EU. The Treaty on the Functioning of the European Union ("TFEU") provides at Article 107(1):

"Save as otherwise provided in the Treaties, any aid granted by a Member State or through State resources in any form whatsoever which distorts or threatens to distort competition by favouring certain undertakings or the production of certain goods shall, in so far as it affects trade between Member States, be incompatible with the internal market."

- 1.7 There are also specified grounds on which state aid can be approved and block exemptions have also been adopted in this area. There are in particular specific rules applicable to funding for the provision of services of general economic interest ("SGEIs") and a block exemption has been adopted by the Commission which deals with hospital services in particular. ⁵⁹ In broad terms, these rules require that public service providers should not be overcompensated for such services and that their public service activities should be accounted for separately to their market activities. In state aid law, it is generally recognised that conducting a fair and transparent public tender process is an effective means of demonstrating that a public service provider has not been overcompensated and thus subsidised by the state.
- 1.8 While the state aid rules may well not be relevant to procurements or other arrangements with local NHS providers, there may be circumstances where the scale of the procurement (for example a £500m community services contract) attracts bidders which are part of international healthcare groups and the requisite cross border effect may then be triggered.
- 1.9 Article 106 TFEU also imposes certain obligations on Member States to observe the Treaty rules including the competition rules in relation to undertakings with special and exclusive rights. These provisions have been relied on by the European Commission to liberalise the telecommunications sector among others. Article 106(2) excludes the application of the Treaty rules to an undertaking entrusted with the operation of services of general economic interest, in so far as the prohibition would obstruct the performance in law or in fact of the particular task assigned to that undertaking. This exclusion has been invoked to justify the protection of ambulance services from competition, including non-emergency services which were necessary

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Commission Decision of 20 December on the application of Article 106(2) of the Treaty on the Functioning of the European Union to State aid in the form of public service compensation granted to certain undertakings entrusted with the operation of services of general economic interest (Official Journal L7, 11.01.2012, p. 3-10). See also the General Block Exemption Regulation (Commission Regulation (EU) 651/2014).

to protect the economic viability, quality and reliability of the core emergency services entrusted to the ambulance services provider. ⁶⁰

Merger control

- 1.10 Finally, there are specific UK and EU rules relating to the approval of mergers between enterprises (UK) and undertakings (EU). In effect, merger control law applies where the cooperation or integration is enduring and structural. Joint ventures for example may be subject to competition law or merger control law depending on the extent to which they involve mere cooperation between entities which remain independent or structural change involving the giving up of that independence. While the EU rules are unlikely to apply to mergers involving NHS bodies, the HSCA has made it more likely that certain NHS related mergers, notably between Foundation Trusts, are subject to competition scrutiny. Merger control is also considered below.
- 1.11 The aim of this publication is to consider in outline terms the extent to which competition law may apply to NHS bodies and the arrangements that they enter into and what changes have been brought about as a result of the HSCA. It also attempts to consider the interface between the procurement and the competition regime as well as the specific features of NHS services, notably the emphasis placed in the HSCA and regulations adopted under it on 'integration'.

2 APPLICATION OF COMPETITION LAW

- 2.1 Section 72 of the HSCA provides for Monitor to apply UK (the Chapter One and Chapter Two prohibitions) and EU competition law as concurrent regulator, alongside the Competition and Markets Authority ("CMA")⁶¹ to activities concerning the provision of health care services in England.⁶²
- 2.2 The remedies available for infringement of the competition rules are wide ranging and onerous.
 - (a) If Monitor or the CMA investigate under the Competition Act 1988, (whether Chapter 1 (anti-competitive agreements) or Chapter 2 (abuse of dominant position)) a finding of breach can result in fines of up to 10% of annual turnover.

Since 1 April 2014, the functions of the Office of Fair Trading (OFT) have been assumed by the Competition and Markets Authority, and the OFT abolished.

Section 73 of the Act provides for Monitor to exercise (concurrently, as above) the functions of competition regulator under Part 4 of the Enterprise Act 2002, which relate to market investigations. Where a particular matter is concerned, neither the CMA nor Monitor may exercise functions which (by virtue of Section 73 of the Act) each of them exercise concurrently, if such functions have been exercised in relation to the particular matter by the other body.



^{60.} See Case C-475/99 Ambulanz Glöckner [2001] ECR 8089.

- (b) It is also possible in Competition Act cases for a direct claim to be made by a person affected, either as a follow on claim from a regulatory investigation, or as a freestanding claim for damages. Where the claim is being made against a contracting party prior to the award of the contract it may be possible to seek an injunction to preserve the status quo, but this would be relatively unusual.
- In general, time limits for a complaint to the CMA or Monitor are undefined, (c) but an old complaint is less likely to be looked at unless the abuse or anticompetitive agreement is continuing. Civil law direct claims are subject to a 6 year limitation period.
- (d) The European Commission or the Courts may require unlawful State aid to be repaid by the recipient of the aid, together with interest and there is scope for civil actions including claims for damages, from those who suffer as a result of the distortive effect of the aid, although these are relatively unusual. There may also be judicial review challenges to the grantor, which can effectively prevent the granting of aid at an early stage if the information is known.
- As regards merger control, the CMA can order separate requirements pending (e) its investigations and if it finds a significant lessening of competition which is not outweighed by relevant customer benefits can either forbid the merger, or require divestments or other behavioural remedies to address this. There is no civil remedy.
- 2.3 The powers conferred on Monitor under section 72 and 73 of the Act are separate from, and should not be confused with, those conferred on Monitor by regulations made under Section 75 of the Act, the NHS Regulations⁶³. The NHS Regulations include powers to conduct investigations, to make declarations of ineffectiveness in relation to contracts entered into by NHS commissioners in certain circumstances, and to direct NHS commissioners to take various steps - including (inter alia) to implement measures to rectify with failures in commissioning, to vary or withdraw invitations to tender, or to refrain from exercising their functions in a particular way. These powers are discussed in Part 2. Some of the obligations arising out of the NHS Regulations relate to competition issues, as the title suggests, and are reviewed below.
- 2.4 The HSCA has also introduced another mechanism by which competition related obligations apply to providers. The provider licence includes an obligation not to act in an anti-competitive manner unless it is in the interests of patients. Monitor's powers here are to impose a 'discretionary requirement' which is defined as :-
 - (a) a requirement to pay a monetary penalty to Monitor of such amount as Monitor may determine (referred to as a "variable monetary penalty"),

⁽SI 2013 No. 500).

- (b) a requirement to take such steps within such period as Monitor may specify, to secure that the breach in question does not continue or recur (referred to as a "compliance requirement"), or
- (c) a requirement to take such steps within such period as Monitor may specify, to secure that the position is, so far as possible, restored to what it would have been if the breach in question was not occurring or had not occurred (referred to as a "restoration requirement")⁶⁴.

3 ARE NHS BODIES 'UNDERTAKINGS' FOR COMPETITION LAW PURPOSES?

- 3.1 Sections 72 and 73 of the HSCA effectively recognise a position which has, in reality, been true for some time: competition law applies to the NHS. 65 At least, competition law may apply to the conduct and agreements of providers or even commissioners of NHS services to the extent that they are acting as 'undertakings' (the terminology used in the EU and UK competition rules see above).
- 3.2 An 'undertaking' is any natural person engaged in economic activity, regardless of its legal form or the way in which it is financed.⁶⁶ A functional approach is taken to the definition of an undertaking, such that a body may be an undertaking for some purposes and not others. Indeed, a public undertaking can be a division or function of a Government department without the need for that body to be a separate legal entity.⁶⁷
- 3.3 The test for identifying economic activity requires consideration of whether the goods or services are being offered on a market, in competition with other economic operators. If the activity in question has not been liberalised that is, opened up to competition and turned into a market the actors will not generally be undertakings. However, the court may determine that an entity acts as an undertaking in any situation where other operators would be willing and able to provide the service in question in other words, where competition is possible.⁶⁸
- 3.4 The exercise of a public power or statutory duty forming part of the essential function of the state is not generally considered economic, ⁶⁹ although the non-core services of public bodies with statutory duties may be economic. An undertaking need not be profit making to be engaged in economic activity. Activities which are "exclusively social" will not be considered economic. Such activities might include those which could not by their nature be profitable without state support or those based on

⁶⁴ HSCA, S105(2).

The purchaser/provider split in the NHS dates back to the early 1990s and more competition was introduced for NHS services (e.g. diagnostic and elective services) in the 2000s.

Hofner & Elser v Macroton, Case C-41/90 paragraph 21. See also joined cases C-264/01, C-306/01 C-354/01 and AOK-Bundesverband and Others, C-355/01, at paragraph 46 onwards.

⁶⁷ Commission v Italy, Case 118/85 paragraph 8.

⁶⁸ See *Ambulanz Glöckner* C-475/99.

⁶⁹ See *Diego Cali* C-343/95.

principles of solidarity rather than capitalisation (for example, entailing a redistribution of income between members in a compulsory social security and insurance system). 70

3.5 It would be inappropriate to apply the blanket classification of 'undertakings' to all providers of health services, or to providers of health services as regards all of their activities. The same applies to commissioners. Indeed, nowhere in the HSCA is any healthcare provider or commissioner expressed – whether by its respective role, its constitution or its structure – to be subject (or not subject) to competition law (save in relation to merger control – see below). The question of whether a particular entity is or is not an undertaking will always depend on the particular activity the entity carries out. An entity may be an undertaking for the purposes of parts of its activity, but not of others. The position is not black and white, and this goes for commissioners and providers alike. We explore these questions in the following paragraphs.

