

# **NHS England: Additional Response to Monitor’s Statement of Issues in relation to the complaint into the commissioning of radiosurgery services by Thornbury Radiosurgery Centre Limited**

## **1. Introduction**

NHS England made an initial submission in this matter dated 16 September 2013. In that initial submission, NHS England referred to the fact that it wished to respond in greater detail to various specific requirements under the Regulations once Monitor had clarified the nature of Thornbury’s complaint under the Regulations, which was not particularised in Monitor’s Statement of Issues<sup>1</sup>. In response to that request, Monitor has referred NHS England to Thornbury’s “Formal complaint submission to the Cooperation and Competition Panel by The Thornbury Radiosurgery Centre Limited” dated 21 March 2013, and some additional correspondence submitted to Monitor by Thornbury. The detail of Thornbury’s complaint under the Regulations (as opposed to any complaint under the earlier Principles and Rules) is clearly significant, given that it is this that would trigger Monitor’s powers to investigate. In the absence of more detailed knowledge as to Thornbury’s complaint under the Regulations, NHS England will explain, in general terms, how its decisions relate to the various requirements of the Regulations.

## **2. Regulation 2: core objectives**

- 2.1 Regulation 2 provides that, when procuring NHS services, commissioners must act with a view to: securing the needs of service users; improving the quality of services; and improving efficiency in the provision of the services. Regulation 2 states that this may include through service integration. These could therefore be termed the ‘overriding objectives’ of commissioning NHS services – although commissioners have other related duties under the National Health Service Act 2006, including exercising their functions effectively, efficiently and economically<sup>2</sup>.

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<sup>1</sup> As noted in NHS England’s initial submission, the Statement of Issues gave details of the complaint dated 21 March 2013, which was also shared with NHS England, but few details of any complaint made in respect of matters from 1 April 2013 covered by the Regulations

<sup>2</sup> National Health Service Act 2006, section 13D

2.2 NHS England has already, in its initial submission, referred to a number of actions undertaken or being undertaken to secure service user needs and improve the quality and efficiency of services. As to whether, for 1 April 2013, a significant change in the way gamma knife services were procured or provided to the NHS would have furthered these objectives, NHS England considers that its actual approach was appropriate in the circumstances, for the reasons set out below.

2.3 Firstly, given the very significant system change at that time, it was appropriate for NHS England to take, as its starting point for 2013/14, the position arrived at by predecessor specialised commissioning groups (SCGs). The views of the predecessor SCGs<sup>3</sup>, on which the starting point were based, were that:

2.3.1 for reasons of ensuring critical mass of patients and infrastructure, specialised services needed to be concentrated in a managed number of providers, with appropriate geographic distribution to optimise patient access;

2.3.2 there were two regional providers in Yorkshire and Humber (Sheffield Teaching Hospitals Trust (STHT), and Nova Healthcare in Leeds) who were already able to deliver the whole stereotactic radiosurgery (SRS) pathway;

2.3.3 there was therefore appropriate capacity and choice, although the shift to nationally based specialised commissioning might change this view.

To have done other than to take this starting point, for contracts that needed to be in place for 1 April 2013, would have required a full national assessment which – given this was one of 200 specialised services – was not practically possible in time to inform any different commissioning policy (and possibly, to operate a full tender process) in time for the new NHS contract year starting on 1 April 2013. Indeed, the decisions to enter into contracts with STHT and Nova Healthcare from April had already been taken by March 2013, before the present Regulations came into effect. Therefore, it was reasonable for NHS England to take this position as its starting point for the assessment of service user needs, and ensuring those needs were met, pending any further work to improve service quality and efficiency.

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<sup>3</sup> as expressed in the letter of 31 January 2013 from NHS South Yorkshire and Bassetlaw to Thornbury (copy already sent to Monitor)

2.4 Secondly, one stated objective of the process of contract transition, between the previous and current commissioning structures, was to ensure that continuity of clinical care was not jeopardised by transition. For that reason, to begin the 2013/14 contract year with providers of gamma knife services that had already held NHS contracts, and which were therefore already providing these services under the clinical governance arrangements required by the NHS Standard Contract, was a reasonable position to ensure that continuity of clinical care was preserved.

