IN THE MATTER OF THE HEALTH AND SOCIAL CARE BILL AND THE APPLICATION OF PROCUREMENT AND COMPETITION LAW

ADVICE

EXECUTIVE SUMMARY

- The current procurement law contained in the Public Contracts Regulations 2006, which derives from European law, has always applied to NHS purchasing with the effect that any goods or services required by NHS health providers to enable them to provide health care themselves are subject to those Regulations where the value of the goods or services required exceed the prescribed thresholds.
- Recent non-legislative reforms in the NHS have encouraged Primary Care Trusts to open up the provision of an increasing number health care services formerly provided in-house to commercial and social (or "third sector") enterprises through, for example, the "Any Qualified Provider" policy. The commissioning of providers in pursuance of that policy, or where any services are contracted out, are also currently subject to the procurement rules.
- The most important impact of the Bill in terms of procurement is the transfer of responsibility for commissioning services from PCTs to commissioning consortia which will be constituted by, amongst others, primary care providers including GP practices. There are likely to be considerably more consortia than there are PCTs.
- Consortia will be subject to the Public Contract Regulations and, where the Regulations are applicable, will likely to be required to conduct some form of competition before awarding a contract with a value above £156,442. That is the case whether the commissioning is for goods and services for the consortia"s own use or in order to secure a provider of health care services.
- The procurement regime is a complicated and developing body of rules and case law which gives rise to enforceable rights in the High Court and makes available draconian remedies and penalties for breach of the Regulations. The practical and

financial implications of ensuring that goods and services are procured compliantly are considerable. There is a real risk that there will be a deficit of incumbent expertise in new consortia to cope with the regulatory burden. It appears however that the government has simply failed to grapple with the frontline issues in procurement, has wholly underestimated the increasing rather than diminishing complexity in the area and has had no or perhaps little regard to the administrative and financial burdens arising from the regime.

- As regards the applicability of domestic and European competition law to the NHS, it is likely that, even as matters stand, and in view in particular of recent non-statutory reforms which increase the involvement of the private and third sector in health services provision, competition law already applies to PCTs and NHS providers.
- The reforms introduced by the Bill however will serve to reinforce that conclusion and introduce elements which make it even more likely that domestic and European competition law applies to the NHS. There is nothing in the Bill which has or can have the effect of preventing the application of competition law. Nor can the Act preserve the enforcement of competition law to the sectoral regulator, Monitor, since a breach of the prohibitions on anti-competitive conduct gives rises to actionable claims in the High Court by any person affected.
- The effect of the application of competition law in the NHS is difficult to predict but potentially brings under scrutiny any collaborative and collective arrangements and the exercise of dominant local purchasing or providing power. The fact however that the government has amended the Bill to remove from the scope of the duties of Monitor the duty to promote competition as an end in itself is arguably futile since the very fact that domestic and European competition law applies to the NHS arguably itself results in the promotion of competition since that is its aim.

INTRODUCTION

1. This advice addresses the potential impact of procurement and competition law for the NHS arising from the Health and Social Care Bill, if enacted in its current form (as of the date of this advice). It does not propose to provide a detailed analysis of the many duties and functions of the various NHS constituents and the full extent of the changes brought about. Further, its conclusions are necessarily broad and cannot be definitive in view of the fact that much of the legislation applicable to the NHS will be enacted as secondary legislation, upon the content and nature of which we cannot speculate and it will remain to be seen how precisely the new structure of the NHS operates in practice.

2. In so far as is relevant to this advice, the Bill seeks to reform the NHS to bring about a decentralisation of health care services and devolution of decision making from central government. Allied to those reforms, the Bill achieves formal separation between the provision of health services and the commissioning of such services for patients. Primary Care Trusts and Strategic Health Authorities are to be abolished to make way for a system of Foundation Trusts, the principal purpose of which is the provision of goods and services for the purposes of the health service in England (Clause 167: s43). The commissioning of services will now however rest predominantly with the new NHS Commissioning Board and commissioning consortia. A fundamental tenet of the Bill is that Trusts and consortia are autonomous and there is a duty upon the Secretary of State to promote autonomy in the exercise by any person of any functions in relation to the health service and those providing services for its purposes[1].

3. Although consortia have the function of commissioning, it will nevertheless be a requirement that all providers of primary medical services (as defined in Clause 22: s14A), including GP practices, will be part of a consortium. It will be the overall duty of the consortia to arrange the provision of services for the purposes

[1] Clause 4: s1C

of the health service. Each consortia must have a governing body (Clause 22: s14L) and may work with other consortia (Clause 23: 14Z1) in order to provide NHS services or jointly exercise their commissioning and other functions or indeed merge with other consortia (Clause 22: s14G).

4. Clause 23: s14Z3 gives consortia the power to raise income (for the improvement of the health service) through engaging in economic activity (as set out in section 7(2)(a),(b) and (e) to (h) of the Health and Medicines Act 1988). Thus consortia may generate income by
   (a) acquiring, producing, manufacturing and supplying goods;.
   (b)acquiring land by agreement and managing and dealing with land;
   (c) providing instruction for any person;
   (d) developing and exploiting ideas and exploiting intellectual property;
   (e) doing anything whatsoever which appears to it to be calculated to facilitate, or to be conducive or incidental to, the exercise of any power conferred by this subsection; and
   (f) by making such charge as it considers appropriate for anything that it does in the exercise of any such power and to calculate any such charge on any basis that it considers to be the appropriate commercial basis.

5. They may also make grants and loans to voluntary organisations providing healthcare services (Clause 23: s14Z4).

6. The Commissioning Board (Clause 6: s1E) has the function of arranging for the provision of services for the purposes of the health service (and may act as commissioner where required by the Secretary of State) and must exercise the functions conferred by the Act in relation to commissioning consortia so as to secure that services are provided for those purposes. It has a supervisory role over the consortia and may provide guidance in relation to commissioning functions (Clause 23: 14Z6).

7. Regulations will impose detailed requirements on the Board and consortia in the carrying out of its functions and may require them to act in a specified manner for

the purposes of securing compliance with EU obligations (Clause 17:s6E).

Monitor

8. The main duty of Monitor in exercising its functions will be to protect and promote the interests of people who use health care services by promoting provision of health care services which (a) is economic, efficient and effective, and (b) maintains or improves the quality of the services. It does not now therefore have the express aim of promoting competition (as was the case in previous drafts of the Bill).

9. Rather, Monitor must exercise its functions with a view to preventing anti-competitive behaviour in the provision of health care services for the purposes of the NHS which is against the interests of people who use such services.

10. Clause 67 provides that Monitor shares concurrent functions with the Office of Fair Trading. Those functions are those that the Office of Fair Trading has under Part 1 of the Competition Act 1998 (other than sections 31D(1) to (6), 38(1) to (6) and 51), so far as relating to any of the following which concern the provision of health care services in England –

    (a) agreements, decisions or concerted practices of the kind mentioned in section 2(1) of that Act (anti-competitive practices);

    (b) conduct of the kind mentioned in section 18(1) of that Act (abuse of dominant position);

    (c) agreements, decisions or concerted practices of the kind mentioned in Article 101 of the Treaty on the Functioning of the European Union (anti-competitive practices);

    (d) conduct which amounts to abuse of the kind mentioned in Article 102 of that Treaty (abuse of dominant position).

11. Monitor also shares the functions of the Office of Fair Trading under Part 4 of the Enterprise Act 2002 (market investigations) (other than sections 166 and 171), so far as relating to activities which concern the provision of health care services in England. Monitor also has function in the field of procurement, patient choice and

competition and by Regulations may impose requirements on the National Health Service Commissioning Board and commissioning consortia for the purpose of securing that, in commissioning health care services for the purposes of the NHS, they:

(a) adhere to good practice in relation to procurement;

(b) protect and promote the right of patients to make choices with respect to treatment or other health care services provided for the purposes of the NHS;

(c) do not engage in anti-competitive behaviour which is against the interests of people who use such services.

12. These Regulations may, in particular, impose requirements relating to (a) competitive tendering for the provision of services; and (b) the management of conflicts between the interests involved in commissioning services and the interests involved in providing them.

13. The Regulations are enforced by Monitor (through declarations, directions and undertakings: Clause 71) and breaches of the Regulations which cause loss and damage are actionable in court unless such right of action is restricted in the Regulations. This places on a statutory footing the current regime of "Principles and Rules for Cooperation and Competition" which is currently applied on a non-statutory basis through the NHS Cooperation and Competition Panel.

14. Clause 74 applies Part 3 of the Enterprise Act 2002 which provides extensively to the regulation and control of mergers to mergers involving NHS Foundation Trusts and those involving merger between Foundation Trust and other businesses in the private sector.

15. Clause 75 of the Bill gives the Competition Commission the task of reviewing and investigating the development of competition in the provision of health care services for the purposes of the NHS and the exercise by Monitor of its competition functions with a view to determining whether the public interest is being adversely affected.