Commissioners

- 3.6 It is arguable that NHS commissioners may be undertakings in certain circumstances.
- 3.7 It is perhaps fair to say that the circumstances in which commissioners might find themselves subject to competition law will be more limited than those in which a provider might. In *Bettercare*⁷¹, the Competition Appeal Tribunal in 2002 had taken the view that competition law applied to both seller and purchaser in a situation where a public-sector purchaser of health services commissioned a particular service from an independent-sector provider, at least in circumstances where it could not be established with certainty that the prices which the purchaser could pay for the services were fixed by the State. Subsequently, the judgment of the CJEU in *FENIN* relating to the Spanish public healthcare system clarified the law at EU level:

"it is the activity consisting in offering goods and services on a given market that is the characteristic of an economic activity..".

The Court of First Instance rightly deduced, in paragraph 36 of the judgment under appeal, that that there is no need to dissociate the activity of purchasing goods from the subsequent use to which they are put in order to determine the nature of that purchasing activity, and that the nature of that purchasing activity must be determined according to whether or not the subsequent use of the of the purchased goods amounts to economic activity.⁷²

See Public bodies and competition law: OFT Guide December 2011 and cases cited at pages 8 to 18. E.g. *Poucet* C-159/91 and 160/91.

⁷¹ [2002] CAT 7, at paras. 278-289.

Case C-205/03 *FENIN*, at paras. 25-26. See also Court of First Instance at paragraphs 37 and 39 (Case T-319/99), where the court concluded that where, as in the case of FENIN, a body purchases goods or services, even in great quantities in order to use them in an activity of a purely social nature they are not acting as an undertaking even though they may in fact a be a monopoly buyer wielding very considerable economic power.

- 3.8 From this it follows that a relevant question in assessing whether the activities of NHS commissioners are to be regarded as economic is how they apply what they have purchased: to the extent that they commercialise (i.e. sell on) their purchased services in any way, then such purchasing is economic in nature and they can be regarded as undertakings as regards that activity. However, it is difficult to see how this would ever be the case with NHS commissioners (though it may well be the case in relation to the buying activities of hospital trusts).
- 3.9 The activities of commissioners therefore seem at first blush to be firmly within the non-economic realm of exclusively social activities. On this basis and applying FENIN, commissioners would not be undertakings subject to competition law.
- 3.10 Nevertheless, there are at least two respects in which this analysis may break down. Firstly, the members of CCGs in England comprise local GPs which are themselves private providers of primary health care services in competition with each other for patients. The GP members of CCGs are therefore, it is submitted, undertakings. While GP representatives on CCG decision making bodies may 'wear a different hat' when exercising the commissioning role, they may well find that they are buying services from a market in which they are themselves operating (e.g. procuring local GP services at the expiry of APMS contracts). This not only gives rise to a conflict of interest (which must be carefully managed), but is also akin to the classic competition law scenario of a 'vertically integrated' market operator buying services from its own upstream affiliate (for example, a ferry company buying slots from a port company owned by the same corporate group). In these circumstances it is not hard to construct an argument that a CCG is an association of undertakings which owes competition law duties when procuring primary care or integrated services in its area.
- 3.11 Secondly, the actual function of providing procurement services is remunerated and competed by various private and public providers. There is at least an argument therefore that CCGs are operating in their core function an economic activity. It would perhaps be more difficult to apply the same analysis to NHS England which is more akin to an emanation of the state whose function is to ensure that NHS services are commissioned and which does not perform any provider services.⁷³

Providers

- 3.12 To the extent that they operate on an economic market, and are subject to competition from other providers (whether those competing providers are in the public or private sector), then, as a matter of competition law, providers of NHS services are generally to be regarded as undertakings.
- 3.13 However, it is not always the case that they do operate on markets.

Though Article 106 and 107, TFEU may arguably be engaged in so far as NHS England favours certain undertakings and distorts competition in, for example, the design of a tender process.

- 3.14 Most NHS providers are engaged in a combination of economic and non-economic activity. In particular, hospital trusts (which can be NHS acute trusts or NHS Foundation Trusts) provide core acute hospital services serving their local populations (and some provide specialist beds to provide treatment over a wider catchment). Such services include Accident and Emergency departments, and also services provided by specialist clinicians for particular conditions (for example, specialist cancer care) or particular types of patient. It can be credibly argued that, in such cases, the providers in question have been entrusted with the provision of the relevant services on a social, rather than an economic, basis: that these services, being financed through state funding on a cost recovery basis and insulated from competition, are thereby non-economic in nature and that the providers are thus not undertakings for competition law purposes.⁷⁴
- 3.15 It may be more difficult to categorise the entire hospital based activity in an 'acute contract' as non-economic where some of the activity is provided in competition with other hospitals, because for example certain outpatient activity is subject to patient choice. Equally, where it would be feasible to tender parts or even the whole of the hospital contract, those parts may be considered economic. Where, however, there are compelling technical or other reasons (*e.g.* due to clinical interdependencies and/or the viability of the core acute services) not to separate out and compete individual activities, this may support the argument that the acute provider is not acting as an undertaking in relation to the acute contract.⁷⁵
- 3.16 Arguably, for these purposes, there is no difference between an NHS acute trust and an NHS Foundation Trust: as both are statutory not for profit entities operating public assets in relation to a non-market activity. However, the argument is most cogent where hospitals continue to be run by NHS acute trusts entities which remain subject to the direction and control of the Secretary of State under the National Health Service Act 2006 as opposed to NHS Foundation Trusts, which are afforded much greater autonomy to engage in commercial activities, often in competition with each other and sometimes involving joint ventures with private providers and sometimes on international projects and are free from supervision by the Secretary of State. Clearly, the direct award of a contract to an autonomous entity such as a Foundation Trust sits uneasily with the argument that the service has not been liberalised. In contrast, the award of an "acute contract" to an NHS acute trust is easier to characterise as non-

⁷⁴See cases above and *CASTA and Others*, Case C-50/14 at paras. 51-67; *Commission v Italy*, Case C-119/06 at paras. 38-39 (not reported in English).

⁷⁵ The public service exemption in Article 106(2), TFEU lends support for this proposition though there is no direct equivalent in UK competition law.

⁷⁶ See for example the conclusions of the Competition Commission on the proposed merger between Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust/Poole Hospitals NHS Foundation Trust. The analysis makes it clear the extent of competition that may exist as between neighbouring NHS Foundation Trusts.

economic activity not least due to the non-binding nature of the "NHS contracts" involved⁷⁷.

- 3.17 Section 79 of the HSCA specifically recognises that mergers involving NHS Foundation Trusts are, by definition, "enterprises" for the purposes of the Enterprise Act and are therefore subject to merger control scrutiny (see below). This certainly supports the notion that NHS Foundation Trusts are subject to competition law and perhaps creates a tension with the argument that they are not necessarily undertakings for the purposes of competition law in relation to the totality of their activities.
- 3.18 Overall, it is submitted that competition law clearly applies to NHS providers where they are engaging in activities in competition with other private or NHS providers. However, arguments will exist at the fringes as to whether a competition analysis is appropriate and the core hospital functions of non-Foundation Trusts in particular may well fall outside the rules.
- 3.19 As for commissioners they may also find themselves subject to the Competition Act, particularly when they are buying primary care services. However, commissioners are also subject to competition law principles as a result of changes introduced by the HSCA, notably Regulation 10 of the NHS Regulations, which is discussed below.

4 REGULATION 10

- 4.1 Regulation 10 of the NHS Regulations provides that when commissioning NHS healthcare services, NHS England and CCGs must not engage in anti-competitive behaviour unless to do so is in the interests of patients, including where services are being provided in an integrated way or by cooperation between providers to improve service quality. NHS service arrangements must not include restrictions of competition that are not necessary for the attainment of intended beneficial patient outcomes or the Regulation 2 'overall objectives' (*i.e.* securing patient needs, improving service quality and improving service efficiency, "including through the services being provided in an integrated way").
- 4.2 The Regulation 10 prohibition therefore first, requires an assessment of whether overall (having regard to the pro competitive and anti-competitive effects) the behaviour restricts competition and second, requires an assessment of whether the behaviour is justifiable by intended patient benefits or the Regulation 2 objectives. In applying the second test there is a proportionality requirement in that the anti-

⁷⁷ Section 9, NHS Act 2006. The award of such a contract is likely to fall outside the application of the procurement rules by reason either of the operation of the *Teckal* exemption (now Article 12, Directive 2014/24 and Regulation 12, 2015 Regulations or cases such as *Helmut Müller* (Case 451/08), which indicate that the procurement rules only apply to the award of legally binding contracts. The question of what types of NHS contracts must be put out to tender is addressed by Part 1. However, the issue of which activities are subject to competition law is analogous.



- competitive effect must be the minimum necessary to achieve the intended benefit. This balancing exercise is further considered below (see Integrated Care).
- 4.3 Monitor has the power under Regulation 13 to 15 to investigate breaches of Regulation 10 either following a complaint or at its own initiative.
- 4.4 Anti-competitive behaviour is defined in section 64(2) of the HSCA as behaviour which would or would be likely to prevent, distort or restrict competition.
- 4.5 Regulation 10 therefore appears to prohibit the sort of conduct or agreements which are prohibited by the Competition Act 1998, but without the need to establish that the commissioners are 'undertakings'.
- 4.6 There is no equivalent to Regulation 10 in UK competition law.⁷⁸
- 4.7 The new rule in Regulation 10 therefore effectively stretches the scope of competition law to cover the commissioning of NHS healthcare services.

What conduct is caught by Regulation 10?

