March 2013

RESPONSE TO OPINIONS OF DAVID LOCK AND THE OPINION OF LIGIA OSEPCIU PUBLISHED BY 38 DEGREES, ON THE APPLICATION OF THE NHS (PROCUREMENT, PATIENT CHOICE AND COMPETITION) REGULATIONS 2013

1. This note sets out the Department of Health's response to the three legal opinions of David Lock ("the Opinion") and Ligia Osepciu (''the further Opinion'') on the application of the NHS (Procurement, Patient Choice and Competition) Regulations 2013 and the revised regulations (the NHS (Procurement, Patient Choice and Competition) (No. 2) Regulations 2013) tabled on the 11 March 2013 (''the regulations''), as published by 38 Degrees[1].

2. The Department does not agree with many of the conclusions drawn from the legal analysis about the likely effect of the provisions of the regulations.

Intent

3. Our response to the advice should be seen within the context of what we are trying to achieve through the Health and Social Care Act 2012 (''the Act'') and the regulations. Our aim is to improve health outcomes for patients and value for taxpayers' money. We therefore want to see NHS services provided by the best providers in the best interests of patients.

4. The purpose of the regulations is simply to transfer to the new NHS commissioners the procurement requirements that currently apply to primary care trusts, and to provide for Monitor – a sector specific regulator with expertise in health care – to enforce the rules rather than action through the courts.

5. This is consistent with the commitment in the Government's response to the NHS Future Forum report to provide certainty and continuity in the management of competition within the NHS by maintaining the Principles and Rules for Cooperation and Competition and transferring the body that applies them - the Cooperation and Competition Panel - to Monitor.[2]

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[1] https://s3.amazonaws.com/38degrees.3cdn.net/c9621f17e1890aa0e4_9qm6iy4ut.pdf

[2] Government response to the NHS Future Forum report, 20 June 2011

Applicability of procurement law to the NHS

6. As the Department's previous response to legal advice obtained by 38 Degrees during the passage of the Act set out:

   "Current procurement law has always applied to, and will continue to apply to the procurement of goods and services by NHS providers, and the commissioning of clinical services (not just those subject to patient choice) is also subject to procurement rules.
   This has been clearly set out in, for example, successive versions of the PCT Procurement Guide provided by the previous Government. The provisions of the Bill do not change the requirement to comply with procurement law, nor do they change that law."[3]

7. The applicability of EU and UK procurement law (the Public Contract Regulations 2006) to the NHS is unaffected by the regulations. Paragraph 2 of the Opinion agrees and states: *"the Regulations substantially replicate the duties which are already imposed by EU law on NHS commissioners".*

8. Therefore, absent the regulations, the requirements of procurement law would continue to apply to the NHS. The regulations provide for Monitor as an expert health-sector regulator with an overarching statutory duty to protect and promote patients' interests to enforce the regulations. This is far preferable to a situation where there is unmanaged competition and the only means of redress for poor procurement practice is through the Courts. Any legal challenge on the basis of the regulations would be to a decision by Monitor and would be by way of judicial review. This would therefore be limited to considering whether Monitor had acted lawfully, fairly or unreasonably. There would not be a complete reconsideration by the Courts of the decision taken by a commissioner, which would be the case if the regulations were not in place and the only means of challenging a procurement decision was under the Public Contract Regulations 2006.

Do the regulations promote the transfer of NHS activities to the private sector?

9. It is entirely inaccurate to claim that "the regulations are likely to have the effect of both permitting and promoting the transfer of NHS services to the private sector". The NHS will remain free at the point of delivery with access based on clinical need not on ability to pay. The reforms to the NHS, including these regulations, are not, and have never been, about privatisation. Section 147 of the Health and Social Care Act 2012 is the first piece of legislation to prohibit the Secretary of State from discriminating in favour of private providers. Section 62(10) of that Act places the same prohibition on Monitor.

[3] Department of Health response to the legal opinion published by 38 Degrees on the application of procurement and competition law, 6 September 2011

10. The Government believes that charities, social enterprises and independent providers play an important part in providing NHS care - and they have done so for many years - helping give patients more choice of where and how they are treated. It is for commissioners to decide, not the Secretary of State and not Monitor, which providers - whether from the public, private or voluntary sectors - can best meet the needs of their patients and deliver high quality care. Therefore, any use of private or other type of provider will be a result of decisions by commissioners taken in the best interests of their patients.

11. The Opinion places much weight on the assertion that the regulations permit or promote the transfer of NHS activities to the private sector because they would remove the *'Teckal'* exception. The Opinion claims that this would mean that commissioners would no longer be able to contract with an NHS Trust without a competition.