2.5 NHS England's work, in gamma knife services, on securing service users needs and improving service quality and efficiency did not involve merely entering into an initial contract position for 2013/14 to ensure initial stability and safe transfer of responsibilities, but has been ongoing, including:

2.5.1 further dialogue with Thornbury, following further assessment of patient flows, leading to the completion of the contract with Thornbury;

2.5.2 the work of the Clinical Reference Group (CRG) to establish specifications and commissioning policies<sup>4</sup>;

2.5.3 review of the gamma knife service specifications, as detailed separately to Monitor, to improve compliance with and consistency of new national standards; and

2.5.4 undertaking a national strategic review of capacity and need for SRS, as detailed separately.

2.6 NHS England submits that its decision to preserve previous SCG contracting arrangements, as an interim position in light of system transition and to secure safe continuity of care, and subsequent actions to evaluate gamma knife requirements through its further work and national strategic review, both demonstrate a commitment to securing service user needs and working to improve service quality and efficiency.

### 3. **Regulation 3: general procurement requirements**

3.1 Regulation 3 outlines a number of requirements that apply to all procurement of NHS services, concerning transparency and proportionality; equal treatment and non-

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<sup>4</sup> See <http://www.england.nhs.uk/resources/spec-comm-resources/npc-crg/group-d/d05/>

discrimination; the procuring of services from providers best able to meet key objectives and provide best value for money; the consideration of appropriate means of improving service quality and efficiency, including through greater integration, through allowing providers to compete to provide services or allowing greater service user choice of providers; and the maintenance of records of how contracts comply with separate duties regarding the commissioning of services.

### ***Transparency***

- 3.2 NHS England has, from 1 April 2013, engaged with Thornbury in a transparent manner. Monitor has seen correspondence between NHS England and Thornbury from 1 April 2013 in which NHS England has set out its initial position for 2013/14 and the reasons for that position; the reasons why that position developed such that a direct contract with Thornbury might be appropriate; and the various concerns NHS England had, regarding compliance with the service specification, and how dialogue between the parties has resolved those concerns.
- 3.3 In addition, NHS England has published and consulted on commissioning strategies for and policies for SRS and stereotactic radiotherapy (SRT). The ongoing national strategic review for gamma knife is involving providers in a transparent manner, since all providers have been invited to input into this review.

### ***Proportionality of dealings with providers***

- 3.4 NHS England assumed responsibility for commissioning SRS on 1 April 2013. SRS had previously been commissioned by SCGs under a variety of individual arrangements with separate providers. The benefits of consolidating commissioning of all specialised services in a single commissioner was one reason behind the health reforms of the Health and Social Care Act 2012.
- 3.5 It was an appropriate use of NHS England commissioning resources, at the time of the system change under the Health and Social Care Act 2012, to begin the 2013/14 contract year with the existing provider landscape, since a full review of commissioning and procurement policies for all specialised services, in time to inform 2013/14 contract awards, was not possible given the resource constraints on NHS England and the other priorities of system change. This system change involved a

reduction of around 50% in commissioning resources (in terms of staff); an expanding scope of services for specialised commissioning; new contracts for all services; and new financial allocations for specialised commissioning. At a time of such exceptional system change and resource constraints, it was proportionate to preserve the existing provider landscape to ensure, as a key short-term priority, a stable transfer and continuity of clinical care under the new system. Going forward, NHS England is working to prioritise, according to various criteria being developed with Monitor, a sequence of review of specialised services to ensure that proportionate use is made of NHS England resources in the development of future procurement strategies.