- 4.8 Many cases of unjustifiable restrictions or distortions of competition brought about by commissioners would also breach principles of transparency and fairness and would thus be likely to infringe procurement law as well as Regulation 2 and 3 of the NHS Regulations. This would cover, for example, any procurement activity which excludes certain bidders or classes of bidders from a tender or a choice framework or unjustifiably favours some bidders over others.
- 4.9 Regulation 10 may also be designed to address concerns that competition distortions arise from procurement activity which does not infringe procurement law, such as the aggregation of buyer power, the imposition of non-market standards, increased transaction costs, barriers to participation and increasing the risk of collusion. Given that (in spite of the fragmentation of commissioning), the NHS is in effect a monopsony (a market with a single buyer), some of these competition concerns may be well-founded in this sector.
- 4.10 However, there are few clues in the Regulations as to what *additional* conduct will be prohibited. In its Substantive Guidance on the NHS Regulations, Monitor set out a number of possible examples of commissioner behaviour that could be caught by Regulation 10, including
 - (a) Preventing a provider entering or causing it to exit the market (*e.g.* agreeing exclusive arrangements with a provider) without objective justification;

⁷⁸ See footnote 4 above in relation to Article 106, TFEU which is in some respects similar.



- (b) Limiting the extent to which providers are able to compete to attract patients (*e.g.* limiting the number of patients a provider can treat) without objective justification;
- (c) Restricting the ability of providers to differentiate themselves (*e.g.* limiting opening times or imposing minimum waiting times) without objective justification;
- (d) Reducing the incentives to compete (*e.g.* disclosing confidential information on one provider's decision to exit a particular market).
- 4.11 Other examples might include the imposition of unreasonably onerous conditions of supply (such as very low prices or unreasonable service conditions). The design of a tender specification could thus potentially be held to infringe Regulation 10.
- 4.12 Further examples may be found in case-law on abuse of dominance (see, for example, *Arriva v Luton Operations*⁷⁹ where an airport operator procuring a bus services concession contract was found to have abused its position by negotiating a 7 year exclusivity on the Luton Airport to London route in circumstances where there would be sufficient capacity at the bus station to allow for multiple operators after 3 years). The court considered that the airport operator was in these circumstances obliged to design the tender and negotiate the contract in the manner which best suited customers (by creating a competitive environment where possible) rather than maximise its own profits.
- 4.13 The Regulation 10 prohibition could, in certain circumstances, require a reduction in tendering as unnecessary or over-formal tendering arguably distorts fair competition by raising transaction costs.
- 4.14 Equally, a decision by commissioners not to tender could be attacked as anticompetitive on Regulation 10 grounds (as well as other grounds under the NHS Regulations) on the basis that it unfairly favours the incumbent.
- 4.15 The interpretation of the prohibition is unpredictable. It also presents an added layer of complexity to commissioners at a time when they have a lot to do in just coping with their procurement obligations.

Case-law and decisional practice

4.16 There is little if any case-law to date on Regulation 10. In its investigation into the commissioning of elective services in Blackpool and Fylde and Wyre, Monitor considered whether the CCG's use of a "block contract" for elective, non-elective and

⁷⁹ [2014] EWHC 64 (Ch).



community services with Blackpool Teaching Hospitals FT and other commissioning practices (such as sending information to GPs about the availability of patient choice, which favoured NHS providers) breached the NHS Regulations. Monitor applied the "standing rules" applicable to commissioners and ultimately accepted undertakings from the CCGs concerned to put in place measures to remedy failures to comply with the relevant requirements.

- 4.17 Regulation 10 was invoked in a complaint brought to Monitor by Northern Devon Healthcare Trust, a provider of community services, relating to the conduct of a selection process for providers of community services by Devon based CCGs. However, Monitor decided that issues of discrimination could be dealt with under Regulation 3 rather than Regulation 10 and no submissions were received on Regulation 10.80
- 4.18 Monitor will, in time, make decisional practice on the prohibition and the courts will no doubt form their own view if faced with a claim based on breach of this provision.

5 IS INTEGRATION CONSISTENT WITH COMPETITION?

The legal framework for integrated healthcare

- 5.1 Integration plays a prominent role in the legal framework underpinning the changes in healthcare introduced in April 2013.
- 5.2 Commissioners (both NHS England and CCGs) have a duty to secure that healthcare services are provided in an integrated way and that health and social care are integrated where integration would:
 - (a) improve the quality of services,
 - (b) reduce inequalities in access to services and
 - (c) reduce inequalities in outcomes for patients/service users.

(NHS Act 2006 s. 13N, s. 14Z1).

5.3 Health and Wellbeing Boards must encourage persons who arrange for the provision of any health or social care services to work in an integrated manner and encourage formal partnership working between health and social care under s 75 of the NHS Act 2006. (HSCA, s 195)

⁸⁰ See Part 2, which goes into the detail of this and other Monitor investigations.



- 5.4 Monitor, the Independent Regulator of NHS Foundation Trusts, has a very similar duty to commissioners. It must exercise its functions with a view to enabling healthcare services to be provided in an integrated way and enable health and social care to be integrated where integration would
 - (a) improve the quality of services,
 - (b) reduce inequalities in access to services and
 - (c) reduce inequalities in outcomes for patients/service users.

(HSCA, s. 62 (4) and (5))

- 5.5 The licence for providers includes an Integrated Care Condition which states that NHS provider licence holders should not do anything that could reasonably be regarded as detrimental to enabling integrated care. An important aspect of the licence condition is the expectation that integrated care will be delivered locally by commissioners specifying their requirements and working with providers capturing integration in contracts and pricing.
- 5.6 Then the NHS Regulations expressly references integration.⁸¹
 - (a) The overriding objective at Regulation 2, which requires commissioners to act with a view to securing needs and improving quality and efficiency of services, states that this could be through integrated provision.
 - (b) And the general requirement under Regulation 3(4) is, in acting with a view to improving quality and efficiency, to consider the making of improvements through services being provided in an integrated manner.
- Many of the references to integrated service were introduced in the 2nd iteration of the NHS Regulations (No 2) after the 1st version of the NHS Regulations provoked much controversy and debate in Parliament over concerns that it encouraged or even required commissioners to compete NHS service contracts and thus liberalise the market. The use of the terminology of integration was therefore used as a counterweight to competition. It is submitted that this was more of a political rather than a legal move and that the references to integrated services do not make substantive changes to the (previous version of) NHS Regulations. The NHS Regulations require a balancing of duties and are not prescriptive as to whether contracts are opened up to competition and whether services are liberalised.

What are integrated healthcare services?

- 5.8 Although integration plays a prominent part in the current legislative framework for the commissioning and provision of NHS funded healthcare, the term is not defined in the legislation.
- 5.9 However, according to a recent report commissioned by Monitor on integration (and despite it referencing research that revealed 175 definitions and concepts of the term) there is a clear consensus that successful integrated care is primarily about patient experience. (*Enablers and barriers to integrated care and implications for Monitor*, 2012).
- 5.10 The report identified three aspects to integrated care:
 - (a) The smoothness with which a patient or their representative/carer can navigate the NHS and social care system in order to meet their needs;
 - (b) The improvement of the quality and cost effectiveness of care for individuals and populations by ensuring services are well co-ordinated around their needs;
 - (c) That it is necessary for anyone for whom a lack of care coordination leads to an adverse impact on their care experiences and outcomes.
- 5.11 What is key in this definition is that integrated care is patient centred. It is not about structures, organizations and pathways, nor about the way that care is funded or commissioned.
- 5.12 The NHS is fragmented with a range of different types of providers from primary healthcare, through secondary and tertiary care to social care. However, integration is not about how care is provided per se but about the patient experience of healthcare. This could mean that different types of providers merge or work in 'partnership'. It could mean certain services in a geographic region are bundled together. However, the mode of delivery should not be the *raison d'être* for integration. Integrated care is primarily about an individuals' experience of care and ensuring better outcomes through coordinated, person-centred care and support.

Integration and competition

- 5.13 Monitor is clear that in its view the delivery of co-ordinated, person-centred care and support is consistent with competition regulation.
- 5.14 A great deal of integrated care is focused on how current providers work together to effect seamless service delivery by professionals from different disciplines and organisations responsible for individual elements of a patient's care. Such an approach has no inherent adverse impact on competition.

- 5.15 However, integration can result in the replacement of a number of providers by one provider: for example the establishment of a provider to support patients with multiple long term conditions rather than the patient interacting with a multiplicity of providers.
- 5.16 The question Monitor looks at here to assess if such a mode of delivery is anti-competitive is twofold.
 - (a) First Monitor looks at whether the behaviour materially reduces or removes the incentives that providers would otherwise have to provide high-quality services and value for money in order to attract patients and/or win contracts with commissioners. If incentives are reduced or removed (or more are removed than are created) then prima facie this is anti-competitive.
 - (b) Then Monitor considers if the initiative results in a better patient experience and better clinical outcomes. If an initiative results in better coordinated care, this will be treated as a benefit. Monitor will also consider whether an initiative gives rise to other types of benefits; these may be clinical or non-clinical. In deciding what weight to give to benefits put forward by providers and/or commissioners, Monitor will consider whether it would have been possible to achieve better integration or other benefits without reducing competition. 82
- 5.17 Integrated health and social care commissioning and provision have been enshrined in statute for a number of years. This may involve the pooling of funds, the delegation by a local authority of the exercise of its health-related functions to an NHS body or the delegation by an NHS body of the exercise of certain of its NHS functions to a local authority. Partnership arrangements must be between a statutory health body (a commissioner or provider trust) and a local authority. In the last year such partnership working, as it is referred to, has been strengthened with its express encouragement in the HSCA and the Better Care Fund.
- 5.18 It is submitted, however, that health and social care organisations can no longer just rely on the statutory provisions for joint working. They need to make sure that in setting up such partnership arrangements they are acting in a manner that is consistent with competition principles and the NHS Regulations. This will require consideration of the need to run a competitive tenders for services in order to establish the provider or providers most capable of delivering the objective and providing best value for money in accordance with Regulation 3(3) and the need to act in a transparent,