Recent non-legislative reforms

16. Although the Bill marks a significant restructuring of the NHS, recent reforms implemented through policy and operational guidance have done much to alter its landscape, even in the absence of legislative change. For example, contracting out services to the private sector is anything but a novel proposition in the NHS and there is an express power in s83 of the National Health Service Act 2006 and following sections for PCTs either to provide primary medical and other services themselves or to arrange for their provision by contracting with anyone[2]. This enables PCTs to contract with commercial providers (through the use of Alternative Provider Medical Services (APMS) contracts) and are intended to be used for the provision of essential services, additional services where GP practices opt out, enhanced services, out-of-hours services or any one element or combination of those services. There is therefore already considerable involvement of the private sector in the provision of NHS health care services. Furthermore the government has for some years rolled out the policy of Any Qualified Provider ("AQP")[3], in order to promote patient choice between providers in an increasing number of areas of primary and secondary care. The intention of the policy is to enable patients, when referred (usually by their GP) for a particular service, to be able to choose from a list of qualified providers (who have met NHS service quality requirements, prices and normal contractual obligations). Applying the policy first to routine elective services, PCTs have been encouraged to use private sector and third sector providers on the basis that any provider which meets criteria for entering the relevant market can compete for business within that market. PCTs are encouraged to extend AQP to any service which they consider could benefit locally from extending the market in providers. Current operational guidance[4] instructs PCTs to extend AQP to a wide range of services including musculo-skeletal, podiatry, psychological therapies, continence,

[2] For those powers under the Bill see eg Schedule 4, Part 4 thereof.

[3] Initially known as "Any Willing Provider".

[4] Operational guidance to the NHS Extending patient choice of provider: Gateway reference 16242 (19 July 2011)

adult hearing and wheelchair services. Irrespective of the content of the Bill, the government intends to widen the reach of AQP to an increasing number of services over the coming years. AQP is essentially implemented consistently with PCT"s obligations under the procurement regime (as to which see below) whereby they must conduct competitions before appointing or commissioning healthcare providers.

17. Alongside that policy, the previous government introduced Principles and Rules for Cooperation and Competition (PRCC)[5] which are not enforceable in the courts but are applied and enforced internally through Strategic Health Authorities and the Cooperation and Competition Panel. The Panel further performs an advisory role to the Secretary of State and Monitor on the PRCC and matters of compliance. They apply both to the commissioning and provision of NHS services and apply to all commissioners and providers of NHS services irrespective of whether they are public, private or third sector organisations and they establish 10 basic rules:

    a. Commissioners must commission services from the providers who are best placed to deliver the needs of their patients and populations;
    b. Commissioning and procurement must be transparent and non-discriminatory and follow the Procurement Guide issued in July 2010;
    c. Payment regimes and financial intervention in the system must be transparent and fair;
    d. Commissioners and providers must cooperate to improve services and deliver seamless and sustainable care to patients;
    e. Commissioners and providers should promote patient choice, including – where appropriate – choice of any willing provider, and ensure that patients have accurate and reliable information to exercise more choice and control over their healthcare;
    f. Commissioners and providers should not reach agreements which restrict commissioner or patient choice against patients" and taxpayers" interests;

[5] Gateway reference 14611 (30 July 2010)

g. Providers must not refuse to accept services or to supply essential services to commissioners where this restricts commissioner or patient choice against patients‟ and taxpayers‟ interests;
h. Commissioners and providers must not discriminate unduly between patients and must promote equality;
i. Appropriate promotional activity is encouraged as long as it remains consistent with patients‟ best interests and the brand and reputation of the NHS;
j. Mergers, including vertical integration, between providers are permissible when there remains sufficient choice and competition or where they are otherwise in patients‟ and taxpayers‟ interests, for example because they will deliver significant improvements in the quality of care.

ANALYSIS

18. This advice proposes first to deal with issues arising in procurement law and then to deal with issues arising under competition law. Before assessing the potential impact of procurement law arising from the Bill it is necessary to examine the procurement regime in general.

General overview of procurement law

19. Community law harmonises procurement law throughout the European Union and is essentially an element of competition law. Directive 2004/18 came into force on 30 April 2004 and its basic rationale is to be found in its Recitals. Recital 2 provides:

> "The award of contracts concluded in the Member States on behalf of the State, regional or local authorities and other bodies governed by public law entities, is subject to the respect of the principles of the Treaty and in particular to the principle of freedom of movement of goods, the principle of freedom of establishment and the principle of freedom to provide services and to the principles deriving therefrom, such as the principle of equal treatment, the principle of non-discrimination, the principle of mutual recognition, the principle of proportionality and the principle of transparency.
>
> However, for public contracts above a certain value, it is advisable to draw up provisions of Community coordination of national procedures for the award of such contracts which are based on these principles so as to ensure the effects of them and to guarantee the opening-up of public procurement to competition. These coordinating provisions should therefore be interpreted in accordance with both the aforementioned rules and principles and other rules of the Treaty."

20. The Directive applies to the award of contracts by "contracting authorities" which are defined as:

> "the State, regional or local authorities, bodies governed by public law, associations formed by one or several of such authorities or one or several of such bodies governed by public law"
>
> A „body governed by public law" means any body:
> (a) established for the specific purpose of meeting needs in the general interest, not having an industrial or commercial character;
> (b) having legal personality; and
> (c) financed, for the most part, by the State, regional or local authorities, or other bodies governed by public law; or subject to management supervision by those bodies; or having an administrative, managerial or supervisory board, more than half of whose members are appointed by the State, regional or local authorities, or by other bodies governed by public law".

21. The Directive goes on to set out detailed rules applicable to the award of public contracts. It is implemented in the United Kingdom through the Public Contracts Regulations 2006. The Regulations list a substantial range of bodies subject to their scope (which include "NHS Trusts") and employ a catch-all definition of contracting authority (broadly following the wording employed by the Directive) as:

> "a corporation established, or a group of individuals appointed to act together, for the specific purpose of meeting needs in the general interest, not having an industrial or commercial character, and –
> (i) financed wholly or mainly by another contracting authority;
> (ii) subject to management supervision by another contracting authority; or
> (iii) more than half of the board of directors or members of which, or, in the case of a group of individuals, more than half of those individuals, are appointed by another contracting authority...

22. The definition also extends to an association of or formed by one or more such corporations or groups.

23. In simple terms, the Regulations apply to any contract or associated group of contracts with a value of more than £156,442[6]. As far as the procurement of

[6] Council Regulation 1177/2009 (L314/64 01/12/09)

services is concerned, the Regulations make a distinction between Part A and Part B services and apply differing obligations in relation to each. For Part A services the full extent of the obligations under the Regulations apply, which provide detailed and mandatory procedural rules for running competitions for the award of the relevant contract or contracts, which are required to be advertised in the Official Journal for European Union. The same rules are applicable to the procurement of goods and works, to which the full extent of the Regulations also apply.

24. In general, where a contracting authority is procuring goods, works or Part A services it must award the contract on the basis of the offer which is either (a) the most economically advantageous from the point of view of the contracting authority; or (b) offers the lowest price. In determining whether it is the most economically advantageous the contracting authority must use and, score bids against, criteria linked to the subject matter of the contract which may include "quality, price, technical merit, aesthetic and functional characteristics, environmental characteristics, running costs, cost effectiveness, after sales service, technical assistance, delivery date and delivery period and period of completion".

25. For Part B services, contracting authorities are not obliged to follow the detailed procedures for tendering a contract but must follow the principles of transparency and non-discrimination as well as the EU principles of freedom of establishment and freedom to provide services. Depending on the scale and nature of the contract therefore, those principles may still require an advertised competition (where appropriate at European level) with procedural safeguards.

26. In so far as is here relevant, health and social services are Part B services. Other services such as information technology services and other non-clinical services are Part A. Any contracts for the supply of goods in connection with the provision of health care are subject to the full extent of the Regulations.

27. In all procurement of contracts therefore, the contracting authority is constrained by Community law, can rarely award a contract in the absence of any competition

and cannot show preference for any bidder based on its nationality or status.

28. In an effort to permit contracting authorities to decrease the administrative burdens involved in procurement and to secure greater economies of scale, the Regulations do permit framework agreements whereby contracting authorities can combine to procure services collectively and/or can undertake a competition for a broad requirement to be fulfilled by subsequent call-off contracts from one or multiple suppliers. Specific rules apply to the award and operation of a framework agreement, as well as the general principles of transparency and non-discrimination and there is an express requirement in the Regulations that framework agreement cannot be used in such as way as to prevent, restrict or distort competition.

29. There are several significant risks of failing to comply or falling short of compliance with not only the detailed procedural rules (where applicable) but also the general principles of transparency and non-discrimination and the relevant Treaty principles applicable to all contracts (including Part B services contracts). The obligations arising from the Regulations are enforceable in the High Court principally by unsuccessful bidders or potential bidders which have been wrongly excluded from a competition.

30. Where the contract has not yet been entered into, a mere issuing of proceedings for non-compliance is sufficient to trigger a statutory "freeze" on the contracting authority taking any further action in relation to that award until a court has examined the case. Even where the contract has been entered into however, a court has the power to impose the draconian sanction of ineffectiveness, which effectively cancels the contract, as well as an "effective, proportionate and dissuasive" civil penalty. Even where the Court does not declare the contract ineffective, it may order the curtailment of the contract and may still impose a penalty.

31. Over and above those remedies, an action for damages for non-compliance may also be pursued.

Application of procurement law to the NHS structure arising from enactment of the Bill.