***Equality of treatment and non-discrimination***

- 3.6 Two decisions of NHS England from 1 April 2013 appear possibly relevant to the issue of equality of treatment and non-discrimination:
- 3.6.1 the initial decision, as of 1 April 2013, not to enter into a contract with Thornbury beginning on 1 April 2013;
  - 3.6.2 following further discussions and developments between NHS England and Thornbury, NHS England's instruction that, since the multi-disciplinary team (MDT) at Thornbury was not compliant with the MDT requirement in the SRS service specification, Thornbury should not accept direct referrals of service users for gamma knife services.
- 3.7 Regulation 3 requires commissioners to treat providers equally and not to discriminate. Where providers are treated differently, Monitor's Draft Substantive Guidance suggests that this will require objective justification – being a proportionate means of achieving a legitimate aim. To the extent there was any differential treatment of Thornbury (if any is alleged), NHS England suggests that this was objectively justified, on the grounds that:
- 3.7.1 one aim behind the initial decision to contract for 2013/14 with providers who had previously been direct contractors under the NHS Standard Contract was to achieve system stability and continuity of care, in the exceptional circumstances that the dissolution of primary care trusts and SCGs and

transfer of a commissioning to a new body represented. This did not preclude continuing dialogue with Thornbury, however;

3.7.2 there were also legitimate reasons to take a cautious approach, for reasons of clinical governance, in the case of a provider that had not previously been responsible for clinical governance for NHS services;

3.7.3 regarding the proportionality of NHS England's decision, this was appropriate to the circumstances in that, bearing in mind these legitimate objectives, NHS England did not simply decline any further possibilities for the 2013/14 contract year that Thornbury might directly provide NHS services, but continued dialogue with Thornbury with a view to Thornbury entering into a contract during the 2013/14 contract year.

3.8 Concerning NHS England's later decision that, since Thornbury was not yet fully compliant with the MDT requirements set out in the clinical commissioning policies and the service specification relating to gamma knife services. Thornbury should not accept direct referrals, NHS England also considers that this was proportionate to achieving a legitimate aim. In this case, the aim was to ensure, to the fullest extent possible, that the delivery of services matched the requirements for MDT teams which the CRG had recommended in the clinical commissioning policies and the service specification. The appropriate constitution and operation of the MDT is clearly an important factor in the clinical oversight of these procedures.

3.9 Regarding the proportionality of NHS England's instruction to refrain from accepting direct referrals, NHS England notes this was a temporary and time-limited position, designed to address the MDT concerns set out above: it was not a final decision, or even a final decision for the 2013/14 contract year. Further, in order to assess the appropriate MDT requirements for SRS services, to ensure optimum clinical involvement, NHS England has engaged in dialogue with Thornbury on this point, and has now resolved this issue to its satisfaction, thereby enabling the National Standard Contract with Thornbury to be entered into<sup>5</sup>. It was appropriate and reasonable for NHS England to: i) challenge Thornbury's compliance against the clinical commissioning policies and the service specification, as these documents existed at

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<sup>5</sup> The NHS Standard Contract between NHS England and Thornbury was completed on 17 October.

the beginning of 2013/14 and given that Thornbury had not previously operated independently in this respect but had been operating with the use of the STHT MDT; ii) enter into constructive dialogue with Thornbury, concerning the aims and intention of the MDT requirements in the commissioning policies and specification; iii) seek appropriate clinical clarification about the MDT element of the commissioning policies and specification; and iv) issue clinical clarification about the MDT requirements, and to adapt its position with Thornbury in line with that clarification. In response, Thornbury submitted revised MDT arrangements which NHS England has reviewed and accepted as compliant against its guidance.