12. This is a reference to the judgment of the European Court of Justice[4] in case C-107/98 *Teckal*[5], the effect of which is to permit arrangements akin to the in-house provision of services without a tender. In this case, the Court said that the public procurement rules do not apply where two conditions are met:

    (a) the public body exercises over the person concerned a control which is similar to that which it exercises over its own departments and, at the same time,

    (b) that person carries out the essential part of its activities with the controlling public body or bodies.

13. However, the regulations do not remove this exception and do not affect its application. The courts have held that the existing Public Contract Regulations 2006 incorporate the *Teckal* exception[6], even though they make no express reference to it, and these regulations are entirely consistent with the Public Contract Regulations.

Single capable provider

14. Paragraph 4 of the first Opinion of David Lock also says that presently "there are many proper reasons why an NHS body might contract with an NHS trust or an NHS Foundation Trust for services without a competition where this 'single capable provider' condition is not satisfied". It suggests that this will no longer be the case under the regulations. However, the circumstances in which a commissioner may award a contract without a competition under the regulations will be identical to the requirements of existing procurement law, as reflected in mandatory guidance to the NHS applicable since 2008. Mandatory guidance published in March 2010 stated:

[4] Now known as the Court of Justice of the European Union.
[5] Case C-107/98 *Teckal SRL v. Commune di Viano* [1999] ECR I-8121.
[6] See the judgment of the Supreme Court in *Brent London Borough Council v. Risk Management Partners Ltd* [2011] UKSC 7.

'Where there is only one capable provider for a particular bundle of services or the objective of the procurement is to secure services to meet an immediate interim clinical need there will be a case for Single Tender Action (ie uncontested procurement)."[7]

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

16. For example, a single tender action may be justified on the basis that there is only one provider able to meet the clinical quality and safety standards required by a commissioner. If a commissioner can properly satisfy itself that the provider of the required services needs to maintain a caseload volume and a certain case mix in order to provide a safe and effective service and there is only one provider capable of doing so, that would be a legitimate justification for awarding a contract without a competition. There may equally only be one provider capable of providing the kind of integrated service the commissioner wants to secure for its patients.

17. Further examples of services where there may typically only be one capable provider include:

    - acute hospital services on single sites and accessible 24 hours a day 7 days a week;
    - a range of integrated services delivered in the community;
    - highly specialised care; or
    - services in more rural or remote areas of the country.

18. Monitor's statutory guidance, which will be published to support commissioners in complying with the regulations, will make absolutely clear that there has been no change to this position. It will set out in exactly the same terms the position in the 2010 procurement guidance.

Do the regulations impose compulsory competitive tendering requirements on commissioners, or give Monitor powers to impose such requirements?

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.

[7] Primary Care Trust procurement guide for health services, March 2010

20. It is misleading to suggest that the regulations place any new obligation on NHS commissioners which would require them to hold a competitive tender. The position is exactly the same as under the existing Principles and Rules for Cooperation and Competition, Procurement guidance and the Public Contracts Regulations 2006.

Fragmentation and the creation of new markets

21. The Department strongly disagrees with the assertion that the regulations would force commissioners to fragment services against the interests of patients. Regulation 2 makes clear that integration is a key tool that may be used to achieve the objective of meeting the needs of patients and improving the quality and efficiency of services. The further Opinion agrees and states: '*regulation 2 makes it fairly clear that CCGs are entitled to formulate requirements for bundles or packages of services'*.

22. Under the regulations, commissioners have discretion to decide whether, where and when to introduce the conditions needed to stimulate or create a market for services. In particular there is no requirement through the regulations for commissioners to:

    - unbundle or fragment services in order to facilitate competition (i.e. to separate out individual services in order that they could be provided by a larger range of providers); or
    - offer contract terms (e.g. prices, and contract durations) that enable new providers to enter a market by offering a return on the investment cost of market entry.

23. The decision about whether and when to create these conditions and the services to which they apply remain entirely with commissioners. So, for example, a commissioner may decide not to create the conditions to enable a market for a particular service, or for a component of a service, or for a fully integrated service (say for end-of-life care, for frail older people with multiple complex problems, for maternity services, or for sexual health services).

24. The Opinion asserts that Monitor could force commissioners to unbundle services through regulation 10(1) which prohibits anticompetitive behaviour unless it is in the interests of patients. However, regulation 10(1) makes it clear that the integration of services and cooperation between providers is something which would be considered in patients' interests for the purposes of the regulations. This is designed to provide NHS commissioners with added surety that, in integrating services in order to improve them, they should not be breaching regulation 10(1).

25. In addition, when investigating behaviour under regulation 10, Monitor will have to take into account the objective of commissioners under regulation 2 to secure patients' needs and improve quality and efficiency. There will be circumstances in which a particular service must be provided alongside others to ensure patient safety – for example, support services needed in the event of clinical complications – or where a range of services needs to be provided in order to ensure their continuity.