⁸² See Monitor Substantive Guidance on the NHS Regulations of April 2013 at section 8 (Guidance on assessing anticompetitive behaviour). The approach followed is not dissimilar to the approach followed by the CMA and European Commission in considering the competitive effects of cooperation arrangements. See Communication from the Commission: Guidelines on the applicability of Article 101 to horizontal cooperation arrangements. OJEU Cc11/1 of 14.1.2011.

proportionate and non-discriminatory manner having regard to the other duties under the NHS Regulations. These duties include:

- (a) Acting with a view to securing patient needs, improving quality and efficiency including through the services being provided in an integrated manner under Regulation 2;
- (b) Not engaging in anti-competitive behaviour (unless to do so is in the interests of patients) under Regulation 10 and compliance with the Chapter One and Chapter Two prohibition in so far as the cooperation affects undertakings;
- (c) Other duties under the HSCA (*e.g.* equal access for patients to NHS services and the need to work within its annual allocated budget); and
- (d) The promotion of patient choice and integrated services.
- 5.19 In broad terms, if the partnership arrangement can be justified as being consistent with a reasonable balancing of these duties and in patients' interests, it will be unlikely to give rise to significant competition risks. However, commissioners will need to consider whether there is an alternative means of achieving the same objective which gives rise to less restriction or distortion of competition and/or a more optimal balancing of the various duties.
- 5.20 Any decision to cooperate or integrate services, including arrangements under s75 of the NHS Act, could be susceptible to challenge (depending on the nature of the services). Therefore health and social care organisations should ensure when setting up partnership arrangements they not only comply with the legislation that specifically governs such joint working but that they also comply with the competition agenda.
- 5.21 In the first court case on the NHS Regulations, *QSRC v NHS England*, the court was asked to apply Monitor guidance issued following the Thornbury investigation into the commissioning of stereotactic radiosurgery services (SRS). SQRC Limited is also a provider of SRS (and a related company to Thornbury Radiosurgery services). The QSRC case itself related to the commissioning of SRS in London and in particular the decision of NHS England not to contract with QSRC (which had invested in a SRS facility at UCLH), pending a national SRS procurement. The Thornbury guidance asked the question whether the commissioner was "objectively justified" in not entering into a commissioning contract with an existing provider of the services. Mr Justice Foskett considered the various applicable statutory duties and the policy reasons put forward (including overcapacity in the London market, the risk of favouring QSRC over other London based providers, the sustainability of the

⁸³ SRS is a targeted form of radiation treatment (e.g. for tumours).



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commissioned London providers (Bart's and the Cromwell) and the need to allocate scarce resources to the national procurement with a view among other things to ensuring equal access on a country-wide basis and greater cost efficiency). The court concluded that the decision not to enter into an interim contract with QSRC was objectively justified and did not reflect an illegality in approach and that other arguments advanced, including the claim that insufficient consideration was given to the benefits of integrated care at QSRC (given its co-location with the neuroscience centre at UCLH⁸⁴), did not change his view.

Summary

- 5.22 The commissioning and provision of integrated services plays a key part in the 2012 architecture of our health services and has a clear statutory underpinning.
- 5.23 There is no legal definition of integration although the generally accepted meaning is an outcomes-based one centred on the patient experience and improved quality of care.
- 5.24 There are a myriad of forms of providing integrated services. Each initiative needs to be assessed as to its compatibility with the rules on competition.
- 5.25 Even if a particular initiative around competition is on the face of it anti-competitive as it could reduce or remove certain competitive incentives to provide high quality services or value for money provision, it will still be deemed by Monitor as acceptable if the benefits to patients outweigh the detriment to the system overall.
- 6 A SCHEME OF MERGER REGULATION FOR NHS FOUNDATION TRUSTS
- 6.1 Section 79 of the Act contains provisions specifically applicable to mergers involving NHS Foundation Trusts and, as such, complements the merger control regime provided for by Part 3 of the Enterprise Act 2002.
- 6.2 Section 79 is engaged in either of two situations, namely where:
 - (a) the activities of two or more NHS Foundation Trusts cease to be distinct activities (which could include a merger of two NHS Foundation Trusts, the

The national SRS Review concluded that while integration of SRS provision with the local neuroscience centre was essential this could be achieved by ensuring sufficient geographical proximity but did not require on site colocation. In effect, if the SRS national procurement had favoured or required on site colocation with the designated neuroscience centre (in the 17 or so geographical areas covered) this would have restricted or removed competition between SRS providers and discriminated in favour of those which are co-located with a neuroscience centre, such as UCLH.



Such co-location meant that it was easier for a patient's neurology consultant to also be its SRS consultant thus avoiding the need for switching consultants.

- acquisition of one NHS Foundation Trust by another, or a structural joint venture between two NHS Foundation Trusts); or
- (b) the activities of one or more NHS Foundation Trusts and the activities of one or more businesses cease to be distinct activities (this could include the (perhaps rare) situation where an NHS Foundation Trust acquires a business, or the (less rare) situation where an NHS Foundation Trust enters into a structural joint venture with a business which is not an NHS Foundation Trust.
- 6.3 Section 79 does not operate as a stand-alone regime for controlling mergers involving NHS Foundation Trusts. Instead, it complements the regime set out in Part 3 of the Enterprise Act 2002, which applies to mergers between enterprises generally.
- 6.4 Specifically, it provides for Monitor to be notified of, and to provide advice to, the CMA in any situation where the CMA decides to carry out an investigation under Part 3 of the Enterprise Act 2002 of a matter involving an NHS Foundation Trust.

What is the role of the CMA in mergers involving NHS Foundation Trusts?

- 6.5 The CMA has the principal role of reviewing mergers⁸⁶ involving NHS Foundation Trusts. The CMA has responsibility for deciding whether an NHS merger falls within its jurisdiction and whether the merger would result in a substantial lessening of competition leading to worse outcomes for patients and commissioners. The CMA will review any notifications submitted to it, and where no notification is made, may send an enquiry letter in respect of an anticipated or a completed merger to the relevant parties involved to obtain further information to determine whether it has jurisdiction to review the merger⁸⁷.
- 6.6 Upon notification of a merger and once the CMA has decided it has jurisdiction to review the merger and that it will proceed to conduct a merger investigation, the CMA must inform Monitor as soon as reasonably practicable.

What is the role of Monitor?

6.7 The role of Monitor is to act in an advisory capacity to the CMA but it does not have the power to clear or prohibit mergers which fall within the Enterprise Act 2002 on the basis that they may give rise to a substantial lessening of competition. Monitor's advice is not binding on the CMA. Whilst Monitor will also review transactions to determine whether Foundation Trusts are in compliance with the governance and

In the case of a completed merger, the merger must have taken place not more than four months before a Phase 2 reference is made, unless the merger took place without having been made public and without the CMA being informed of it (in which case the four month period starts from the earlier of the time the merger was made public or the time the OFT was told about it).



^{&#}x27;Merger' is defined broadly in this section to refer to any type of transaction that may be considered a 'relevant merger situation' and one which is capable of review by the CMA under the Enterprise Act 2002.

- continuity of service conditions of their provider licence and whilst it will conduct a risk evaluation process, this does not form part of the CMA merger process.
- 6.8 The matters on which Monitor must provide the CMA with advice are closely aligned to the matters on which, under the Enterprise Act 2002, the CMA must focus when carrying out a merger investigation but with a healthcare "slant". As is the case in the Enterprise Act (and specifically section 30(1)(a) of that Act⁸⁸), the emphasis is on the effect of the merger on end users: customers in the case of a non-health service merger, and users of health care services provided for the purposes of the NHS in the case of section 79.
- 6.9 Monitor will in practice take a central role in ascertaining relevant customer benefits. In a joint statement issued by the OFT, Competition Commission ("CC") and Monitor in October 2013, the regulators noted that, given Monitor's expertise, the OFT and CC (now collectively the CMA) will place significant weight on Monitor's advice concerning the patient benefits of a proposed merger involving NHS hospitals.

What types of transactions are reviewable by the CMA?

- 6.10 The CMA has jurisdiction to review all types of arrangement that may give rise to two or more enterprises 'ceasing to be distinct'.
- 6.11 An 'enterprise' is defined broadly under the Enterprise Act 2002 and may refer to a whole organisation or a part of it, whether or not it operates for profit. An enterprise can therefore comprise a variety of components including staff, assets (for example, equipment, premises, patient records), the benefit of contracts and goodwill. The CMA will assess on a case-by-case basis whether the combination of relevant components constitutes an 'enterprise'.
- 6.12 Two enterprises will cease to be distinct if they are brought under common ownership or control. This requires that there must be a change in the level of control over the activities of one or more enterprises. Control need not be outright control but could constitute 'material influence' whereby the acquirer obtains the ability materially to influence policy and strategy relevant to the behaviour of the target entity in its provision of NHS healthcare services; de facto control which occurs where in practice a party holds control of the target's policy, notwithstanding that it holds less than the majority of voting rights in the target; the acquisition of a 'controlling' interest which would occur, for example, where an NHS Foundation trust acquires all the rights over all or part of the activities of another NHS provider, or circumstances in which joint or shared control is acquired with other providers.



Section 30(1)(a) articulates and defines the concept of "relevant customer benefits" as being a benefit to customers in the form of lower prices, higher quality or greater choice of goods or services in any market in the United Kingdom".