***Award of contracts to providers best placed to deliver overriding objectives while providing best value for money.***

- 3.10 NHS England's view, for the start of the 2013/14 contract year, was that those providers who were under contract for 2012/13 were best placed to meet the overriding objectives, given the factors referred to at sections 2.3, 2.4 and 3.5 above. The optimum provider model going forward, and how to select which providers are best placed to deliver SRS/SRT, is one of the subjects of the ongoing national review, on which NHS England has provided separate details to Monitor.
- 3.11 There is an understanding with Monitor that until NHS England has reviewed all services in terms of capacity and route to market there would be no new market entrants unless there were urgent or significant issues of capacity or clinical quality. This position is further reinforced in the Prescribed Specialised Services Commissioning Intentions 2014/15-2015/16 recently issued by NHS England. This would appear to support the use of established providers as best placed to deliver key objectives for 2013/14.

***Consideration of how best to improve services, including whether through greater integration, competitive tender and/or greater patient choice***

- 3.12 These are factors which are being considered by NHS England as part of the ongoing national review. As noted above, it appeared to NHS England that, for the start of the 2013/14 contract year, services would not be best improved by competitive tender, since the national service review needed to properly assess optimum provider numbers,

distribution and clinical volumes which was not possible in time to inform any such tender exercise.

3.13 Going forward, NHS England will consider whether (depending on the outcome of the review), these services are ones where, because of the limited number of capable providers and the detailed work being conducted, appropriate providers might be identified without a formal procurement process (as envisaged in Monitor’s Draft Substantive Guidance at section 4.2.2), whether a formal process would be proportionate, or whether a contested process could bring tangible benefits to service users.

3.14 Patient choice is not a standard element of a complex specialised service pathway, but choice and access will be considered in the strategic review, in particular in relation to the important issue of geographic distribution of SRS services and service user access.

#### 4. **Publication of new contract opportunities for NHS services – Regulations 4 and 5**

The Statement of issues refers (paragraph 33) to the obligations on commissioners under Regulation 4 and 5 in relation to the publication of new contract opportunities for NHS services.

#### 5. **Regulation 4**

5.1 Under Regulation 4(1), NHS England is required to maintain and publish details of a website dedicated to the advertisement of commissioners’ invitations to tender for NHS services and the publication of certain contract records. This is currently the “Supply2Health”<sup>6</sup> website.

5.2 Under Regulation 4(2) commissioners must, where advertising an intention to seek offers for a new contract, publish a contract notice in the required form (described in Regulation 4(3)). NHS England has not, since 1 April 2013, advertised an intention to seek offers for new contracts for gamma knife services, and so has not carried out activity to which Regulation 4(2) and 4(3) might apply.

5.3 Regulation 4(4) requires commissioners to ensure that arrangements exist for providers to express an interest in providing NHS services. Regarding this requirement,

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<sup>6</sup> see <https://www.supply2health.nhs.uk/S2H-Home.aspx>



the Supply2Health website contains resources by which “*Providers of high-quality healthcare who would like to provide NHS services, can find step-by-step guidance on how to apply*”<sup>7</sup>. Further, Thornbury sent a submission directly to NHS England on 14 February 2013<sup>8</sup> on the possibility of directly providing NHS services (as noted in the Statement of Issues), and so Thornbury was directly able to express an interest in providing NHS services.

## 6. Regulation 5 – “single capable provider”

6.1 Regulation 5 provides that a commissioner may award a new contract for NHS services to a single provider, without advertising an intention to seek tenders, “*where [the commissioner] is satisfied that the services to which the contract relates are capable of being provided only by that provider*”. Regulation 5 does not itself prohibit direct contract awards in other circumstances (so long as the other requirements of the Regulations are satisfied), and Monitor’s Draft Substantive Guidance describes various situations in which other direct contract awards may be compatible with the Regulations<sup>9</sup>.

6.2 It appears that a commissioner would only be in breach of Regulation 5 itself where the commissioner had directly awarded a contract for services to a single provider only but had failed (reasonably) to satisfy itself that the relevant services were capable of being provided only by that single provider. Regulation 5 itself does not appear directly relevant to the Thornbury investigation since NHS England has contracts for NHS gamma knife services with a number of providers, and so it has not entered into a contract for gamma knife services with a single provider, but with a number of providers.

