

Statement of issues

Complaint into the commissioning of radiosurgery services

1. On 5 June 2013, Monitor opened an investigation¹ into matters raised in a complaint by the Thornbury Radiosurgery Centre Limited (Thornbury). The complaint relates to the conduct and procurement practices of the North of England Specialised Commissioning Group in the Yorkshire and Humber area (NESCAG) and its successor the NHS Commissioning Board (NHS England) in relation to Gamma Knife radiosurgery services which are specialised services.
2. Thornbury submits that the NESCAG has acted in breach of Principles 1, 2, 5 and 6 of the Principles and Rules for Co-operation and Competition in the context of the commissioning and procurement of Gamma Knife radiosurgery services in Yorkshire. Among other things the Principles and Rules required commissioners to: commission from providers who are best placed to deliver the needs of their patients; commission and procure services in a transparent and non-discriminatory manner; and foster patient choice.
3. As we explained when we opened the investigation Monitor is also considering whether or not NHS England's actions after 1 April 2013 comply with the National Health Service (Procurement, Patient Choice and Competition) (No.2) Regulations 2013 (the Procurement, Patient Choice and Competition Regulations) which came into force on 1 April 2013.
4. We understand that negotiations between NHS England and Thornbury to agree an NHS standard contract for the provision of Gamma Knife radiosurgery services are ongoing. Nevertheless based on the information we have received to date, it appears to us that the complaint raises important issues which are appropriate for Monitor to investigate.
5. The purpose of this statement of issues is to explain that Monitor has decided to focus its investigation on NHS England's compliance with the Procurement, Patient Choice and Competition Regulations and to set out the issues we have identified to date in the context of this case. We have not reached any conclusions on any of the issues set out in this statement.

¹ Notice of initiation of investigation and press release, www.monitor.gov.uk.

6. Interested parties, including NHS England, Thornbury, other providers and NHS health care service users are invited to respond to this statement of issues by close of business on Monday 16 September 2013. Please email your response to coopandcompases@monitor.gov.uk. We intend to publish non confidential versions of all submissions received. If your submission contains confidential information, please submit a non confidential version of your response at the same time, indicating clearly what information has been excised.

Background²

7. Gamma Knife radiosurgery is a method for treating selected tumours or lesions within the brain. Very precisely focused beams of radiation are directed to a treatment area within the brain, optimised to treat only the target area without damaging the surrounding healthy tissue. In England, Gamma Knife radiosurgery is a specialised service for the purpose of commissioning.
8. Before 1 April 2013, NHS Primary Care Trusts (PCTs) were responsible for specialised commissioning. PCTs collaborated to exercise this responsibility through Specialised Commissioning Groups. Between 1 April 2007 and January 2012, the 14 PCTs in Yorkshire and the Humber collaborated through the Yorkshire and the Humber Specialised Commissioning Group to commission specialised services for the population of Yorkshire and the Humber. From January 2012 to 31 March 2013, the commissioning of specialised services in Yorkshire and the Humber was undertaken by the NESCG which commissioned specialised services on behalf of PCTs across the north of England. Specialised Commissioning Groups were responsible, among others, for negotiating and entering into contracts with providers.³ Specialised Commissioning Groups would also confer designation status to local providers that complied with set service standards. Designation was a requirement in order for a provider to be deemed to be appropriate for commissioning on a national basis. Only designated providers were allowed to enter into direct contracts for the services with Specialised Commissioning Groups or to provide the services on a spot basis through individual funding requests to Specialised Commissioning Groups.
9. NHS England became responsible for specialised commissioning in England on 1 April 2013. NHS England contracts with providers to provide specialised

² This background section is based on our understanding of the information received to date.

³ Other responsibilities of Specialised Commissioning Groups included service planning, publishing commissioning policy describing clinical eligibility and access to NHS funded treatments, negotiating and agreement contracts, and monitoring contract performance.

services for all NHS patients in England. NHS England operates local area teams, ten of which are responsible, among other things, for negotiating and entering into contracts with providers of specialised services based in their respective areas and assessing compliance of these providers against NHS England's service specifications (replacing the designation process before 1 April 2013). NHS England's local area team with responsibilities for the area in which Thornbury is based is the South Yorkshire and Bassetlaw Area Team.

10. Thornbury has provided Gamma Knife radiosurgery services since September 2008. It is a joint venture between BMI Healthcare Group Limited and Medical Equipment Solutions Limited. It operates one Gamma Knife from the Thornbury Gamma Knife Centre located in the BMI Thornbury Hospital in Sheffield and treats NHS and private patients. Thornbury has treated NHS patients on behalf of the Sheffield Teachings Hospitals NHS Foundation Trust under a sub-contracting arrangement since January 2009. As a designated centre since 2011, it has also treated NHS patients which were referred directly to it before 1 April 2013.