32. The application of procurement law is not by any means new to the NHS since all "NHS Trusts" are expressly referred to in Schedule 1 to the Regulations are currently within the scope thereof. They routinely engage with the procurement regime. Schedule 1 states that "where an entity listed in this Schedule is succeeded by another entity, which is itself a contracting authority, the successor entity shall be deemed to be included in this Schedule". There is no question but that Foundation Trusts will therefore be within the scope (whether through this provision or through falling within the catch-all definition of contracting authority). Foundations Trust will continue to need to procure goods and services necessary to carry out their functions and for the provision of NHS goods and services in much the same way as contracts are currently procured by PCTs and other NHS Trusts for the carrying out of their functions. Furthermore there is no question but that the Commissioning Board is within the scope of the Regulations whenever it purchases goods and services above the relevant threshold values. By far the greatest impact of the Bill however comes with extension of the procurement regime to commissioning consortia.

33. There is little question that the consortia fall within the definition of contracting authority since they are statutory corporations and publicly funded and are likely in any event to fall within the scope of Schedule 1 to the Regulations. It seems likely that there will be considerably more consortia than there are currently PCTs and it is likely that the commissioning and supply of health services will become more complex.

34. The application of procurement to consortia will have an impact not only on their purchasing of NHS services but on their purchasing of ANY goods or services if the value of the contract exceeds the relatively low threshold of £156,442. Many non-clinical services such as the procurement of IT infrastructures will fall under Part A and will be subject to the full extent of the Regulations.

35. Health services will be provided not only by Foundation Trusts but also by private and third sector providers under APMS contracts and the "Any Qualified Provider" regime which has already been rolled out by the Department of Health and will be extended in 2012 and over time, irrespective of the new legislation.

36. In relation to an increasing number of areas of the NHS therefore, consortia will be conducting competitive tenders in which potentially both public bodies, including Foundation Trusts, the constituent members of consortia and commercial providers will be bidding.

37. The most immediate practical impact of the enactment of the Bill will be that there is a risk of insufficiency of incumbent expertise in the application of procurement rules in the consortia and their governing bodies. The complexity of the regime and the administrative burden in complying with the rules (which are constantly evolving through a rapidly expanding body of case law) cannot be underestimated. Even if consortia were to expend resources recruiting the expertise of procurement consultants in order to assist in early stages, it is very likely that those consultancy services themselves would require to be procured through the Regulations through a full competition where those contracts exceed the relevant threshold of £156,000.

38. The relative ease with which bidders can bring claims in the High Court, at any stage of the procurement has led to an increased appetite for litigation and administrative challenge.

39. There do not appear to be any publicly available statistics for PCTs but the experience of local authorities with regard to procurement has been documented in a survey undertaken by the Local Government Association[7]. The average cost to sample authorities of running a single procurement process under the Regulations ranged from £5000 up to over £30,000 depending on the complexity of the procurement and the procedure used, with considerable time reported as spent on

[7] http://www.lga.gov.uk/lga/aio/16083425

negating or reducing the risk of challenge. It is not unreasonable to assume that consortia will face similar burdens in the carrying out of its commissioning functions which will inevitably require multiple and regular procurements. Even where framework agreements are used, their complexity is not to be underestimated and mini-competitions amongst framework providers will often be required for call-off contracts.

40. In the course of the Bill there does not appear to have been any consideration of the likely costs or regulatory impact of the procurement rules. Indeed, the Government‟s response the NHS Future Forum report rather blithely states at paragraph 5.23:

"To give commissioners further reassurance, the NHS Commissioning Board will be expected to produce guidance on procurement. Commissioning groups should be at little risk of challenge if they work within the Board‟s choice offer and follow its guidance".

41. Anyone charged with conducting a procurement process and any consultant or practitioner in the field of procurement might consider that remark as wholly divorced from reality, if not rooted in naïve and wishful thinking. The Office of Government Commerce continually issues Guidance on various aspects of procurement but compliance with such guidance does little if nothing to limit challenges at every stage of the procurement process. Similarly, the Department of Health issues operational guidance and procurement guides which are designed to ensure PCTs conduct procurement compliantly, yet both administrative challenges and litigation is commonplace and increasingly likely.

42. The practical difficulty in complying with procurement obligations will more often relate to the individual decisions taken by contracting authorities as to, for example, the criteria used, the scoring mechanisms applied to individual competitions or to the judgments made in the scoring of bids. Guidelines can do little to assist in minimising the risk of challenge here. More importantly, the fact that in some cases the constituent members of the consortia will be bidding in

processes being run by the consortia themselves will inevitably be problematic, even if legislation, guidance and Regulations exist to seek to manage conflicts of interest.

43. It appears therefore that the government has simply failed to grapple with the frontline issues in procurement, has wholly underestimated the increasing rather than diminishing complexity in the area and has had no or perhaps little regard to the administrative and financial burdens arising from the regime. This is compounded by the apparent lack of any consideration given to the fact that Monitor has a role in the enforcement of procurement rules which rests alongside the remedies available to unsuccessful or excluded bidders under the Public Contracts Regulations. There will be therefore two tiers of enforcement and consequently two avenues of challenge to increase the administrative and litigation burden on consortia. Even under the current "informal" system applied by the Cooperation and Competition Panel bidders frequently pursue both this and the enforcement route under the Regulations in tandem.

44. In assessing the potential impact of procurement legislation, regard must also be had to the likely EU reforms which are likely to come about following the European Commission‟s recent consultation[8]. The Commission proposes to abolish the distinction between Part A and Part B services and apply the full extent of the procedural rules to all services. If no other simplification of the procedures comes about following the consultation, consortia may in the foreseeable future be required to undertake a fully advertised competitive tender process in relation to each contract it enters into above the relevant threshold.

Brief conclusions in relation to procurement law

45. Just as procurement law currently applies to NHS bodies engaged in purchasing, there is no question but that it will apply to the purchasing functions of Foundation Trusts, the Commissioning Board and consortia under the new Act. By far the greatest impacts of the application of procurement law are wholly

[8] (COM(2011)15)

practical in nature owing the complexity and administrative burden involved in compliance. Given that there might be no or insufficient incumbent expertise in procurement in consortia, there is a very real risk that the functioning of consortia is compromised, at least initially, by the sheer regulatory burden involved, under threat of potentially draconian remedies available to unsuccessful bidders through litigation. Commercial providers on the other hand will already be familiar with and are likely to have had considerably more experience of the procurement regime.

THE APPLICABILITY OF COMPETITION LAW

46. In essence, both domestic and European competition law seek the promotion of competition to maximise consumer welfare through:
    a. the prohibition of agreements, decisions and concerted practices which have as their object or effect the prevention, restriction or distortion of competition;
    b. the prohibition of abuse of dominant positions in the market;
    c. the regulation of mergers to prevent market distortion.

47. UK competition law derives for the most part from the Competition Act 1998 and the Enterprise Act 2002. Domestic law competition law is generally sought to be construed consistently with European law[9].

48. Although there is a prima facie prohibition on anti-competitive agreements both domestic and European law provide scope for competition authorities to exempt from the prohibition where certain public interest criteria are satisfied, for example where there is a resultant consumer benefit or where efficiency and technological advancement is promoted. Unless and until such an exemption is extended, arrangements in breach of the prohibition are automatically void.

[9] See for example s60 Competition Act 1988

49. Infringements of competition law, both in respect of anti-competitive agreements and practices and abuses of dominant position, are not only enforceable by the competition authorities (principally the OFT) through powers of investigation, the obtaining of formal undertakings and the imposition of fines but are also enforceable by individuals and companies in the domestic courts and can give rise to a claim in damages.

Is the NHS within the scope of competition law?

50. Albeit that the government has acceded to pressure to re-focus the duties of Monitor such that they do not now expressly include the direct promotion of competition as an aim in itself, this may well have been a futile drafting concession if the full extent of competition law is or will in any event be applicable to the NHS. After all, one might argue that competition law prevents anti-competitive behaviour precisely in order to promote competition.

51. As recorded above, Monitor will become the competition regulator for the health sector and will share the functions of the OFT in relation to the Competition Act and enforcement thereof especially in relation to agreements, decisions and concerted practices and abuse of dominant position under both domestic and EU competition law. It may be argued that by merely giving Monitor such a function it does not follow that competition law applies to the NHS. The question arises however why the Bill confers upon Monitor such functions, if the substantive law of competition does not apply in any event?

52. In its response to the NHS Future Forum report the government states this:

> "5.16….we recognise that many people thought we were promoting greater application of competition law in the NHS. To make clear that this is not our intention, we will **maintain the existing competition rules for the NHS** that were introduced by the last Government (the Principles and Rules for Co-operation and Competition), and give them a clearer statutory underpinning. The body that applies them, the Co-operation and Competition Panel will transfer to Monitor and retain its distinct identity. This will provide certainty and continuity for the NHS while ensuring that proper, independent regulation is in place.
>
> 5.17. We will retain our proposals to give Monitor concurrent powers with the Office of

Fair Trading, to ensure that competition rules can be applied by a sector-specific regulator with expertise in healthcare. The Future Forum recommended that this was the best safeguard against competition being applied disproportionately. The Bill does not change EU competition law".