- 6.13 In broad terms, if there is a combination of assets, staff and other rights which is sufficient to form an enterprise, and that enterprise is transferred in some way to another party, it is likely that a merger situation will arise. Thus in the context of the NHS, the CMA potentially has jurisdiction to review a very broad range of transactions including mergers, acquisitions of the whole or part of other NHS providers (regardless of whether any financial consideration is payable), joint ventures, the transfer or pooling of assets, divestments, vertical integration arrangements, hosting arrangements, management alliances, management contracts, shared management contracts, franchising arrangements, the transfer of individual services or activities to another provider and any integrations involving all or part of an organisation.
- 6.14 Neither the CMA nor Monitor provide detailed guidance on the specific scenario of a merger arising from an NHS procurement or outsourcing process. However, given the broad definition of a merger, where an NHS body is involved in reconfiguration, or where a procurement process involves the commissioning of services, the parties should consider whether a 'relevant merger situation' is triggered that will be subject to the CMA's jurisdiction.
- 6.15 In the circumstances of an award of a contract following a competitive process, then provided there is no structural change (such as the incorporation of a JV which takes the assets and staff of the co-bidders), a merger situation is unlikely to arise. However, it is sometimes the case that more complicated outsourcings may involve the ceasing to be distinct of enterprises and allow the CMA competence to review the transaction. A competition analysis should therefore be built into the process to ensure that, if reviewed, the winning bidder would not cause any competition concerns and the resultant merger would be cleared.
- 6.16 Mergers reviewed by the CMA so far illustrate how different structures may be caught by the merger rules. Whilst the CMA has reviewed a number of straightforward acquisitions or mergers of foundation trusts which clearly qualify as relevant merger situations, the CMA has also considered a number of other more complex arrangements which has involved the CMA conducting a detailed examination of whether the specific factual arrangements involve enterprises ceasing to be distinct.
- 6.17 The reorganisation of pathology services following the Carter Review has been a key example of the way in which the CMA's merger control powers apply and is illustrative of the application of merger control requirements to outsourcing arrangements, particularly where a joint venture is formed ⁸⁹. In 2013, the OFT considered under its merger control powers the pathology joint venture between University College London Hospitals NHS Foundation Trust, Royal Free London

See Monitor's 'Briefing note on the application of merger control rules to pathology service reconfigurations', 3 June 2013.

NHS Foundation Trust and the Doctors Laboratory Limited ⁹⁰. The joint venture involved the establishment of a limited liability company to which the staff, assets and UCLH and RFL's pathology requirements were contributed and which would provide services to RFL, UCLH, TDL and North Middlesex University Hospital NHS Trust with whom the JV had a 10-year pathology services agreement. The OFT concluded that the staff, assets and pathology work of UCLH and RFL were sufficient to constitute enterprises and these would cease to be distinct and with TDL taking a controlling interest and UCLH/RF having material influence over the JV. As the turnover of the business contributed to the JV exceeded £70 million, the OFT had jurisdiction to review it.

- 6.18 In 2014, a similar arrangement was reached in a joint venture between Basildon and Thurrock University Hospitals NHS Trust, Southend University Hospital NHS Trust and Integrated Pathology Partnerships formed to supply outsourced pathology services to the NHS⁹¹. The arrangements involved the transfer of all pathology staff (other than consultant pathologists) and all assets relating to pathology services to IPP, which would act as subcontractor to two LLPs jointly controlled by the parties. The LLPs would in turn contract with each of BTUH and SUH to be the exclusive provider of pathology testing and logistics services. Since the JV was estimated to have a share of supply of pathology testing and logistics services to the four CCGs in South Essex of over 25%, the CMA took the view that the arrangements amounted to a relevant merger situation over which it had jurisdiction.
- Not all joint ventures will fall within the jurisdictional remit of the CMA, and other arrangements to cooperate or coordinate activities, without transfers of contracts, assets and personnel will not trigger the application of the Enterprise Act 2002. The OFT decided that a pathology joint venture formed between a number of East Anglian Foundation Trusts⁹² did not create a relevant merger situation and it had no jurisdiction to review it. The JV partners signed a consortium agreement forming a contractual joint venture, but not a structural one with separate legal identity. After detailed analysis of the facts and the structure of the joint venture, the OFT decided that no enterprises ceased to be distinct. Whilst each of the JV partners transferred staff, equipment and assets, the CMA concluded that no party ceased to be distinct and thus had any form of control over any enterprise contributed by another JV Partner. In particular, the CMA found that none of the JV partners had the ability to materially influence policy relevant to the behaviour of the joint venture in the market place.

Decision of the OFT, 8 November 2013.

Decision of the CMA, 28 August 2014.

Decision of the OFT of 27 March 2014 concerning a joint venture between Cambridge University Hospitals NHS Foundation Trust, Colchester Hospital University NHS Foundation Trust, East and North Hertfordshire NHS Trust, Hinchingbrooke Health Centre Care NHS Trust, The Ipswich Hospital NHS Trust and West Suffolk NHS Foundation Trust.

- 6.20 A feature of an outsourcing arrangement is that the arrangements are typically for a defined term. This will not necessarily disapply the merger control rules. Whilst the Enterprise Act 2002 does not define the period of time that a merger situation should last to qualify as a relevant merger situation, in the OFT's review of the award of contracts to SSP Health Limited to manage and operate 22 GP practices⁹³, the OFT commented that it is of the view that any transaction no matter how short in duration could qualify as a relevant merger situation. However, it noted that there may be circumstances where the duration of the contract may affect the ability to materially influence the strategic direct of a company and its ability to define and achieve its commercial objectives. In this instance the OFT did not need to come to a view on duration given it concluded that SSP did not acquire a sufficient level of control over the GP practices.
- 6.21 The development of new service models has also been considered by the CMA using its merger control powers. The proposed development of a new NHS cancer treatment centre at Guy's Hospital involved Guy's and HCA International Limited entering into a collaboration agreement⁹⁴. This involved a 25 year lease agreement whereby HCA would complete the interior works of the premises, operate and manage a private patient unit within the cancer treatment centre to provide inpatient and day care medical and surgical cancer patient services. The parties argued that the arrangements did not involve the transfer of an enterprise. The OFT agreed noting that no services, staff, customer assets, liabilities or patients were to transfer to HCA, commenting that a lease of space to be fitted out by HCA at its own expense did not amount to the transfer of an 'enterprise'. However, the OFT also noted that should the structure change, for instance if there were to be a transfer of activities, those arrangements may fall to be assessed under the OFT's merger control powers. Notwithstanding this, the decision noted certain third party concerns about the impact of the transaction on competition, particularly given the position of HCA in relation to the provision of private patient services in London. In concluding it had no jurisdiction, the OFT did not rule on any of these issues; however, the decision is an example of the need to review the broader competition aspects of any transaction under the provisions of the Competition Act 1998, even where it does not fall to be considered by the CMA under its merger control powers.

When are mergers reviewable by the CMA?

- 6.22 The UK merger regime is voluntary and there is no requirement to notify. This similarly applies to all NHS mergers. However, the CMA keeps mergers under review any may investigate any merger that has not been notified to it. The CMA has jurisdiction to review a merger where two or more enterprises cease to be distinct and:
 - (a) either the UK turnover of the acquired enterprise exceeds £70 million; or

Decision of the OFT, 8 August 2013.

OFT decision of 30 October 2012.

(b) the enterprises which cease to be distinct supply or acquire goods or services or any description and, after the merger, together supply or acquire at least 25% of all those particular goods or services of that kind supplied in the UK or in a substantial part of it.

How are NHS mergers assessed?

- 6.23 The CMA's merger review process is a two stage process. During the Phase I process, the CMA will determine whether it has a reasonable belief, objectively justified by relevant facts, that there is a realistic prospect that the merger will lessen competition substantially. If this test is met, the merger is referred for a Phase II investigation process during which an Inquiry Group reviews the merger in more depth and considers whether in its view a substantial lessening of competition is likely to arise.
- 6.24 The CMA will consider a range of factors when assessing a merger. Its starting point is to consider the relevant product and geographic markets to frame the analysis. This will be fact specific but given the nature of the markets in question it is typical for the product and geographic markets to be drawn narrowly, and it will be on local markets that the merger will principally be analysed. The CMA will proceed to consider the parties' positions within those markets, the competitive situation without the merger (the counterfactual), conditions of competition, effects of the merger, entry and expansion into the relevant market(s) by other providers, any efficiencies brought about by the merger and whether there is any countervailing buyer power.
- 6.25 However, the CMA's approach to assessing NHS mergers is principally based on two models of competition in the provision of NHS healthcare services. Firstly, providers compete to attract patients (competition in the market) and this will occur where patients have a choice between providers of the same service, which will lead providers to compete on quality such as waiting times, infection rates, mortality rates, equipment, best practice, and cleanliness. Price is not usually a relevant factor as the majority of services are covered by national prices and the payment-by-results rules. To the extent that the merging providers have overlapping services, the CMA will consider the above quality factors, and identify whether the merging providers would have an incentive to compete to attract patients in the absence of the merger, and whether they are close competitors.
- 6.26 Secondly providers compete to attract contracts to provide services (competition for the market) across a clinical commissioning group or other locality and are incentivised to maintain quality standards and provide value for money, as well as performing well under existing contracts. As such, the CMA will consider whether the merger will lead to a loss of competition potentially jeopardising the quality in services, value for money and choice. In particular, the CMA will consider whether the merger would lead to fewer bidders for competitive tenders and thus potentially 90

leading to reduced value for money, as well identifying whether providers of existing contracts may provide lower-quality services since they would be aware that commissioners have fewer alternative providers of those services.