The regulations will not force commissioners to fragment such services against the interests of patients.

26. Monitor is also required, by section 66 of the Act, to exercise its functions with regard to:

- in particular, the need to maintain the safety of people who use health services;
- the desirability of securing continuous improvement in the quality of services;
- the need of commissioners to ensure people have access to the services they need and for them to make the best use of resources when doing so; and
- the desirability of providers cooperating with each other in order to improve the quality of services.

27. Overall, therefore the regulations and the Act provide additional comfort to NHS commissioners that they would not be required to divide up or fragment services against the interests of their patients.

Strategic needs and the relationship between regulation 2 and regulation 5

28. 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 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.

29. The NHS Commissioning Board and clinical commissioning groups (CCGs) will also have a number of other statutory duties which will apply when commissioning health care services for the purposes of the NHS and which will mean that they can, and should, take into account wider strategic needs. These include:

(a) section 3 of the 2006 Act – duty of a CCG to arrange for the provision of certain services as it considers necessary to meet the reasonable requirements of the persons for whom it has responsibility;
(b) section 13A(7) of the 2006 Act – duty on the Board to seek to achieve the objectives specified in the NHS mandate;
(c) sections 13E and 13N of the 2006 Act – duties on the Board as to improvement in quality of services and to promoting integration;
(d) sections 14R and 14Z1 of the 2006 Act - duties on CCGs as to improvement in quality of services and to promoting integration; and
(e) section 14Z11 of the 2006 Act – duty on CCGs to prepare commissioning plans for each financial year.

30. Moreover, we do not agree that regulation 5 means that the objective of regulation 2 cannot be achieved in practice. As set out above, it is for commissioners to decide how best to meet the objective of securing the needs of their patients and improving quality and efficiency. Commissioners will decide where the integration of services

will help them to achieve that objective and regulation 5 does not prevent this. For example, the integrated services required by the commissioner may mean that there is only one provider capable of providing those services.

31. In addition, as the NHS Future Forum noted, competition and integration are not opposing forces, and competition can and should be used by commissioners as a powerful tool to drive integration for patients.[8] The regulations recognise this and allow commissioners to specify an integrated service and run a tender to secure the best possible provider, or providers, to deliver that integrated service.

32. Indeed, the further Opinion agrees and sets out that "*read in light of regulation 2, regulation 5 places no restriction or limit on the 'services to which a contract can relate'; it simply supposes a requirement of services formulated in accordance with regulation 2. On this interpretation, regulation 5 would allow a CCG to award a contract for bundled health care services…*".

Best value

33. A further misunderstanding is to suggest that there is a conflict between the requirements in regulation 3(3) for a commissioner to choose the provider that a) is the most capable provider of delivering the objective of securing the needs of patients and improving quality and efficiency; and b) provides best value for money in doing so. The Opinion suggests that this may mean that a commissioner is forced to choose a lower cost provider for an individual service over an integrated service.

34. However, this misinterprets the effect of the regulations, which is to require commissioners to choose the provider which can meet their requirements *and* provide best value in doing so. Where the commissioner requires an integrated service, there is nothing in the regulations to require them to procure a different service that does not meet their requirements just because it can be provided more cheaply. Moreover, the Opinion reaches the false conclusion that achieving best value means selecting the lowest price. 'Best value' is the best combination of quality and price. There is nothing in the regulations to force commissioners to select providers on lowest price alone. Monitor's guidance will make this absolutely clear.

Guidance

35. Finally, the Department is concerned that the Opinion makes no attempt to consider or anticipate the effect of statutory guidance for commissioners on compliance with the regulations.

36. A key benefit of having a sector-specific regulator - Monitor – to oversee compliance with the regulations is that it is able to provide support to the system through guidance. It will also avoid action being taken through the courts and the associated costs.

[8] Choice and Competition Delivering Real Choice, a report from the NHS Future Forum

37. Monitor and the NHS Commissioning Board have committed to work jointly to support commissioners through advice and guidance. This will include guidance to help commissioners make decisions on the circumstances in which competitive tendering would be likely to be effective and where it would not be appropriate. In addition, Monitor is required (under section 78 of the Health and Social Care Act 2012) to publish guidance explaining how it will use its investigative and enforcement powers under the regulations. This will reduce uncertainty for commissioners and give them greater confidence that decisions in patients' best interests should not lead to regulatory intervention. Monitor will conduct a public consultation on this guidance and it must be approved by the Secretary of State.

38. Finally, Monitor and the NHS Commissioning Board will be producing a one-stop web-based resource to help commissioners, providers and patients understand and use choice and competition in the health care system. Further details are in their joint note on *Choice and competition in commissioning clinical services in the NHS in England*, available here: http://www.commissioningboard.nhs.uk/wp-content/uploads/2013/03/choice-comp-note.pdf