53. There is an interesting choice of words in this extract which gives rise to a number of observations.

54. First, the extract as a whole appears to suggest that the only competition rules that will be applicable to the NHS are those which are currently in the non-statutory Principles and Rules for Cooperation and Competition which will become statutory obligations through Regulations made under Clause 70 of the Bill. The investigation and enforcement mechanisms and Monitor"s powers in relation to those Regulations however are those laid out in Clauses 71 and 72 of the Bill. There is therefore a separate and distinct set of competition rules and an enforcement regime under Clauses 70 to 72 (which may of course be developed and extended over time through the use of Regulations) which is wholly unrelated to the regulatory functions Monitor is to share with the OFT.

55. The shared functions of Monitor and the OFT do not relate to those competition rules but, rather, as Clause 67 makes express, the shared functions relate to agreements, decisions and concerted practices within s2(1) of the Competition Act 1998 and Article 101 of the TFEU and abuse of dominant position within s18(1) of the Competition Act and Article 102 TFEU.

56. The reference in the legislation to those general provisions of competition law must, at the very least anticipate that they may be applicable to health services. Otherwise, they are completely otiose.

57. Secondly, the extract also states that, by vesting powers in Monitor as a sectoral specific regulator with expertise in health care this prevents competition being applied disproportionately. Again, the government is not declaring that competition law does not apply. Indeed the fact that Monitor will be sectoral specific does nothing to limit or restrict the applicability of competition law. Simply because a particular sector is regulated does not exclude it from the

scope of competition law. Clearly however, sectoral expertise will inform Monitor's approach to competition law and the market and economic analysis necessary in the application of competition rules, where they apply.

58. Lastly, as regards the final sentence, it stands to reason that the Bill cannot change EU competition law since the latter has supremacy over domestic law, whatever the source of that domestic law. The sentence does not suggest that EU competition law does not apply and cannot offer any comfort in that regard.

59. Essentially, the Bill cannot and does not seek to limit the application of competition law.

60. Rather, the applicability of domestic and European competition law to the NHS essentially turns on whether the entity concerned is an "undertaking" for the purposes of competition law since only agreements between undertakings and abuses committed by dominant undertakings are within the scope of the Competition Act 1998 and Articles 101 and 102 TFEU. There is no definition of the term in either domestic or European legislation and so the scope of the term has been developed and considered though the case law of the domestic and European courts. Is has been consistently held that the concept of an undertaking encompasses every entity engaged in economic activity regardless of the legal status of the entity and the way in which it is financed[10].

61. The question whether an NHS Trust is an undertaking for the purposes of competition law has been considered by the Competition Appeals Tribunal in the case of BetterCare Group Ltd (BetterCare)[11]. BetterCare was a UK provider of residential and nursing home care and complained to the OFT that North and West Belfast Health and Social Services Trust, acting as a purchaser of nursing and

[10] See for example Case C-41/90 Hofner and Elser v Macrotron GmbH [1991] ECR I-1979

[11] [2002] CAT 7

residential care home services, was abusing its dominant market position in Belfast. The OFT rejected the complaint on the basis that the Trust was not an undertaking for the purpose of competition law.

62. On appeal of the OFT's decision by BetterCare, the Tribunal determined that the Trust was acting as an undertaking both in the purchasing of services from BetterCare and the direct provision of elderly care by its own statutory homes. It relied on various factors to support its conclusion that the Trust‟s activities in running its statutory residential homes and engaging in the purchase of social care from independent providers are to be regarded as economic activities for the purpose of deciding whether the Trust is an undertaking which included, *inter alia*:

    a. The Trust, as well as providing care through its own statutory homes was fulfilling its statutory responsibility to provide care through "contracting out" or entering into commercial transactions with independent healthcare providers thus expanding the commercial market for the supply of residential and nursing care services generally and specifically by private providers to Trusts and local authorities;
    b. In providing care through its own homes it was also a participant in the market for residential care;
    c. a key consideration arising from European case law was whether the entity in question is in a position to generate the effects which the competition rules seek to prevent and the Trust was clearly in a position to do so;

63. The Tribunal remitted the complaint to the OFT for investigation which subsequently found that the Trust's conduct did not constitute an abuse of a dominant market position. The OFT did not make a finding as to whether or not the Trust was acting as an undertaking for the purposes of competition law because, at asserted, the notion of an undertaking in public sector purchasing cases under Community competition law is in a state of development[12].

[12] Policy note 1/2004: http://www.oft.gov.uk/shared_oft/business_leaflets/ca98_mini_guides/oft443.pdf

64. It may be the case that the government places all its proverbial eggs in the basket of the Court of Justice"s decision in the case of FENIN[13].

65. FENIN is an association of undertakings involved in the marketing of medical goods used in Spanish hospitals. The European Commission (the Commission) had dismissed a complaint by FENIN that various public bodies which were responsible for the management of the Spanish health service (SNS) had abused their position as dominant purchasers of the goods produced by FENIN members. The Commission's grounds for dismissing the complaint were that the public bodies in question did not act as undertakings when they purchased goods from FENIN members.

66. The Court of First Instance concluded that:

    a. it is the activity consisting in offering goods and services on a given market that is the characteristic feature of an economic activity, not the business of purchasing as such;
    b. it would be incorrect, when determining the nature of that subsequent activity, to dissociate the activity of purchasing goods from the subsequent use to which they are put;
    c. it is therefore necessary to consider whether or not the use of the purchased goods amounts to an economic activity;
    d. the body in question was managed by the ministries and other organisations cited in the applicant"s complaint, operates according to the principle of solidarity in that it is funded from social security contributions and other State funding and in that it provides services free of charge to its members on the basis of universal cover;
    e. accordingly, the purchasing activities linked to an activity which was not of an economic nature were classified in the same way and the relevant

[13] Case C-205/03 P (on appeal from Case T-319/99)

organisations were accordingly not undertakings for the purposes of Art 86 EC (now Article 102 TFEU).

67. That decision was appealed to the European Court of Justice on the ground that the Court of First Instance had misinterpreted the definition of "undertaking" in that not only had it failed to consider whether purchasing activity itself could be considered an economic activity and also whether the provision of medical care was an economic activity. The Court of Justice refused to consider the second argument on the basis that it had not been raised in the appeal before the CFI and was therefore inadmissible before it. As regards the first argument, it upheld, without any substantial reasoning, the conclusion of the CFI that, in examining whether an entity is engaging in economic activity there is no need to dissociate the purchasing activity from the subsequent use to which those purchases are put. The Court wholly failed therefore to grapple with the question whether the public body was an undertaking or any of the considerations which, in the case of BetterCare, led the Competition Appeal Tribunal to find that NHS Trusts were undertakings because they engaged in economic activity.

68. The Advocate General (who provides an opinion on each case for the assistance of the Court which opinion, though not binding is often persuasive where the Court has not disagreed with it) provided a much more illuminating analysis of the case. He, having surveyed the case law of the Court, considered that what was crucial to the question whether an entity was an undertaking was an examination the nature and degree of involvement of private entities in the provision of healthcare and the degree to which the State intended to exclude such provision from all market considerations. For that reason he considered that the CFI simply had not had enough facts before it and had not asked itself the right questions in reaching its conclusion. He recommended therefore that the appeal be upheld in relation to FENIN"s second argument and be remitted to the CFI for further consideration. The Court did not of course consider or comment at all upon the Advocate General"s conclusions since it declared the point inadmissible.

69. The sophisticated legal and economic analysis applied by the CAT to the NHS

Trust in BetterCare has simply not been undertaken at the European level in relation to the NHS and its constituent bodies. It is therefore very far from certain and it is not safe to assume that the FENIN decision determines that competition law is not applicable to the NHS, either as it currently stands or as it will emerge from the Bill.

70. There are several important factors which were not present or not considered in the FENIN case which are germane to the NHS, even as it operates today which include the following:

    a. The use of commercial providers of primary care services through APMS contracts for essential services such as out of hours services, coupled with the "Any Qualified Provider" policy and wider implementation of patient choice has led and will lead to a proliferation in private and third sector providers of healthcare (wherever based in the EU). The result is that there is a growing market in healthcare provision in which both public bodies and private companies engage and compete. There is no question but that private entities engaged in healthcare provision are undertakings for the purposes of competition law.
    b. The current internal Principles and Rules for Cooperation and Competition in themselves seek to inject market forces, promotion of choice and competition principles into the operation of the NHS and are applicable to both private and public providers, as well as commissioners.
    c. PCTs themselves do have the ability to engage in commercial enterprise under the Health and Medicines Act 1988 (see paragraph 3 above) and Foundation Trusts have the freedom under s44 National Health Service Act 2006, albeit currently restricted, to provide and charge for private health care thus themselves competing in the private healthcare market. It is more than likely that they are acting as undertakings when they engage in the provision of private health care.

71. In the light of these significant distinctions, it is indeed more likely than not that a Court or Tribunal seized of the question now would conclude, as in ***BetterCare***,

that PCTs are undertakings for the purposes of competition law. There is at the very least a considerable risk that such a finding would be made. It cannot therefore be assumed that competition law does not currently apply to the NHS system, even in the absence of reforms. This would lead to the conclusion that not only domestic but also EU competition law is in principle applicable. EU competition law will apply where the anti-competitive behaviour affects or may affect trade in goods or services between Member States.