Summary of the complaint

11. Thornbury has raised a number of issues dating back to 2008 including in relation to requirements for commissioners to commission from providers who are best placed to deliver the needs of their patients; commission and procure services in a transparent and non-discriminatory manner; and foster patient choice. In relation to the decisions of NHS England, Thornbury has in essence complained that these have resulted in Thornbury not being able to accept direct referrals of NHS patients.
12. Thornbury told us that prior to 2011 the NESCG had refused to designate Thornbury. Thornbury complained that at the same time the NESCG had designated and contracted with Nova Healthcare (in partnership with the Leeds Teaching Hospitals NHS Trust) in Leeds around 2009. Thornbury said that the reason given by the NESCG for the refusal was that there were no capacity issues in Sheffield at that time. Thornbury submits that on the contrary, there were capacity issues in Sheffield.
13. Thornbury said that even after it was designated in 2011 NESG refused to pay Thornbury for a patient to be treated. Thornbury said that it was the designated centre of the patient's choosing with capacity to carry out the procedure at NHS tariff pricing. Thornbury told us that it had received no response to its

request to the NESCG for an explanation of why the patient was refused funding for treatment by Thornbury. It said that as a result the patient's treatment was delayed by at least four months. Thornbury submits that it was best placed to deliver the needs of this patient at that time.

14. Thornbury also complained that the NESCG refused to enter into discussions on how the contract with Nova Healthcare in Leeds was awarded and whether a tender process was carried out for that contract. Thornbury said the NESCG has also not responded to repeated requests to disclose the terms on which the contract was awarded and the date on which that contract will terminate or come up for renewal / retender. Thornbury considers that the commissioning of Gamma Knife radiosurgery services by the NESCG has not been carried out in a transparent and non-discriminatory manner.
15. Thornbury also told us that without details being provided of the contract between Nova Healthcare and the NESCG and coupled with the NESCG's refusal to fund a patient wishing to be treated by Thornbury and the consequent four month delay in the patient receiving treatment, it believed that the arrangements in place are restricting patient choice and are against patients' interest.
16. Thornbury said that that in anticipation of the transfer of the responsibility for commissioning specialised services to NHS England, Thornbury made a submission to NHS England on 14 February 2013 to enter into an NHS standard contract with NHS England to provide Gamma Knife radiosurgery services. On 23 May 2013, NHS England informed Thornbury that it had not identified the need to commission Gamma Knife radiosurgery services directly from Thornbury.
17. Thornbury also told us that on 11 July 2013, NHS England informed Thornbury that it had decided that Thornbury does not comply with a requirement relating to multi-disciplinary teams set out in NHS England's service specifications⁴ for stereotactic radiosurgery which includes Gamma Knife radiosurgery. Following that decision, NHS England has asked Thornbury to stop accepting direct referrals of NHS patients for Gamma Knife radiosurgery services. These service specifications will be formally adopted in October 2013.

⁴ Service specifications are set out in NHS England, [D05/S/a, Schedule 2 of NHS Standard Contract for Stereotactic Radiosurgery and Stereotactic Radiotherapy \(Intracranial\) \(All Ages\)](#), 2013.

Decision to focus on Procurement, Patient Choice and Competition Regulations

18. Monitor uses its prioritisation principles to ensure that we make appropriate judgements about which projects and programmes of work we undertake, including whether or not to continue investigations. This enables us to make the best use of our finite resources to maximise the benefits of our work for patients. We have thought carefully about the matters raised by Thornbury's complaint in light of our published prioritisation criteria and the CCP's case acceptance criteria.⁵ In particular, we have considered the complaint in light of the information received to date, the changes that have happened to the NHS on or around 1 April 2013 including the transfer of the responsibility for the commissioning of specialised services to NHS England and the coming into force of the Procurement, Patient Choice and Competition Regulations.
19. Having considered this investigation against our prioritisation criteria in the round, we have decided to continue investigating matters raised by Thornbury's complaint, focusing on whether or not NHS England has complied with the Procurement and Patient Choice and Competition Regulations rather than on whether or not the NESCAG has complied with the Principles and Rules prior to 1 April 2013. If in the course of our investigation we identify any broader lessons which may be learned from the conduct of the NESCAG before 1 April 2013 we may comment on those but the focus of our investigation will be on NHS England's compliance with the Procurement and Patient Choice and Competition Regulations.