- 6.27 A key area for assessment by the CMA, and to date the most contentious, is the issue of customer and patient benefit. The Competition Commission's decision in 2013 to block the merger of The Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust and Poole Hospital NHS Foundation Trust⁹⁵ was based on its conclusion that the merger would not yield any relevant customer benefits (in the form of lower prices, higher quality, greater choice and greater innovation). Despite the CMA being aware of the financial pressures the hospitals were under, the CMA claimed a lack of evidence of the claimed benefits the merger would bring. In the absence of suitable remedies, the CMA blocked the merger.
- 6.28 This decision, together with guidance issued by the CMA⁹⁶, illustrates that the focus of the CMA will be examining whether a merger will lead to higher quality services through, for instance, implementing a particular model of care, through service reconfiguration, through increased staff cover, access to equipment or financial savings. The CMA will require a clear indication that any such benefits are expected to accrue within a reasonable period of time after completion of the merger, and will in practice review in detail implementation and strategy plans.

7 LEVEL PLAYING FIELD ISSUES

- Regulation 3(2) of the NHS Regulations imposes on relevant bodies the duties to "act in a transparent ... way" and to "treat providers equally and in a non-discriminatory way". There are obvious parallels between these obligations and the EU principles of "transparency" and "equal treatment" under general procurement law. But Regulation 3(2) elaborates the duty to "treat providers equally and in a non-discriminatory way" by adding the words "including by not treating a provider, or type of provider, more favourably than any other provider, in particular on the basis of ownership". Such express prohibition on treating a provider more favourably on the basis of "ownership" is not found in the 2015 Regulations and is presumably intended to emphasise to NHS commissioners that they must avoid providing favourable treatment to certain categories of providers (by, for example, favouring a provider owned by another NHS body, or indeed by a 'social enterprise', over a competing private sector provider).
- 7.2 The question arises as to how far these duties go in requiring NHS commissioners to take positive steps to create a 'level playing field' for competition, in particular between NHS owned bodies and private sector competitors. In this connection, it is submitted that a distinction is to be drawn between:

Decision of the Competition Commission, 17 October 2013.

⁹⁶ CMA guidance on the review of NHS mergers, July 2014.

- (a) on the one hand, advantages created by the NHS commissioner for example, advantages created by the design or conduct of the competition, whether directly (such as by awarding additional marks to NHS bodies) or indirectly (such as by conducting the competition in a way that favours the incumbent provider); and
- (b) on the other hand, advantages that are not created by any decision on the part of the commissioner, but which exist due to factors external to the procurement. Such external factors may include, for example, differences between NHS and non NHS bodies in the costs they incur (such as irrecoverable VAT, pension costs, etc.) or the costs of their supplies to the commissioner (such as VAT that the commissioner is unable to recover).
- 7.3 While the distinction between these two categories of advantages is easy to draw in principle, it can sometimes be less clear in practice. A commissioner might, for example, make a deliberate choice to structure its procurement requirements in such a way that it is procuring a service in relation to which an NHS body will, by reason of VAT treatment or other factors external to the procurement, have a cost advantage over competing private sector providers.
- 7.4 It is submitted that, while Regulation 3(2) restricts NHS commissioners from designing or conducting their procurement competitions in such a way as to advantage NHS bodies, it does not go as far as to require (or perhaps even to permit) commissioners to seek to create a level playing field by making adjustments directed at 'cancelling out' advantages created by VAT rules or other external factors. A commissioner is entitled to evaluate tenders on the basis of the cost to the commissioner of each tenderer's supply of the services, and to identify the most economically advantageous tender on that basis. Thus, although external factors have a significant competition distorting effect on competition to provide NHS services (as discussed further below), the NHS Regulations do nothing to address this. 97

Distortions arising from a commissioner's design or conduct of their commissioning approach – The need to limit incumbency advantages

7.5 An issue to which NHS commissioners are well advised to pay particular attention when procuring services is the need to ensure a level playing field between the incumbent provider and other potential providers. This is a concern to which Regulation 3(2) duties are plainly relevant, given that the extent to which the

As noted above, it is possible to conceive of a commissioner making a deliberate choice to structure its procurement requirements in such a way that it is procuring a service in relation to which an NHS body will, by reason of external factors, have a cost advantage over competing private sector providers. It is arguable that such a commissioner would, at least in some such scenarios, be breaching its duties under Regulation 3(2). In practice, however, the difficulties of establishing such a breach mean that few, if any, challenges are likely to be brought against commissioners alleging a breach of Regulation 3(2) on that basis.

incumbent provider enjoys advantages in the competition is a matter largely within the control of the commissioner through the design and conduct of the procurement.

- 7.6 Incumbency advantage is frequently an issue in procurements in both the public and private sectors, but may be of particular significance in relation to complex services. An incumbent provider may enjoy significant practical advantages in bidding for the contract, as a result of its experience of delivering the commissioner's relevant requirements. It is, to an extent, inevitable that the incumbent will benefit from a unique depth of insight regarding matters such as likely service volume requirements, staffing requirements, costs, the capacity of the staff involved in delivering the contract (who may 'go with' the contract under the TUPE Regulations), and how demand for the services is likely to develop in the future. But, equally, there is much that commissioners can do to reduce the incumbent's advantage and hence 'level the playing field'.
- 7.7 A particular area of concern is incumbency advantages arising from computer and other systems and processes that have been developed by the incumbent for the purpose of delivering the contract, and which may not always be contractually required to be transferred to the new provider. Such advantages can be exacerbated where the existing contract has been poorly designed so that the existing provider is not under a duty to transfer critical systems or know how developed in the course of delivering the existing contract. Similar difficulties may arise where NHS owned bodies (or, indeed, bodies which have been 'spun out' from the NHS) own critical know how. Particular difficulties can also arise in relation to the software to be used by a new provider, given that the new provider's software solution may not be easily interoperable with a related or wider software or hardware solution being provided or used by the incumbent.
- 7.8 Under the general principles of equal treatment and transparency, a commissioner should avoid designing or carrying out a procurement competition in such a way as advantages the incumbent over alternative providers. That is so even where the commissioner is of the view that it has an economic or practical interest in seeing the contract stay with the existing provider. For example, the commissioner may be keen to avoid the costs and inconvenience associated with transferring to a new provider; but such costs and inconvenience should not be taken into account when identifying the most economically advantageous tender.
- 7.9 On the other hand, it is submitted that there is no duty on commissioners to apply a 'handicap' to the incumbent provider to adjust for advantages enjoyed by the incumbent which do not arise from the design of the procurement that is now being undertaken. Thus, even where such advantages arise from, or have been exacerbated by, unfortunate aspects of the design of the existing contract, the commissioner is not under a duty to find a way to 'cancel out' such advantages; and it will, of course, be too late at tender award stage for anyone to challenge the lawfulness of the design of the procurement process (if any) which led to the award of the existing contract.

- 7.10 Steps which commissioners would be well advised to take in order to avoid challenges to the design or conduct of their procurements based on allegations of breach of equal treatment or transparency by favouring the incumbent provider include the following:
 - (a) The commissioner should consider all available options for providing and improving patient services. They should seek to avoid setting unnecessarily high levels of minimum reserves and working capital for providers, which might operate to exclude certain types of providers, such as charities and social enterprises. 98
 - (b) It is often helpful for the commissioner to carry out pre-competition engagement with potential suppliers in order to better understand what is available in the market. Such engagement can help reduce incumbency advantage. Commissioners should, however, be carefully to maintain a 'level playing field' when conducting such engagement. The incumbent provider should not be afforded a privileged degree of involvement in the commissioner's development of its requirements for its approach to market. If, for example, the incumbent (but not other potential providers) were invited to comment on the draft approach to market documents, this could lead to reasonable complaints that the requirements are likely to have been tilted to favour the incumbent provider, or that the incumbent provider has been advantaged by receiving advance access to the information.
 - (c) Commissioners should generally err on the side of giving potential providers more, rather than less, information about the way that the contract has been or is being performed (albeit that information that is genuinely commercially confidential to the incumbent provider may have to be withheld). Information can be given in the documents issued by the purchaser, or via a data room, or by conducting briefings to familiarise all potential providers with the commissioner's requirements.
 - (d) Provide potential providers with scenarios illustrating how the services operate or are performed or are utilised on a day-to-day basis.
 - (e) Ensure that potential providers are allowed adequate time to review the information provided to them, and seek any clarifications, before submitting their bids.
 - (f) Ensure that there are appropriate separations of roles well before the procurement process is undertaken (i.e. that contract management and tender evaluation functions are separated).

⁹⁸ Guidance on these matters is set out within the Monitor publication, "Substantive guidance on the Procurement, Patient Choice and Competition Regulations" (19 December 2013), available online via: https://www.gov.uk/government/collections/procurement-choice-and-competition-in-the-nhs-documents-and-guidance.

- (g) Consider appointing an external probity adviser to independently monitor the fairness of the process.
- (h) Provide meaningful debriefs to unsuccessful tenderers.