72. The reforms under the Bill however, make it even more likely that domestic and, in principle, European competition law applies to the NHS for the following reasons:

    a. The intention of the Bill is that there will be a clearer distinction between commissioners and providers of health services which makes market economy principles easier to apply. In addition, rather than central regulation of services by the Department of Health, there will be a duty upon, inter alia, the Secretary of State and the Commissioning Board to promote autonomy of consortia and Foundation Trusts in their functions.
    b. Foundation Trusts will no longer be restricted in their provision of both NHS and private services and any cap on income earned through private services is removed. There is therefore greater scope for Foundation trusts to actively compete alongside the private sector in commercial health care provision.
    c. The membership of commissioning consortia can include commercial providers who are engaged under an APMS contract for the provision of primary medical services[14].
    d. The extension of commissioning activity to consortia is likely to result in a far greater number of commissioning bodies than at present. The continued use of APMS contracts for primary care services and the continuation and extension of the AQP policy to an increasing number of areas will lead to greater and wider participation by the private and third sector in the

[14] Clause 22: s14A

provision of an increasing range of healthcare services. In future, Foundation Trusts may potentially be competing alongside other private bidders and constituent members of consortia in tenders run by the Board and commissioning consortia.

e. The power to engage in commercial enterprise under the Health and Medicines Act 1988 is given to consortia which, as stated, may have a constituency comprised of both public and commercial health care providers [15].

f. The Principle and Rules of Cooperation and Competition are, through Regulations to be put on a statutory footing and will involve legally enforceable obligations actionable by Monitor and by private individuals in the Courts. This demonstrates a clear intention to apply market forces and the injection of competition into NHS health care commissioning and provision. Moreover, the vesting in Monitor of the function to enforce the Competition Act and European competition law signals a clear anticipation if not an intention that competition law will apply to the NHS.

73. In the light of the above, it is likely that Foundation Trusts, consortia and their constituent members will all fall within the definition of "undertaking" for the purposes of domestic and European competition law.

74. The impact of the application of competition law in practical terms for the NHS is difficult to predict, even in relation to its current operation. However a few considerations are highlighted in the following paragraphs.

75. As do PCTs currently join forces to, for example, procure goods and service, it is likely that consortia will seek to collaborate with each other in order achieve economies of scale. Not only will they need to comply with procurement law but they must also ensure that they do not otherwise operate collusively with the effect of restricting or distorting the market in, for example, the provision of health care.

[15] Clause 23: s14Z3

Further, it not impossible to imagine that some consortia or consortia networks will occupy, for example, a local or regional dominant position.

76. Where a breach of either UK or EU competition law occurs, the OFT currently has, and Monitor will have, the power to take enforcement action against the undertakings concerned. Not only can they investigate, issue directions and seek formal and binding commitments from the undertakings addressing the anticompetitive behaviour but they may also impose fines of up to 10% of turnover. Furthermore, as stated above, an agreement which breaches competition is void and unenforceable and can give rise to claims for damages from undertakings affected by the behaviour.

77. The application of competition law would not simply be limited however to the prohibition on agreements, decisions and concerted practices which restrict or distort competition, or to abuses of dominant position. It also engages the rules of State aid (Articles 107 and 108 TFEU) and mergers and acquisitions (applied and enforced through the Enterprise Act.

State aid

78. State aid is defined as an advantage, in whatever form, conferred on a selective basis to undertakings by public authorities. State aid can take the form of loans and grants, tax breaks, goods and services offered at preferential rates, or loan guarantees that render the borrower a lesser credit risk. EU law generally prohibits state aid in order that government interventions do not distort competition and intra-community trade. There are however a number of permitted exemptions from this prohibition when government interventions are generally beneficial or in the common interest. The application of these exemptions is however essentially in the domain of the European Commission and is out of the hands of national authorities.

79. State aid principles may well be applicable to the payments made by consortia to private healthcare providers where, for whatever reason, a procurement process

was not employed. Any above-market rate paid may well constitute State aid[16]. State aid law may also be applicable to the government payments made to consortia for the provision of their services.

Mergers

80. Mergers and takeovers of one company by another can be disallowed or restricted by both UK and EU competition law. The OFT (and the Competition Commission) in the case of domestic mergers and the European Commission in the case of mergers having transboundary implications if the merger has the following consequences:

    a. the enlarged company could edge out other market players
    b. the merger would result in market conditions under which innovation would be hampered
    c. the merger would result in significant reduction in cost-competition or consumer choice.

81. There is no question but that the merger rules apply to Foundation Trusts by virtue of Clause 74 of the Bill. However, it is possible that the structure of the emerging NHS may well result in various new forms of merger between healthcare organisations. The applicability of both domestic and EU merger control cannot be ruled out in circumstances wider than that envisaged by Clause 74.

Brief conclusions concerning competition law

82. The NHS has already developed a structure whereby it is more likely than not that NHS Trusts are undertakings for the purposes of competition law. The reforms brought about by the Bill merely serve to reinforce the proposition that Foundation Trusts, consortia and their members will each fall within the definition such that competition law applies to virtually the entirety of the NHS. There is

[16] Compensation provided to an undertaking for the carrying out of public service obligations may not in some circumstances be considered to be State aid but in order to escape the definition of aid, there are strict criteria established by the Court of Justice decision in Altmark which must be satisfied.

nothing in the Bill which has or can have the effect of preventing the application of competition law. Certainly, the fact that Monitor is a sectoral regulator does not and cannot have that effect. Furthermore, the enforcement of competition law is not the preserve of competition authorities since a breach of the prohibitions on anti-competitive conduct in the Competition Act and Treaty gives rises to actionable claims by private individuals in the High Court.

83. If the government wishes to protect the NHS from the application of competition law, there is little it can do unless each and every element and characteristic of the NHS structure and functioning which gives rise to both Trusts and consortia falling within the definition of "undertaking" is removed.

IN THE MATTER OF THE HEALTH AND SOCIAL CARE BILL 2011

AND IN THE MATTER OF THE DUTY OF THE SECRETARY OF STATE FOR HEALTH TO PROVIDE A NATIONAL HEALTH SERVICE

EXECUTIVE SUMMARY OF OPINION

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1. It is clear that the drafters of the Health and Social Care Bill intend that the functions of the Secretary of State in relation to the NHS in England are to be greatly curtailed. The most striking example of this is the loss of the duty to provide services pursuant to section 3 of the NHS Act 2006, which is currently placed on the Secretary of State. This will be transferred to the commissioning consortia, and reformulated accordingly. In real terms this means that, effectively, the government will be less accountable in legal terms for the services that the NHS provides.

2. Currently, the duty in section 3(1) has been delegated to Primary Care Trusts (PCTs). However, this is pursuant to statutory powers of delegation (for example under section 7 of the NHS Act 2006), and these powers can be exercised in a different way, or not exercised at all, if the Secretary of State so chooses.

3. Effectively, the duty to provide a **national** health service would be lost if the Bill becomes law. It would be replaced by a duty on an unknown number of commissioning consortia with only a duty to make or arrange provision for that section of the population for which it is responsible. Although some people will see this as a good thing, it is effectively fragmenting a service that currently has the advantage of national oversight and control, and which is politically accountable via the ballot box to the electorate.

4. As set out in case law relating to the 2006 Act and its predecessor, the NHS Act 1977, when the Secretary of State or his delegates carries out the section 3(1) duty to provide services, the duty to promote a comprehensive health service in England, under section 1(1), has to be borne in mind at all times. There will be severance between the two duties, if the Bill becomes law, as the bodies that will have the duty to arrange services pursuant to section 3(1) (the commissioning consortia) do not have a duty to promote a comprehensive health service.

5. The Secretary of State's functions are reduced to a series of powers and duties related to provision, but not including provision itself, except in limited circumstances. The exercise of all these functions, however, is subject to an autonomy or "hands off" clause. This provides that in exercising his functions the Secretary of State must, so far as is consistent with the interests of the health service, act with a view to securing that the consortia, the NHS Commissioning Board and others are free to exercise their functions

and to provide services in the manner that they consider most appropriate, and free from unnecessary burdens. This kind of wording means that the Secretary of State only has the power to act when steps to be taken are "really needed" or "essential", rather than because the Secretary of State thinks something is desirable or appropriate.

6. A court would expect the Secretary of State to demonstrate why no other course of action could be followed, which is a high test to meet. If the Secretary of State attempts to use his or her powers to impose requirements on commissioning consortia, for example, then there could well be a judicial review challenge from a consortium which opposed the requirements on the basis that they infringed the principle of autonomy and could not be justified as necessary or essential. This approach replaces the, more or less, unfettered power that the Secretary of State currently has to make directions, for example to PCTs.

7. Under the proposed new section 3(1)(d) and (e), it would be for individual consortia to decide what services under those subsections (services for pregnant and breast feeding women and children, and services for people suffering from illness, and aftercare and prevention) it is appropriate to be provided as part of the health service. This function is currently delegated to PCTs by the Secretary of State and so there is already room for different PCTs to reach different conclusions on what is appropriate. But the Secretary of State currently can give directions to PCTs as to the carrying out of these functions.

8. Under the Bill, this would be a lot more difficult in relation to consortia given the "hands off clause." Encouraged by the structure and clear intention of the Bill to give consortia autonomy from the Secretary of State, there is a real risk of an increase in the "postcode lottery" nature of the delivery of some services, depending on the decisions made by consortia in relation to these subsections. And the intention of the Bill, is that there will be very little that the Secretary of State can do about this in practice.