Legal context

20. The role of Monitor in this case is to assess whether or not NHS England has complied with requirements set out in the Procurement, Patient Choice and Competition Regulations.⁶ Monitor has published draft guidance for consultation on the application of the Procurement, Patient Choice and Competition Regulations (the Draft Substantive Guidance) and our approach to enforcement under them (the Draft Enforcement Guidance).⁷ Although this guidance is currently subject to consultation and is expected to be finalised

⁵ Prioritisation criteria are outlined in Co-operation and Competition Panel, [CCP Prioritisation Criteria](#), and Monitor, [Enforcement guidance on the Procurement, Patient Choice and Competition Regulations](#) (the Enforcement Guidance), 20 May 2013, pages 7-8.

⁶ The Procurement, Patient Choice and Competition Regulations are available [here](#).

⁷ This draft guidance is available at [Draft substantive guidance on the Procurement, Patient Choice and Competition Regulations](#) and [Draft enforcement guidance on the Procurement, Patient Choice and Competition Regulations](#).

later in the year, Monitor will have regard to it in so far as relevant in carrying out this investigation.

Issues

21. Monitor will assess whether NHS England's conduct complied with the Procurement, Patient Choice and Competition Regulations which came into force on 1 April 2013. Regulation 2 sets out the objective that commissioners pursue when procuring NHS health care services. Regulation 3 sets out general requirements and Regulations 4 to 12 set out particular requirements that commissioners must comply with when procuring NHS health care services. Based on the evidence currently available to us, it appears to us that this case raises a number of potential issues around the compliance by NHS England with some of these rules. Our assessment will cover the issues set out below.

Procurement objectives - Regulation 2

22. Commissioners, when procuring NHS health care services, must act with a view to achieving the following objectives set out in Regulation 2 of the Procurement, Patient Choice and Competition Regulations:

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

23. Commissioners must pursue these objectives whenever they procure NHS health care services. This is also relevant to decisions that do not in themselves result in the award of a contract to provide services, such as deciding which providers to enter into a framework agreement with and selecting providers to bid for potential contracts.⁸ We will consider whether and how NHS England took into account these objectives in relation to its actions since 1 April 2013. We will consider this in relation to the relevant general and specific requirements of the Procurement, Patient Choice and Competition Regulations discussed below.

General requirements - Regulation 3

24. When procuring NHS health care services, commissioners must comply with the following general requirements:

- to act in a transparent, proportionate and non-discriminatory way;

⁸ See Draft Substantive Guidance, pages 9-11.

- to procure services from the providers most capable of achieving the objectives in Regulation 2 that provide best value for money; and
- to consider appropriate ways of improving services including through services being provided in a more integrated way, enabling providers to compete to provide services and allowing patients a choice of provider.

25. Commissioners must comply with these requirements whenever they procure NHS health care services. This is also relevant to decisions that do not in themselves result in the award of a contract to provide services.⁹ We set out below in further detail these requirements and the issues that our assessment will cover in relation to these requirements. To the extent that some of these requirements are closely linked with specific requirements set out in other parts of the Procurement, Patient Choice and Competition Regulations, we will consider these together.

Transparency and proportionality - Regulation 3(2)(a)) and publication of contracts awarded - Regulation 9

26. Transparency is fundamental to accountability and is closely linked to the requirement to treat providers equally. Commissioners must ensure that they conduct all procurement activities openly.¹⁰ We will consider whether or not NHS England has acted in a transparent way. In doing so, we propose to consider: what information NHS England has published on its commissioning strategies and intentions and whether and what feedback was provided by NHS England to Thornbury about the decisions it took. We will also consider what records NHS England has maintained of the key decisions it has taken including the reasons for those decisions.

27. Commissioners must also publish details of all contracts they award and must do so on www.supply2health.nhs.uk.¹¹ We propose to consider whether NHS England has published details of contracts it has awarded, if any, in relation to Gamma Knife radiosurgery services and whether it has done so in a timely manner.

28. Commissioners' actions must be proportionate to the value, complexity and clinical risk associated with the provision of the services in question.¹² We will consider whether or not NHS England has complied with this requirement. In particular we will consider how NHS England allocated resources to the

⁹ See Draft Substantive Guidance, page 11.

¹⁰ See Draft Substantive Guidance, page 12.

¹¹ See Draft Substantive Guidance, pages 32-33.

¹² See Draft Substantive Guidance, page 12.

commissioning of Gamma Knife radiosurgery services and specialised services in general, including through the development and the application of appropriate commissioning priorities.

Equality / non-discrimination - Regulation 3(2)(b)

29. Commissioners must treat all providers equally and must not favour one provider over another. Differential treatment between providers requires objective justification.¹³ We will consider whether or not NHS England has treated providers of Gamma Knife radiosurgery equally. In particular we propose to consider the steps that NHS England has taken to satisfy itself that its commissioning decisions, including its interpretation of the service specifications for stereotactic radiosurgery, do not exclude Thornbury, other providers or a wider category of providers from providing Gamma Knife radiosurgery services to NHS patients without objective justification. We also propose to consider whether NHS England has treated Thornbury, other providers or a wider category of providers differently without objective justification in relation to the other aspects of the commissioning of Gamma Knife radiosurgery services.