'External distortions': Advantages enjoyed by certain types of providers which are not attributable to the commissioner's design or conduct of the procurement

- 7.11 As already stated above, it is submitted that there is no duty under Regulation 3(2) of the NHS Regulations for commissioners to adjust for advantages enjoyed by particular types of provider where such advantages are due to factors external to the procurement and therefore outside of the commissioner's control. Thus, commissioners are not required, or perhaps even permitted, to adjust for VAT or other external factors that increase certain providers' costs that they would need to carry when providing the required services. The commissioner's interest is in identifying the most economically advantageous provider taking account of the cost to the commissioner itself; the difference in cost to the commissioner is an objective criterion that it may legitimately rely on when choosing between competing providers.
- 7.12 It follows that, insofar as there are external factors that are distorting competition, the remedy is likely to require legislation or policy intervention at the national level; the remedy is not within the hands of individual commissioners.
- 7.13 In March 2013 Monitor published a report entitled 'A fair playing field for the benefit of NHS patients Monitor's independent review for the Secretary of State for Health'. This was the first major report to be published by Monitor and addressed the extent to which all potential providers of NHS care have a fair opportunity to offer their services to patients. Monitor approached its task by asking itself this question: are there unfair aspects of the healthcare playing field the removal of which would improve patient care? In asking that question, Monitor deliberately avoided making any assumption that certain types of provider might be better than other types of provider in meeting patients' needs. Monitor's approach was instead to seek to identify any systemic distortions of the playing field which might prevent providers (regardless of type) with the best services reaching patients.
- 7.14 The report identified a number of playing field distortions that have, or potentially have, a significant impact on patients. It divided those material distortions into three categories:
 - (a) <u>Participation distortions</u>: Some potential providers were being artificially excluded from competing for some opportunities to provide NHS care. In

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/284634/The_Fair_Playing_Field_Review_FI_NAL.pdf.

⁹⁹ The report is available online at:

¹⁰⁰ On 1 April 2016, Monitor was subsumed into a new organisation, NHS Improvement.

some cases this was because commissioners were failing to consider alternative providers where it would have been appropriate to do so. In other cases, the procurement processes being used were unnecessarily complex. In both types of cases, the effect was to confer an unwarranted advantage on incumbent providers over potential alternative providers, meaning that patients might be receiving poorer care than they would otherwise have received. (Such advantage, where it arises, will be attributable to the choices made by the commissioner in its design or conduct of the procurement. It is therefore not an 'external factor'.)

- (b) Cost distortions: Monitor found that there were "many circumstances" in which some types of provider faced externally imposed costs that did not fall on other types of provider at all or to the same extent. In particular, Monitor found that private and charitable sector providers faced a number of significant cost burdens that disadvantaged them *vis-à-vis* NHS bodies and were likely to be material in terms of potentially affecting the care provided to patients. Some of those higher costs burdens namely, pension costs, the costs of clinical negligence indemnity insurance, and the costs of providing education and training were already being ameliorated to some extent by Government measures. However, two other heads of higher cost burdens for private and charitable sector providers namely, cost of capital, and inability to recover VAT were not being addressed at all. Monitor found that NHS bodies might also face certain higher costs; in their case because of dealing with a greater number of the more complex medical cases.
- (c) <u>Flexibility distortions</u>: Public sector bodies faced a number of restrictions on their flexibility which other providers did not face. These included: mandatory service obligations; being subject to the Secretary of State's power of direction; rigidities in the public sector workforce; and the higher likelihood of government intervention.

The VAT distortion

PROCUREMENT LAW

7.15 Amongst the external factors identified by Monitor as constituting unfair aspects of the healthcare playing field the removal of which would improve patient care, Monitor recognised the cost distortion relating to VAT recovery as being of particular significance and recommended that the Government review the VAT treatment of NHS and non NHS bodies so as to ensure a more level playing field. Thus far, it appears that no action has yet been taken on Monitor's concern regarding the distortion of competition caused by the VAT regime. As explained below, however, it may be that the case-law pertaining to the interpretation and application of the relevant VAT legislation will clarify and develop the law in a way which limits the extent to which NHS bodies can recover VAT. This may reduce the extent and significance of the VAT-related distortion of competition, albeit not removing it entirely.

- 7.16 The VAT regime is notorious for its complexity, and there are a number of aspects of the regime which may serve to distort competition between different types of provider in relation to the provision of NHS services. It is not possible to provide within this present document a full account of all those aspects. What is provided here is an outline consideration of the most significant of those aspects, namely the "Contracted Out Services Rules" ("COS Rules") an expression that refers to section 41 of the Value Added Tax Act 1994 ("VATA") and the directions published by HM Treasury thereunder.
- 7.17 Ironically, the COS Rules which are not mandated by the EU VAT Directives, but have been adopted by the United Kingdom of its own volition and according to its own design were adopted with a view to creating a more level playing field by removing a disadvantage suffered by certain private sector providers wishing to supply services to public sector bodies. Government Departments and NHS bodies were being discouraged from 'contracting out' elements of their public service functions in circumstances where the contractor would be required to charge them VAT on its supplies. Government Departments and NHS bodies generally cannot reclaim such VAT as 'input tax' under the EU-mandated VAT regime. Under the COS Rules, however, Government Departments and NHS bodies can, in relation to certain categories of services, obtain from the Treasury a rebate of the VAT which has been charged to them by the contractor. By this device, VAT is removed as a deterrent to Government Departments and NHS bodies choosing to contract out such services.
- 7.18 In the healthcare sector, however, the COS Rules can have the effect of distorting competition to provide medical, and certain other types of, services to NHS bodies, by disadvantaging private and charitable sector entities competing to provide such services. That is because:
 - (a) Supplies of medical care are exempt from VAT. It follows that a supplier of medical care cannot reclaim as 'input tax' any VAT it has been charged on supplies it purchases for the purpose of making supplies of medical care. For example, in circumstances where the medical care supplier, in order to

That is because their carrying out of their public functions will generally be classified as 'non-business' activity falling outside the scope of VAT. The right to deduct input tax (i.e. reclaim VAT charged on supplies made to you by suppliers) arises only where the supplies were purchased for use in making supplies as part of a business activity and which would themselves be subject to VAT.

See, e.g., GSTS Pathology Services LLP v HMRC [2014] UKFTT 211 (TC) in which the First-tier Tribunal upheld a decision of HMRC that pathology services fell within the scope of the 'medical care' exemption from VAT. In so deciding, the Tribunal expressed itself as follows (at [1]): 'It is with reluctance that we find ourselves forced to dismiss this appeal. Our decision produces unsatisfactory consequences: our conclusion that the appellant's supplies are to a large extent exempt from VAT means that it is to that extent unable to recover input tax, of which it incurs a substantial amount; whilst treatment of the supplies in issue as taxable would require output tax to be charged, the supplies are principally made to entities in the healthcare sector that can recover VAT paid out by them pursuant to s 41 of the Value Added Tax Act 1994. The effect of our decision will be to make the supplies more costly to the recipients, as the charges will have to incorporate irrecoverable input VAT.'

make its supplies of medical care, needs to buy in laboratory testing services and is charged VAT on the price it pays for those services, the medical care supplier cannot reclaim that VAT through its VAT return.

- (b) The consequence, if the medical care supplier is not an NHS entity, is that the VAT it pays on the laboratory testing services is 'stranded' in the sense that the medical care supplier needs to bear the cost of that VAT. That VAT therefore forms part of its overhead costs of the medical care supplier's business of supplying medical care.
- (c) If, however, the medical care supplier is an NHS entity, then it may reclaim, under the COS Rules, the VAT charged to it on its purchases of laboratory testing services (though, as explained further below, the NHS entity's entitlement to reclaim the VAT under the COS Rules may be legally questionable).
- (d) The consequence is that non NHS entities competing to supply VAT exempt services incur overhead costs that are inflated by irrecoverable VAT, whereas NHS entities are often able to obtain a rebate of the VAT from the Treasury. This difference in treatment plainly operates to disadvantage non-NHS entities vis-à-vis NHS entities, where they are both competing to supply VAT exempt medical services. Non-NHS entities may also be disadvantaged as compared with a 'self-supply' alternative that is available to a potential customer that is an NHS entity.
- (e) The COS Rules can also distort competition in another way. That is because rebates of VAT under the COS Rules are available only for certain categories of services. NHS trusts therefore have a strong incentive to structure their operations, not by reference to what is most efficient from the point of view of operational practicality, but instead with a view to ensuring that the inputs they buy in from non-NHS entities consist of supplies of services which are either VAT exempt or fall within those particular categories of services for which VAT rebates can be claimed under the COS Rules. 103
- 7.19 It is submitted, however, that it may be arguable that the COS Rules, properly interpreted and applied, do not entitle an NHS entity to claim from HM Treasury a rebate of VAT charged to it on supplies purchased for use in providing services in competition with other entities. At this point in the discussion, it is necessary to set out the primary legislation for the COS Rules: VATA, sections 41 and 41A(3), which provide as follows:

An NHS trust might, for example, be incentivised not to outsource a particular set of requirements to a non-NHS entity because the supply would be subject to VAT and no VAT rebate would be available under the COS Rules. The NHS trust might instead outsource a different set of requirements, because that set of requirements would constitute a services supply falling into a category for which rebates are available.

- (3) Where VAT is chargeable on the supply of goods or services to a Government department, ... and the supply, acquisition or importation is not for the purpose –
- of any business carried on by the department, or (a)
- (b) of a supply by the department which, by virtue of [section 41A,] is treated as a supply in the course or furtherance of a business,

then, if and to the extent that the Treasury so direct ..., the Commissioners shall, on a claim made by the department at such time and in such form and manner as the Commissioners may determine, rebate to it the amount of the *VAT so chargeable.*

...