7. Legal challenges to the provision of health services in particular cases have always been difficult. The Bill does nothing to make the system more amenable to challenge in the courts, although the target of most legal actions will now be the commissioning consortia rather than PCTs.

IN THE MATTER OF THE HEALTH AND SOCIAL CARE BILL 2011

AND IN THE MATTER OF THE DUTY OF THE SECRETARY OF STATE FOR HEALTH TO PROVIDE A NATIONAL HEALTH SERVICE

OPINION

Introduction

1. I am asked to provide an Opinion by 38 Degrees as to the effect that the Health and Social Care Bill (the Bill) (as currently promulgated) would have on the key duties of the Secretary of State for Health in relation to the National Health Service (NHS) as set out in the National Health Service Act 2006 (NHS Act 2006).

2. The concern of 38 Degrees, Kath Dalmeny, Eamann Devlin, Joe Short and many others, is that the Bill will have the effect of removing from the Secretary of State's functions the overarching duties which ensure that the NHS is delivered

to the population of England, and by replacing those duties with much less comprehensive functions placed on other bodies much less able to ensure that a comprehensive health service is delivered.

3. I will begin this Opinion by analysing the existing functions in the NHS Act 2006 before explaining the changes that the Bill will make.

The NHS Act 2006

4. The NHS Act 2006 was a consolidating Act which essentially continued functions which were prominent in the NHS Act 1977. Many of the functions of course have an even longer history. Some of the case law I refer to below is based on the NHS Act 1977, but the points which are made apply also to the 2006 Act.

5. From the point of view of individual rights, it is well known and well documented that the nature of the duties as set out in s1-3 of the NHS Act are difficult to interpret in a way which gives any particular individual the right to a particular service. The duties are often described as ―target" or ―general" duties. Thus section 1 NHS Act 2006 says

> **1 Secretary of State's duty to promote health service**
> (1) The Secretary of State must continue the promotion in England of a comprehensive health service designed to secure improvement–
> (a) in the physical and mental health of the people of England, and
> (b) in the prevention, diagnosis and treatment of illness.
> (2) The Secretary of State must for that purpose provide or secure the provision of services in accordance with this Act.
> (3) The services so provided must be free of charge except in so far as the making and recovery of charges is expressly provided for by or under any enactment, whenever passed.

6. In *R v North and East Devon Health Authority, ex p Coughlan* [2001] QB 213, Lord Woolf commented, at paragraph 22 that

> It will be noted that section 1(1) does not place a duty on the Secretary of State to provide a comprehensive health service. His duty is "to continue to promote" such a service

7. Thus the ~~"p~~purpose" set out in s1(2) NHS Act 2006 for which the Secretary of State must provide or secure the provision of services, is the promotion of the comprehensive health service, rather than the delivery of such a service.

8. Section 2 of the NHS Act 2006 actually adds very little other than empower (rather than impose a duty upon) the Secretary of State to provide services or do anything else he considers appropriate to discharge his duty. This includes issuing guidance that trusts must have regard to; : see R v North Derbyshire Health Authority, Ex p Fisher (1997) 38 BMLR 76 , 80–81, 89–90, per Dyson J.

9. Section 3(1) is the main duty for the provision of health services. The duty is again described in general terms (rather than in terms of providing services to individuals who have particular needs), but it is, at this point in the statutory framework at least, very much a function which rests with the Secretary of State. It also lists the services that must be provided. Thus, section 3 reads as follows:-

> **3 Secretary of State's duty as to provision of certain services**
> (1) The Secretary of State must provide throughout England, to such extent as he considers necessary to meet all reasonable requirements–
> (a) hospital accommodation,
> (b) other accommodation for the purpose of any service provided under this Act,
> (c) medical, dental, ophthalmic, nursing and ambulance services,
> (d) such other services or facilities for the care of pregnant women, women who are breastfeeding and young children as he considers are appropriate as part of the health service,

(e) such other services or facilities for the prevention of illness, the care of persons suffering from illness and the after-care of persons who have suffered from illness as he considers are appropriate as part of the health service,
(f) such other services or facilities as are required for the diagnosis and treatment of illness.

10. In the *Couglan* case which I have cited above, Lord Woolf had the following to say about s3

> 23 It will be observed that the Secretary of State's section 3 duty is subject to two different qualifications. First of all there is the initial qualification that his obligation is limited to providing the services identified to the extent that he considers that they are *necessary* to meet all reasonable requirements. In addition, in the case of the facilities referred to in (d) and (e), there is a qualification in that he has to consider whether they are appropriate to be provided "as part of the health service"….
>
> 24 The first qualification placed on the duty contained in section 3 makes it clear that there is scope for the Secretary of State to exercise a degree of judgment as to the circumstances in which he will provide the services…..In certain circumstances he can exercise his judgment and legitimately decline to provide….services.
>
> **25 When exercising his judgment he has to bear in mind the comprehensive service which he is under a duty to promote as set out in section 1. However, as long as he pays due regard to that duty, the fact that the service will not be comprehensive does not mean that he is necessarily contravening either section 1 or section 3. The truth is that, while he has the duty to continue to promote a comprehensive free health service and he must never, in making a decision under section 3, disregard that duty**, a comprehensive health service may never, for human, financial and other resource reasons, be achievable. Recent history has demonstrated that the pace of developments as to what is possible by way of medical treatment, coupled with the ever increasing expectations of the public, mean that the

resources of the NHS are and are likely to continue, at least in the foreseeable future, to be insufficient to meet demand.

11. However, in *R (Booker) v NHS Oldham* [2010] EWHC 2593 (Admin) another judge having cited the *Coughlan* case, explained the s3 duty in a slightly different way when he said

> 23….Section 3 creates an enforceable duty to provide care facilities for those who are ill or have suffered illness subject to the qualification that the secretary of state or the PCT as his delegate need not provide such services where he or it does not consider they are reasonably required or would be necessary to meet a reasonable requirement

12. The *Booker* case was a case where it was possible to enforce the duty: the PCT had argued, unsuccessfully, that ongoing health services to quadriplegic woman were not a ~~"r~~easonable requirement" because she was indemnified for the purposes of paying for services privately by an insurance company.

13. The qualification added, of course, very much dilutes the enforceability of the duty described by the judge, but nevertheless the duty lies directly with the Secretary of State, or with a body (see below) that the Secretary of State has chosen to delegate it to.. Thus, section 7 NHS Act 2006 reads:-

> **7 Distribution of health service functions**
> (1) The Secretary of State may direct a Strategic Health Authority, a Primary Care Trust or a Special Health Authority to exercise any of his functions relating to the health service which are specified in the directions.
> (2) The Secretary of State may direct a Special Health Authority to exercise any functions of a Strategic Health Authority or a Primary Care Trust which are specified in the directions.
> (3) The functions which may be specified in directions include functions under enactments relating to mental health and care homes.

14. The duties set out in Sections 1 and 3 of the 2006 Act are executed on behalf of the Secretary of State by Primary Care Trusts pursuant to Section 7 of the 2006 Act and the NHS (Functions Of Strategic Health Authorities and Primary Care Trusts and Administrative Arrangements (England)) Regulations 2002 . Thus, in practice, it is the PCTs which decide which services are prioritised in each local area, on behalf of the Secretary of State. How this works was described *R v North West Lancashire Health Authority ex p A* [2000] 1WLR 977 where Auld LJ said at p 991D:

> –As illustrated in the *Cambridge Health Authority* case [1999] 1 WLR 898 and *Coughlan's* case [2001] QB 213 , it is an unhappy but unavoidable feature of state funded health care that regional health authorities have to establish certain priorities in funding different treatments from their finite resources. It is natural that each authority, in establishing its own priorities, will give greater priority to life-threatening and other grave illnesses than to others obviously less demanding of medical intervention. The precise allocation and weighting of priorities is clearly a matter of judgment for each authority, keeping well in mind its statutory obligations to meet the reasonable requirements of all those within its area for which it is responsible …
>
> However, in establishing priorities — comparing the respective needs of patients suffering from different illnesses and determining the respective strengths of their claims to treatment — it is vital for an authority: (1) accurately to assess the nature and seriousness of each type of illness; (2) to determine the effectiveness of various forms of treatment for it; and (3) to give proper effect to that assessment and that determination in the formulation and individual application of its policy."

15. However, the Secretary of State retains direction making powers in s8 of the NHS Act 2006. These directions can be about any aspect of the delivery of services or the functions which have been delegated to these bodies by the Secretary of State. For example, the Secretary of State can direct which

treatments approved by NICE (see below) should be funded. There is no statutory fetter on how or when the Secretary of State can use this power.

> **8 Secretary of State's directions to health service bodies**
> (1) The Secretary of State may give directions to any of the bodies mentioned in subsection (2) about its exercise of any functions.
> (2) The bodies are–
> (a) Strategic Health Authorities,
> (b) Primary Care Trusts,
> (c) NHS trusts, and
> (d) Special Health Authorities.

16. In summary then, these provisions contain an aspirational target duty in section 1 of the NHS Act 2006 to promote a comprehensive NHS, which the Secretary of State must always bear in mind when fulfilling the duty in s3 NHS Act 2006. That duty itself is also a general or target duty (these terms are often used interchangeably) rather than an individual duty, as it is couched in terms that mean that it is the Secretary of State's opinion as to what is necessary to meet ~~"r~~easonable requirements" for health services as a whole. In certain circumstances, though, a service user may be able to enforce at least the continuation of a service where, for example, an unlawful factor has been taken into account in deciding whether there is a reasonable requirement for the service. Such cases are, however, rare and the majority of the case law in this area consists of cases where judicial review claims have been unsuccessful.