## 7. Regulation 7: qualification of providers

7.1 Regulation 7 requires commissioners to establish and apply transparent, proportionate and non-discriminatory criteria in relation to a number of different decisions

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<sup>7</sup> see <https://www.supply2health.nhs.uk/S2H-Home.aspx> and related web-pages

<sup>8</sup> NHS England became responsible for commissioning specialised services on 1 April, but had already been constituted for certain purposes before that date.

<sup>9</sup> see Draft Substantive Guidance, section 4.2 at page 23, section 4.2.2 and section 4.2.3. Some commentators have suggested that Regulation 5 creates, by implication, an obligation to advertise an intention to seek tenders where there is more than one potentially capable provider, but that view does not appear to be supported by the guidance.

concerning patient choice and procurement. These requirements may not relate directly to the Thornbury issue, since it appears that the decisions in question (set out at Regulation 7(2)) are not ones that currently apply to gamma knife services:

- 7.1.1 the requirement of Regulation 7(2)(a) – determining which providers qualify to be included on a list from which patients are offered choice of provider for first outpatient consultant appointment – appears to broadly align with the NHS Constitution rights of patient choice<sup>10</sup>. Service users are referred to gamma knife services through consultant-to-consultant referrals at a later stage of the pathway, and so Regulation 7(2)(a) does not appear to apply to these services;
- 7.1.2 Regulation 7(2)(b) – on determining which providers should be included on a list from which patients are otherwise offered a choice of provider, appears to apply to services where commissioners have introduced choice over and above the choices set out in the NHS Constitution. Monitor’s Draft Substantive Guidance explains that this decision applies “where a commissioner has decided to introduce choice for other services”. Gamma knife services, being a consultant-to-consultant referral for specialised services, are not services for which (currently) commissioners have decided to introduce patient choice, and so this provision does not appear to apply to these services at present;
- 7.1.3 the requirement of Regulation 7(2)(c) – determining which providers to enter into a framework agreement with – does not appear one that could apply to the NHS National Standard Contract, since “framework agreement” is defined in the Regulations as an arrangement between commissioners and providers by setting out the terms under which that provider “will enter into one or more contracts”. That reference to future contracts appears to refer to call-off contracts, whereby the framework agreement sets the terms on which future contracts are called off<sup>11</sup>. It does not appear that the NHS National

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<sup>10</sup> as also suggested by Monitor’s Draft Substantive Guidance at section 5.1 which refers to this choice being “consistent with [patients’] rights under the NHS constitution”

<sup>11</sup> Clearly, the definition of “Framework Agreement” in the Regulations is based on the corresponding definition of Framework Agreements in the Public Contracts Regulations 2006, which supports its application to separate call-off contracts (“specific contracts” in the Public Contracts Regulations 2006)

Standard Contract is such a framework agreement, since it does not set out the terms on which a provider “will enter into one or more contracts” – rather, the NHS National Standard Contract *is itself* the contract for services, not a framework governing future call-offs;

7.1.4 likewise, the requirement of Regulation 7(2)(d) – selecting providers “to bid for potential future contracts” does not appear to apply here, since NHS England has not, since 1 April 2013, selected any providers to bid for potential future contracts. NHS England is aware that the work on the national strategic review could possibly lead to a decision about how to invite tenders from at a future point, and if so what pre-qualification criteria might apply, but at present no decision has been taken that might be within the scope of Regulation 7(2)(d).

7.2 Regarding the question of whether, for SRS, there may be clinical reasons for limiting the number of providers with which NHS England enters into contracts, this is one of the issues being directly addressed by the national strategic review. Should future commissioning policy lead to the introduction of patient choice for gamma knife, such that Regulation 7(2)(b) might apply, any decisions in this respect will be made transparently and with appropriate stakeholder involvement, to ensure that any limit to the number of SRS providers is in service users’ best interests.