Procuring services from the providers most capable of delivering commissioners' objective and that provide best value for money - Regulations 3(3) - (5)

30. Commissioners must procure NHS health care services from one or more providers that:

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

31. In acting with a view of improving the quality and efficiency of NHS health care services, commissioners must consider appropriate means of making such improvements, including through services being provided in a more integrated way, allowing patients a choice of provider and enabling providers to compete for contracts to provide services.¹⁴

32. We will consider whether or not NHS England has complied with these requirements. We propose in particular to consider the steps NHS England

¹³ See Draft Substantive Guidance, pages 13-14.

¹⁴ See Draft Substantive Guidance, pages 16-20.

has taken to identify the appropriate model of provision for Gamma Knife radiosurgery services. In particular, we will consider whether it has taken a decision that only a limited number of providers should be contracted to provide these services or whether it has adopted an Any Qualified Provider type model. We will also consider whether, in doing so, it has considered the objectives set out in paragraphs 30 and 31 above. Any decision that limits the number of providers may also have implications for the requirements that relate to the qualification of providers set out at Regulation 7 (see below).

Publishing new contract opportunities for NHS health care services - Regulation 4 and 5

33. Commissioners should consider whether and how to publish contract opportunities, including in cases where the services in question are capable of being provided only by one provider. In addition, when advertising contract opportunities, commissioners must publish a notice on www.supply2health.nhs.uk.¹⁵ From the information we have received to date, it appears that NHS England has not invited offers from prospective providers to provide Gamma Knife radiosurgery services.

Qualification of providers - Regulation 7

34. Commissioners are also required to apply and establish transparent, proportionate and non-discriminatory criteria when qualifying providers for any of the following:

- to be included on a list from which a patient is offered a choice of provider for their first outpatient appointment with a consultant or a member of a consultant's team;
- to be included in a list from which a patient is otherwise offered a choice of provider;
- to enter into a framework agreement with the commissioner; or
- to bid for future contracts.

35. This issue is related to the requirements set out at Regulations 3(3), 3(4) and 3(5) discussed above. If this requirement is relevant to the process NHS England has adopted for the commissioning of Gamma Knife radiosurgery services (i.e. whether to select a limited number of providers or to adopt an AQP type model), we will consider the steps that NHS England has taken to satisfy itself that it has complied with the requirements relating to the transparency, proportionality and non-discriminatory nature of qualification

¹⁵ See Draft Substantive Guidance, pages 21-28.

criteria in a manner which is consistent with our approach to the general requirements relating to transparency, proportionality and non-discrimination discussed at paragraphs 24 to 29 above.¹⁶

Anti-competitive behaviour - Regulation 10

36. Commissioners must not engage in anti-competitive behaviour unless it is in the interests of NHS healthcare services users. Additionally, arrangements for the provision of NHS healthcare services must not include any term or condition restricting competition that is not necessary for the attainment of intended outcomes which are beneficial for people who use such services or to attain the objectives in Regulation 2.

37. Some of the commissioner's actions in this case could be assessed to establish whether those amounted to anticompetitive behaviour which would give rise to an adverse effect on patients (for example in the form of lower quality or less efficient services). However at this stage in our investigation it appears to us that the issues which have been raised in this case can properly be assessed under the regulations set out above. In particular, in this case it appears to us that if the commissioner's actions have led to lower quality or less efficient services for patients this can be addressed through our assessment under Regulation 3. For these reasons and based on the information we have received to date it does not appear to us that Regulation 10 should be the focus of our investigation. However, if we receive submissions from any stakeholder (including patients or other providers) who believes that patients' interests may have been affected as a result of anticompetitive behaviour which cannot be addressed through the other aspects of our investigation we may consider this again.

Offering choice of an alternative provider, when maximum waiting times are not going to be met - Regulation 12

38. Commissioners are required to offer patient choice when maximum waiting times are not going to be met, in accordance with Regulation 48(4) of the Standing Rules and Responsibilities Regulations. We will consider whether or not NHS England has complied with this requirement. We propose to consider the steps that NHS England has taken to ensure that a patient is offered an appointment with a clinically appropriate alternative provider or, if relevant, with

¹⁶ See Draft Substantive Guidance, pages 29-31.

more than one provider when maximum waiting times are likely to be exceeded.¹⁷

¹⁷ See Draft Substantive Guidance, pages 45-50.