17. In practice, the Secretary of State delegates his or her functions to PCTs, but this is something for which there is a power and not a duty, and so the Secretary of State retains overall control of the health service, which is reinforced by the additional power to give directions to PCTs and other bodies.

The Health and Social Care Bill 2011

18. Having set out the essential features of the duty to provide in the NHS Act 2006, and some of the case law which has interpreted those functions, I now turn the changes which are proposed in the Bill.

19. The Bill ended its re-committal in the Public Bill Committee on 14 July 2011, and what follows discusses the Bill as it now stands after that date. The Bill amends the NHS Act 2006 rather than repealing it, although some sections are replaced completely.

20. Thus, section 1 NHS Act 2006 will reads as follows if it is passed in its current form as proposed in the Bill:-

> **1 Secretary of State's duty to promote comprehensive health service**
> (1) The Secretary of State must continue the promotion in England of a comprehensive health service designed to secure improvement—
>
> (a) in the physical and mental health of the people of England, and
>
> (b) in the prevention, diagnosis and treatment of illness.
>
> (2) For that purpose, the Secretary of State must exercise the functions conferred by this Act so as to secure that services are provided in accordance with this Act.
>
> (3) The services provided as part of the health service in England must be free of charge except in so far as the making and recovery of charges is expressly provided for by or under any enactment, whenever passed."

21. Thus, there is no change at all in section 1(1), but as explained above the only duty her on the Secretary of State is to "promote" the comprehensive health service, rather than to provide for it, secure its provision, or make arrangements for such a service.

22. However, section 1(2) would have two changes from the NHS Act 2006 as it is currently enacted. Firstly, for the purpose of promoting a comprehensive health service, the duty is now only to ~~"s~~ecure that services are provided in accordance with this Act" rather than ~~"p~~rovide or secure the provision of services". I think this reflects the very important aspect of the Bill that may well have escaped public notice, and this is the intention clearly contained in the Bill that the Secretary of State is no longer to be involved in the direct provision of services. There is no secret about this. It is made express first by paragraph 7 of the Explanatory Notes to the Bill which states that

> 7. Part 1 sets out a framework in which functions in relation to the health service are conferred directly on the organisations responsible for exercising them and the Secretary of State retains only those controls necessary to discharge core functions. The Secretary of State will continue to be under a duty to promote the comprehensive health service, but the focus of the role of the Secretary of State will shift to public health, and there will be a responsibility (with local authorities) to protect and improve public health.

23. And by paragraph 66 of the Explanatory Notes which states

> 66. Currently, the Secretary of State is directly responsible for providing or securing the provision of all health services as set out in the NHS Act, a function which is largely delegated to Strategic Health Authorities and Primary Care Trusts (PCTs) under section 7 of the NHS Act. However, the new commissioning structure proposed by the Bill means that this would no longer be the case. Instead, the Secretary of State would have the duties described above. Direct responsibility for securing the provision of these services would be conferred on the Board and commissioning consortia by new section 1D of the NHS Act, inserted by clause 5 and new section 1E, inserted by clause 6 of the Bill.

24. The government recommends this structure on the basis that it will prevent political interference. However, another way of looking at it of course is that it removes political accountability, the only real control that ordinary voters can have on the way the NHS is delivered.

25. This can be compared with the position in relation to public health services for which as paragraph 67 of the Explanatory Notes states the –Secretary of State would however remain directly responsible" .

26. The second change is that the duty is now a duty to exercising the functions conferred by the Act as it will be amended. So, if the Bill were to confer no functions on the Secretary of State then this particular duty would have no teeth at all. More specifically, as explained below, the Secretary of State is to lose the main duty to provide services currently set out in s3 NHS Act 2006 (see above) and so the duty to promote a comprehensive health service will lose the most important function by which this is to be achieved (see further below).

27. I do not think that clause 1(3) has any substantive changes to s1(3) of the NHS Act 2006.

28. There are then a series of clause which add sections to the NHS Act 2006 after section 1. Thus, there will be a new section 1A under which the Secretary of State will have a duty to exercise functions so as to secure continuous improvement in the quality of services in relation to both illness and public health. There is a similar duty placed on the National Commissioning Board by what would be a new s13D to the NHS Act 2006. The Secretary of State and the NHS Commissioning Board are to be required to have regard to the quality standards that will be commissioned by them from the National Institute for Health and Care Excellence (NICE). NICE itself, which is currently constituted as a Special Health Authority by subordinate legislation, would become a body set up by the new statute (see Part 8 of the Bill) with members appointed by the

Secretary of State. (I do not think that this change of status will change the nature of NICE). The exact relationship between NICE and commissioning consortia appears to be something which will be developed through regulation making powers which are set out in the Bill. How this will work is presently uncertain as the the regulations have not yet been drafted.[1]

29. Section 1B is a duty on the Secretary of State to have regard to the need to reduce inequality which I doubt adds anything to the public sector equality duty to be found in s149 of the Equality Act 2010.

30. However, what is proposed to be a new section 1C of the NHS Act 2006, does seem to me to be of importance. This would read

> ~~1~~C Duty as to promoting autonomy
>
> In exercising functions in relation to the health service, the Secretary of tate must, so far as is consistent with the interests of the health service, act with a view to securing—
>
> (a) that any other person exercising functions in relation to the health service or providing services for its purposes is free to exercise those functions or provide those services in the manner that it considers most appropriate, and
>
> (b) that unnecessary burdens are not imposed on any such person."

31. Therefore, so long as the Secretary of State does not think that it is inconsistent with the interests of the NHS, s/he must positively act to allow any other person exercising health service functions to do so in the way that that person thinks appropriate. This is what I described in conference as a ~~h~~ands off" clause. Although the Secretary of State keeps some form of oversight, it is the other persons and bodies delivering the health service whose views are important as to

[1] A criticism that is sometimes made of statutes that rely on regulations to be drafted later the Secretary of State is that it is not possible from the statute itself to see the detail of how a particular system will work.

how those services are to be delivered. This is further explained in the Explanatory Notes as follows

> 74. This clause seeks to establish an overarching principle that the Secretary of State should act with a view to promoting autonomy in the health service. It identifies two constituent elements of autonomy: freedom for bodies/persons in the health service (such as commissioning consortia or Monitor) to exercise their functions in a manner they consider most appropriate (1C(a)), and not imposing unnecessary burdens from those bodies/persons (1C(b)). The clause requires the Secretary of State to act with a view to securing these aspects of autonomy in exercising his functions in relation to the health service, so far as is consistent with the interests of the health service.
>
> 75. This duty would therefore require the Secretary of State, when considering whether to place requirements on the NHS, to make a judgement as to whether these were in the interests of the health service. If challenged, the Secretary of State would have to be able to justify why these requirements were necessary.

32. This kind of wording is often used in statutes to mean that a public body only has the power to act when steps to be taken are ~~"r~~eally needed" or ~~"e~~ssential", rather than because the public body thinks something is desirable or appropriate. A court looking at this kind of wording would expect the public body (the Secretary of State in this case) to demonstrate why no other course of action could be followed, which is a high test to meet.

33. I think the reference to potential challenges at the end of this note is significant and reflects the limit of the Secretary of State's powers. If the Secretary of State attempts to use his or her powers to impose requirements on commissioning consortia, for example, then there could well be a judicial review challenge from a consortium which opposed the requirements on the basis that they infringed the principle of autonomy in the new section 1C and could not be justified as necessary or essential. This approach replaces the, more or less, unfettered power that the Secretary of State has to make directions currently to be found in s8 NHS Act 2006 (as explained above), with a duty not to interfere unless

essential to do so. It is also noteworthy that the same ~~–a~~utonomy" or ~~–h~~ands off" duty is also placed on the NHS Commissioning Board, by what would be a new s13E of the NHS Act 2006 (and it is, of course, the Board who will have closer contact with commissioning consortia than will the Secretary of State).

34. What will be s1E of the NHS Act 2006 is also important as this sets up the NHS Commissioning Board. The chair of the Board and its members are appointed by the Secretary of State. The Board will have the same promotion duty as does the Secretary of State as set out above in s1(1) above (other than in relation to the public health functions of the Secretary of State). Section 1E (3) will read

> For the purpose of discharging that duty, the Board—
>
> (a) has the function of arranging for the provision of services for the purposes of the health service in England in accordance with this Act, and
>
> (b) must exercise the functions conferred on it by this Act in relation to commissioning consortia so as to secure that services are provided for those purposes in accordance with this Act.
>
> (4) Schedule A1 makes further provision about the Board.

35. So it is the Board that has the function of ~~–a~~rranging for the provision" of services rather than the Secretary of State. The members of the Board, however, will be appointed by the Secretary of State. But the duty set out in the new s1E(3) does not set out anything about the *extent* to which services are to provided in the same way that s3(1) currently does in relation to the Secretary of State. Thus, there is no duty on the Board to provide (or event to arrange for provision of) services to meet what, in its view, are necessary to meet *all reasonable requirements*. Only the commissioning consortia will have this duty.