## 8. **Regulation 9: publication of contract awards**

8.1 Regulation 9(1) requires commissioners, including NHS England, to publish on a dedicated website a record of each contract awarded for NHS services. The details to be published in relation to each contract are described in Regulation 9(2). NHS England acknowledges that it has not, as yet, been able to publish details of current gamma knife contracts on the Supply2Health website. NHS England recognises the requirement in Regulation 9 to maintain publication of records of all contracts awarded, and acknowledges that NHS England still has work to do in this area.

8.2 NHS England, as sole commissioner of 200 prescribed specialised services for England, is commissioner for a very significant number of different specialised commissioning contracts. While recognising that the requirements of the Regulations must be met irrespective of the administrative requirements involved, NHS England

welcomes that fact that Monitor's Draft Substantive Guidance appears to acknowledge that some account may need to be taken about the effects of system change and the transfer of commissioning responsibilities under the Health and Social Care Act 2012 on these requirements<sup>12</sup>;

8.3 Further, given the limited number of gamma knife providers nationally, and the various links between them, it is likely that much of the relevant contract information was already known to Thornbury, including: the identity of providers providing NHS gamma knife services under contract to NHS England, the nature of the services involved (being governed by a publically available service specification and commissioning intentions); the approximate value of the services (since Thornbury was aware of approximate pricing through its subcontract with Sheffield); contract duration (since these are on the terms of the NHS Standard Contract which, for 2013/14, has a duration of one year up to 31 March 2014); and the process involved for selecting providers (since NHS England has engaged in correspondence with Thornbury on this point).

8.4 Therefore, while NHS England recognises the importance of working towards full compliance with Regulation 9, NHS England considers that in this particular case, lack of published information in this form may not have caused Thornbury any material disadvantage regarding its wish to offer NHS services.

**9. Regulation 12: duty to offer choice of alternative provider when prescribed waiting times are not, or will not, be met.**

9.1 Regulation 12 provides that, where regulation 48 of the 2012 Regulations<sup>13</sup> applies, commissioners must offer a person a choice of alternative provider in accordance with regulation 48(4) of the 2012 Regulations. This requires that, where a service user has been referred for assessment or treatment by a consultant or member of a consultant-led team and the 18 weeks referral-to-treatment target (RTT) has not or will not be met, the relevant commissioner (if notified of this fact) must take all reasonable steps to

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<sup>12</sup> For example, the statement that “[Monitor] recognise[s] that this is a period of transition for the sector and that commissioning responsibilities have only recently been transferred to clinical commissioning groups and the NHS Commissioning Board (which has recently adopted the name NHS England).” (Draft Substantive Guidance, page 1)

<sup>13</sup> the National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012, SI 2012/2996. Regulation 48 applies where the conditions in paragraph (2) to (6) of Regulation 47 are met.

offer earlier treatment by a different provider and, where more than one suitable alternative provider exists, a choice of more than one alternative provider for earlier consultant-led appointment.

- 9.2 It is the duty to offer the choice – where relevant – of more than one suitable alternative provider that is covered by the present Regulations. NHS England notes that this obligation would not of itself necessarily require referral to Thornbury – and indeed, that until the MDT position had been resolved to enable Thornbury to become a direct contractor, Thornbury would not have been a suitable alternative provider that could have been offered for an alternative appointment.
- 9.3 With regard to waiting times, NHS England is aware that, since 1 April 2013, STHT has exceeded the 18 weeks RTT for gamma knife on 9 occasions. These instances relate to procedures on children, cerebral arteriovenous malformations (AVMs) or trigeminal neuralgia cases.
- 9.4 With regard to children there is a clinical need to ensure that the timing for treatment is right for the child and their condition, and that the appropriate anaesthetic support is available, and Thornbury would not have been a suitable alternative provider in these cases. With regard to AVMs, again, Thornbury would not have been suitable to be offered as an alternative provider, since this particular procedure is one that Thornbury cannot perform since it does not have the necessary angiography equipment.
- 9.5 With regard to the trigeminal neuralgia cases, for reasons of clinical safety, all the patients have to follow a particular pathway under a specific consultant. Occasionally the wait can therefore exceed 18 weeks. This procedure could be carried out by Thornbury, and there have been some cases transferred from STHT to Thornbury (under Thornbury's subcontract with STHT) where they fall within the scope of what Thornbury is able to deliver.
- 9.6 The national strategic review will take into account, in its assessment of demand and capacity, the need to offer alternative provision where RTT is at stake. On the individual STHT cases, STHT is going to undertake a case-by-case audit to establish why RTT was breached and what if any arrangements could have been made for alternative provision – that analysis will assist with the work of the national strategic review work. At present, information is not available to ascertain whether any of the