- *(5)* For the purposes of this section goods or services obtained by one Government department from another Government department shall be treated, if and to the extent that the Treasury so direct, as supplied by that other department and similarly as regards goods or services obtained by or from the Crown Estate Commissioners.
- (6) In this section "Government department" includes ... any body of persons exercising functions on behalf of a Minister of the Crown, including ... any part of a Government department (as defined in the foregoing) designated for the purposes of this subsection by a direction of the Treasury.
- For the purposes of subsection (6) above, a health service body as (7) defined in section 60(7) of the National Health Service and Community Care Act 1990, and a National Health Service trust established under Part I of that Act, section 18 of the National Health Service (Wales) Act 2006 or the National Health Service (Scotland) Act 1978, an NHS foundation trust and a Primary Care Trust and a Local Health Board and a clinical commissioning group, the Health and Social Care Information Centre, the National Health Service Commissioning Board and the National Institute for Health and Care Excellence shall be regarded as a body of persons exercising functions on behalf of a Minister of the Crown.

s.41A:

- (1) This section applies where goods or services are supplied by a body mentioned in Article 13(1) of the VAT Directive (status of public bodies as taxable persons) in the course of activities or transactions in which it is engaged as a public authority.
- (2) If the supply is in respect of an activity listed in Annex I to the VAT Directive (activities in respect of which public bodies are to be taxable persons), it is to be treated for the purposes of this Act as a supply in the course or furtherance of a business unless it is on such a small scale as to be negligible.
- (3) If the supply is not in respect of such an activity, it is to be treated for the purposes of this Act as a supply in the course or furtherance of a business if (and only if) not charging VAT on the supply would lead to a significant distortion of competition.
- (4) In this section "the VAT Directive" means Council Directive 2006/112/EC on the common system of value added tax.
- 7.20 Since it its referred to in section 41A(1), it is necessary also to consider Article 13(1) of the VAT Directive (Council Directive 2006/112/EC), which has the effect that public bodies are generally not regarded as taxable persons (for VAT purposes), and are therefore not required to charge VAT on their supplies, where they are carrying out activities as public authorities. Article 13(1) provides:

"States, regional and local government authorities and other bodies governed by public law shall not be regarded as taxable persons in respect of the activities or transactions in which they engage as public authorities, even where they collect dues, fees, contributions or payments in connection with those activities or transactions.

However, when they engage in such activities or transactions, they shall be regarded as taxable persons in respect of those activities or transactions where their treatment as non-taxable persons would lead to significant distortions of competition.

In any event, bodies governed by public law shall be regarded as taxable persons in respect of the activities listed in Annex I [this is the same Annex I to which reference is made in section 41A(2) VATA], provided that those activities are not carried out on such a small scale as to be negligible."

7.21 The CJEU has explained that a public body is to be regarded as carrying out "activities or transactions in which they engage as public authorities", within the

meaning of Article 13(1) of the VAT Directive, only if and when they are carrying out activities "under the special legal regime applicable to them and do not include activities pursued by them under the same legal conditions as those that apply to private economic operators". Such a body's transactions fall outside the scope of VAT, save where this would lead to "significant distortions of competition". ¹⁰⁵

- 7.22 It is submitted that the intention and effect of section 41 VATA is to allow certain public bodies (including NHS Bodies: see section 41(6) (7)) carrying out activities that are non-taxable by reason of Article 13(1) of the VAT Directive nevertheless to obtain from the Treasury a rebate of VAT incurred on purchases made by them for the purpose of carrying out those activities.
- 7.23 It appears to be at least arguable that an NHS entity that is providing services in competition with other entities is properly to be recognised as, when so doing, carrying on "business", so that it is caught by section 41(3)(a) and is, for that reason, unable to reclaim VAT under the COS Rules. Looking at sections 41(3) and 41A together, it appears that the reference in section 41(3)(a) to "business" is intended to refer to and should anyway be interpreted as referring to situations where the public body is carrying out "activities or transactions in which they engage as public authorities". It is questionable whether an NHS entity would be acting as a public authority where it is performing essentially the same tasks as could have been performed, on similar terms, by private sector entities with which it competed for the commission to carry out those tasks.
- 7.24 Further and in the alternative, it appears to be arguable that an NHS entity competing with other entities in relation to making medical care supplies would be caught by section 41(3)(b), read with section 41A(3). That would be on the basis that, although the NHS entity is making the supplies in its capacity as a public authority (and is therefore within Article 13(1) of the VAT Directive), the removal of those supplies from the scope of VAT (i.e. from the scope of the EU VAT regime, under which the supplies would be exempt supplies, with the consequence that VAT incurred on purchases used in making those supplies would be irrecoverable) would lead to significant distortions of competition. Such an analysis would admittedly sit uncomfortably with the wording of section 41A(3), which refers to a significant distortion of competition arising as a result of VAT not being charged on the public body's supplies, rather than to a distortion arising as a result of VAT being rebated. It

¹⁰⁴ Revenue and Customs Commissioners v Isle of Wight Council (C-288/07) [2008] ECR I-7203; [2009] 1 CMLR 4, at [21]. See also Ayuntamiento de Sevilla v Recaudadores de las Zonas Primera y Segunda (Case C-202/90) [1991] ECR I-4247, [1994] 1 CMLR 424 at [18]; and Fazenda Publica v Camara Municipal do Porto (Case C-446/98) [2000] ECR I-11435 at [15]. Judicial clarification as to the assessment of whether, and in what circumstances, a public authority may be considered to be providing services under a "special legal regime", notwithstanding that it is competing directly with private sector providers to supply the services on similar terms, may be provided later this year when the Upper Tribunal gives its decision following its forthcoming preliminary issues hearing in R (Durham Company t/a Maxrecycle) v HM Revenue & Customs.

¹⁰⁵ It is apparent from the CJEU's judgment in Isle of Wight Council (see preceding footnote) that "significant distortions of competition" means "a distortion that is more than merely negligible".

is submitted, however, that section 41A(3) is intended to implement, and must be read compatibly with, Article 13(1), which is drafted in broader terms and is not limited to distortions arising from the public body not charging VAT on its supplies.

- 7.25 For these reasons, it may be that the legal effects of the creation and development of market competition to provide NHS services include the bringing to an end of the entitlement of NHS entities to claim rebates, under the COS Rules, of VAT incurred on their purchases used for making supplies in the course of activities in which they are competing with other entities. Notably the Monitor report hinted at such an outcome, stating (at p.7) that public sector providers "may no longer be eligible for all of this rebate because of changes in the healthcare sector".
- 7.26 The payment of such rebates under the COS Rules (which, as already noted, are not part of the EU VAT regime, but have been developed by the United Kingdom) may also be arguably unlawful by reason of constituting unlawful state aid. For the reasons discussed earlier in this section, NHS entities competing to provide NHS services are likely to be 'undertakings'. The cost of irrecoverable VAT is an ordinary incident of supplying VAT exempt services, and is therefore a cost that an undertaking engaged in supplying exempt services would normally have to bear. Insofar as NHS entities are being relieved of that cost, they would appear to be receiving an advantage that is capable of distorting competition. Given that there is likely to be at least some cross-border participation in competition to provide NHS services, all the elements necessary for constituting state aid appear to be present.
- 7.27 It is difficult to be certain as to the basis on which NHS entities are currently calculating their rebate claims under the COS Rules, or the approach that the Treasury and HM Revenue & Customs are taking to such claims. On the basis of the information available in the public domain, however, it appears that HMRC's stance remains that NHS bodies can treat all their healthcare supplies as 'non-business' and thus submit rebate claims under the COS Rules for VAT incurred on purchases used for making all such supplies. ¹⁰⁶

8 CONCLUSION

- 8.1 The NHS is a sector of the UK economy as well as a highly prized public service. It is also unique in that, being free at the point of delivery to patients, the NHS is all procured directly or indirectly by the Government via commissioners.
- 8.2 Public procurement law is therefore a significant consideration and increasingly so with the coming into force of the relevant provisions of the 2015 Regulations. These

¹⁰⁶ See, e.g., HMRC Local Compliance, Public Bodies Group, Section 41 Guide for NHS Bodies, dated 24 April 2014. The Guide states (at p.5): "In the majority of cases the activities carried out by NHS bodies are statutory in nature and are treated as non-business for VAT purposes. For NHS bodies the non-business activity is the provision of healthcare."

EU based obligations sit, not entirely harmoniously, alongside the various procurement obligations applicable under the NHS Regulations brought in further to the HSCA. Central to these obligations are the duties of transparency, non-discrimination and proportionality and the duty to procure from the most capable and 'best value for money' provider. But other considerations must also be taken into account, including efficiency, quality, choice, patient needs, integrated care and equal access to treatment. All this must be done within the allocated commissioner budget.

- 8.3 In addition to these procurement obligations applicable to commissioners, various competition duties also need to be considered. Regulation 10 applies to anti-competitive conduct by commissioners which is not necessary to achieve patient benefits. Under EU law, commissioners need also ensure that state aid obligations (Article 107, TFEU) and duties arising under Article 106, TFEU are not infringed by subsidies or practices which distort competition by favouring some providers over others. When participating in an economic capacity (such as, it may be argued, buying primary care services), commissioners may in addition qualify as 'undertakings' and be subject to competition law obligations (e.g. the prohibition on abuse of dominance).
- 8.4 If there is a single common thread to navigate through all of these myriad duties it is not easy to detect. However, a rule of thumb might be to conduct a fair and open tender process on a level playing field (where possible), with a carefully considered and well-designed specification and criteria, which will achieve an optimal balance of relevant considerations and where possible maintain a sustainable market of capable providers for future competitions. Where competition is not feasible, commissioners will need to be able to provide valid justifications for continuing to contract with the incumbent provider having regard to all applicable duties, exemptions and exclusions under competition and procurement law.
- 8.5 As for providers in the NHS, with some exceptions (such as non-liberalised activities where competition is not feasible), competition law will be applicable as in any other sector. This means that price fixing (where there is price competition), bid rigging and other collusion may result in serious penalties. This certainly does not mean that all forms of cooperation or integration is outlawed but a justification based on patient interests may be required where the cooperation reduces competitive incentives between the participants, just as consumer benefits in other sectors forms the basis of the relevant analysis. Where the cooperation is structural and enduring, Monitor and the CMA may also have a role under the merger control rules.