36. It is also noteworthy that the new ~~–c~~ommissioning consortia" will also have ~~–t~~he function of arranging for the provision of services for the purposes of the health

service in England in accordance with this Act" by way of what would be s1F of the amended NHS Act 2006.

37. But that this is not sufficient to replicate the duty in s3(1) NHS Act 2006 is clear because it is now these consortia, rather than the Secretary of State, upon which is imposed the important s3 duty which, as currently formulated, is set out above. Section 3(1) NHS Act 2006 as amended would read as follows (with the important changes in bold) :-

> **3 Duties of consortia as to commissioning certain health services**
>
> **(1)– A commissioning consortium must arrange for the provision of the following to such extent as it considers necessary to meet the reasonable requirements of the persons for whom it has responsibility.**
> (a) hospital accommodation,
> (b) other accommodation for the purpose of any service provided under this Act,
> (c) medical, dental, ophthalmic, nursing and ambulance services,
> (d) such other services or facilities for the care of pregnant women, women who are breastfeeding and young children as **the consortium** considers are appropriate as part of the health service,
> (e) such other services or facilities for the prevention of illness, the care of persons suffering from illness and the after-care of persons who have suffered from illness as **the consortium** considers are appropriate as part of the health service,
> (f) such other services or facilities as are required for the diagnosis and treatment of illness.

38. Thus, on the face of it the important duty to provide as explained above in the case of *Coughlan* and *Booker* has been transferred from the Secretary of State to the commissioning consortia. The law at present means that the Secretary of State has the power to direct that this function is carried out by PCTs or SHAs (see section 7), but the Secretary of State would always have the option to bring

the function back ~~–in~~ house" and can of course give directions to these bodies pursuant to section 8. The difference now is that the primary duty will lie with the commissioning consortia, in circumstances where the Secretary of State is also told to encourage commissioning consortia to decide for themselves the most appropriate way to do so.

39. There is not room in this advice to set out the rules for commissioning consortia, but typically they will consist of groups of local GPs who have joined to provide the services which are currently provided by PCTs and other health bodies. It is the responsibility of the Board to ensure that consortia do, in fact, cover the whole of England: see the new proposed section 14A. And a consortium will be responsible for any person in its area who is not provided with services by a member of any consortium. Nevertheless there are concerns (beyond the scope of this Opinion) that consortia will be able to cherry pick patients in a way that is not possible under the current system.

40. It is noteworthy that the Explanatory Notes do not fully spell out this change. So, paragraphs 117 and 119 explain that commissioning consortia will be the ~~–a~~ppropriate commissioner" under the amended Act, but do not explain that the duty has been removed from the Secretary of State.

> **Clauses 9 and 10 - Duties and powers of consortia as to commissioning certain health services**
>
> 117. This clause amends section 3 of the NHS Act to provide for the duties of commissioning consortia (consortia) in relation to commissioning certain health services.
>
> 119. Commissioning consortia will be the appropriate commissioner under the Act unless there is a duty on the Board to commission that service. Subsections (1) and (2) amend section 3 of the NHS Act to provide that consortia must arrange for the provision of the services and facilities in section 3(1) of the NHS Act to such extent as they consider necessary to meet the reasonable requirements of the persons for whom they have responsibility.

41. The government has recently disavowed any intention of diluting the Secretary of State's role, in its response, dated 20 June 2011, to the NHS Future Forum report. Thus, the response states

> 2.8. Our policy is that the Secretary of State will be responsible – as now – for promoting a comprehensive health service. The wording of section 1(1) of the 2006 NHS Act will remain unchanged in legislation, as it has since the founding NHS Act of 1946. We will amend the Bill to make this clear.
> 2.9. We will also make clear that the Secretary of State will retain ultimate accountability for securing the provision of services, though rather than securing services directly, the Secretary of State will be exercising his duty in future through his relationship with the NHS bodies to be established through the Bill, for example the NHS Commissioning Board by way of the ~~m~~mandate".
> 2.10. We will make clear that Ministers are responsible, not for direct operational management, but for overseeing and holding to account the national bodies – in particular, the NHS Commissioning Board and the regulators – backed by extensive powers of intervention in the event of significant failure.

42. But what this response does not make clear, is that the s3(1) duty has been lost by the Secretary of State and it has not been moved to the NHS Commissioning Board. Instead it has been moved to the commissioning consortia.

43. The Secretary of State does retain the power to make regulations which mean that it is the Board rather than the commissioning consortia who provide a particular service: see the proposed new s3B. But this power only relates to a limited group of services[2], and the Bill is worded in such a way that this is

[2] (a) dental services of a prescribed description;

(b) services or facilities for members of the armed forces or their families;

(c) services or facilities for persons who are detained in a prison or in other accommodation of a prescribed description;

(d) such other services or facilities as may be prescribed.

clearly seen as a step that would be unusual, and not apply to the provision of mainstream services.

44. The next change worth mentioning is to the nature of the duty itself. The current s3(1) fixes the Secretary of State with the duty to ~~"p~~provide" services ~~"h~~e considers necessary to meet all reasonable requirements". Not only would the new section 3(1) transfer that duty to commissioning consortia, but the duty now is to ~~"a~~rrange for the provision" of services (and not for everyone but only those for whom each consortium is responsible). It may be that this change of wording will not make too much difference: the ~~"a~~rrange for permission" formula is used already in social care statutes like the National Assistance Act 1948 (care homes) and the Chronically Sick and Disabled Persons Act 1970 (domiciliary care), and simply indicates that the public body can, for example, contract with private or voluntary sector providers for services. But the loss of an actual duty to provide (rather than to arrange for the provision) may be seen as hugely symbolic of the dilution of the powers of the Secretary of State as set out in the Bill.

45. Finally, it is important to note that, pursuant to what would be the new s3(1)(d) and (e), it will be for individual consortia to decide what services under those subsections (services for pregnant and breast feeding women and children, and services for people suffering from illness, and aftercare) it is appropriate to be provided as part of the health service.

46. This function is currently delegated to PCTs by the Secretary of State and so there is already room for different PCTs to reach different conclusions on what is appropriate. But as set out above the Secretary of State currently can give directions to PCTs as to the carrying out of these functions, but under the amended Act as proposed by the Bill, this will be a lot more difficult in relation to consortia given the ~~"h~~ands off clause" set out above. Encouraged by the

structure and clear intention of the Bill to give consortia autonomy from the Secretary of State, there is a real risk of an increase in the postcode lottery nature of the delivery of some services, depending on the decisions made by consortia in relation to these subsections. And the intention of the Bill, it seems to me, is that there will be very little that the Secretary of State can do about this in practice, despite the duty to have regard to reducing inequalities set out in the new section 1B.

47. It should also be noted that any consortium which attempts to reduce the services which are considered as part of the health service, may well find itself coming into conflict with social services authorities. This is because by s254 and Sch 20 to the NHS Act 2006, if the services described in s3(1)(d) and (e) are not provided as part of the health service, then they will become –ecommunity care services" for which a social services authority will have the power to provide. Other than this, however, it will prove very difficult (because of the very wide nature of the power) to challenge the view of a consortium as to what is or is not to be provided as part of the health service under these subsections.

Conclusions

48. In conclusion, therefore, I comment as follows on the changes proposed in the Bill

    (a) It is clear that the drafters of the Bill intend that the functions of the Secretary of State in relation to the NHS are to greatly curtailed. The most striking example of this is the loss of the duty to provide services pursuant to section 3 NHS Act 2006, which is currently placed on the Secretary of State but which will be transferred to the commissioning consortia as explained above. In real terms this means that the

government will be less accountable for the services that the NHS provides;

(b) Although currently the s3(1) duty has been delegated to PCTs, this is further to statutory powers which can be exercised in a different way if the Secretary of State so chooses.

(c) Effectively, the duty to provide a **national** health service would be lost if the Bill becomes law, and would be replaced by a duty on an unknown number of commissioning consortia with only a duty to make or arrange provision for that section of the population for which it is responsible. Although some people will see this as a good thing, it is effectively a fragmenting of a service that currently has the advantage of national oversight and control, politically accountable via the ballot box to the electorate.

(d) As set out in case law relating to the NHS Act 2006 and its predecessor, the NHS Act 1977, when the Secretary of State or his delegates carried out the s3(1) duty to provide services, the s1(1) duty to promote a comprehensive health service in England had to borne in mind at all times.

(e) There will be severance between the two duties, if the Bill becomes law, as the bodies that will have the duty to provide services pursuant to s3(1) (the commissioning consortia) do not have a duty to promote a comprehensive health service in England.

(f) The Secretary of State's functions are reduced to series of powers of duties related to provision, but not including provision itself, except in limited circumstances as set out above (I have seen the list of functions of the Secretary of State if the Bill passes into law). And all these functions are subject to the autonomy or ~~"h~~ands off" clause as set out above which could lead to legal challenges from commissioning consortia which object to any steps proposed by the Secretary of State on the basis that they are a breach of the autonomy clause.

(g) Legal challenges to the provision of health services in particular cases has always been difficult (as explained above). The Bill does nothing to make the system more amenable to challenge in the courts, although the target of most legal actions will now be the commissioning consortia.

49. I hope I have answered the questions posed in a way which makes sense and is understandable, but if this is not the case I would be happy to revisit any aspect of this Opinion and to advise further.

STEPHEN CRAGG
Doughty Street Chambers
26 July 2011