exceptions to the RTT duties applied in any individual STHT cases, or whether possible RTT breaches were notified to the provider or commissioners so as to require the offer of alternative provision.

## 10. **Proportionality and enforcement**

- 10.1 NHS England considers that it is important to separate out, in the consideration of the Complaint, those issues that can properly be addressed in relation to the Regulations, and those which might be described as “historic” since they relate to a previous policy regime and previous commissioning structures, and which cannot be considered under the Regulations which are necessarily be confined to actions or decisions taken since the Regulations came into force and by the bodies to which the Regulations apply. The relevant actions therefore relate to the period between 1 April 2013, when the Regulations came into force, and 5 June 2013 when Monitor initiated its investigation.
- 10.2 As already discussed, NHS England began the 2013/14 contract year in dialogue with Thornbury, and moved, following additional information about patient flows, to an intention to enter into contract with Thornbury. Following work to establish and clarify the appropriate MDT arrangements that should be in place for these services, NHS England has now resolved the issues around the NHS National Standard Contract. Further, as Monitor is aware, NHS England is conducting a detailed strategic review of SRS to inform future commissioning and procurement policy.
- 10.3 Accordingly, what is at issue under the Regulations from 1 April appears not to be any of the points raised in Thornbury’s complaint going back to 2008 but rather the fact that NHS England, as the commissioner responsible for the commissioning of specialised services, decided – at a time of exceptional system change – not to enter into a contract with a potential provider until certain matters, relevant to issues of clinical safety, were resolved to NHS England’s satisfaction. It is unfortunate that it has been considered necessary to instigate and continue a formal statutory investigation while the key element that appears to be complained of – that “in essence” Thornbury was not at that time directly providing services to NHS patients – was being directly addressed by NHS England and Thornbury with a view to enabling Thornbury to enter into precisely such a direct contractual relationship. The substance of the issue would therefore appear to be whether NHS England, as commissioner for

these services, is entitled to continue negotiations with a provider before contract close in order to reach a position acceptable to NHS England as the commissioner with clinical responsibility, or whether NHS England should have moved to contract signing while it still had material concerns relating to service delivery; and whether NHS England's continuing work with Thornbury to resolve the MDT issue was evidence of discrimination against Thornbury, or rather a reasonable and proportionate way of addressing the issues in question.

- 10.4 Monitor's Draft Enforcement Guidance states that "*[a]t any point during an investigation, Monitor may close a case without further action, if for example, Monitor considers that continuing with a case would no longer be consistent with its prioritisation framework*". Given that Monitor has accepted in the Statement of Issues that actions falling before April 2013 are outside the scope of the Regulations, which very significantly reduces the scope of the complaint under investigation; that the essence of what remains under the Regulations appears to be a question as to whether NHS England was entitled to delay entering into a contract while certain clinical arrangements were being settled; that the issue with Thornbury is now resolved, and contract documents are ready for signature; and that demonstrable steps are being taken to review nationally the provision of SRS services to provide a basis for future commissioning and procurement strategies, NHS England would again invite Monitor to consider the proportionality of continuing this investigation.

**NHS England**

**18 October 2013**