

COMPETITION COMMISSION PRIVATE HEALTHCARE MARKET INVESTIGATION

NUETERRA SUBMISSION TO COMPETITION COMMISSION

1. INTRODUCTION

- 1.1 This submission is made by Nueterra Healthcare UK Limited ("Nueterra").
- 1.2 Nueterra is the London based subsidiary of Nueterra Healthcare International, and is an affiliate of Nueterra Holdings, whose corporate headquarters is located in Kansas City in the US. Nueterra is a developer of hospitals, surgery centres, and other healthcare providers and currently operates some 79 healthcare facilities in the US. Over the last 4 years, Nueterra has been developing its operations outside the US, including, in the last 2 years, its potential entrance into the UK private healthcare market.
- 1.3 Nueterra has been following first the OFT's and then the Competition Commission's inquiries into the UK private healthcare sector but, as our plans have been confidential and until recently relatively uncertain, we have not considered it appropriate or desirable to contribute in a way that might make our investment approach public and until now, we have not considered it necessary to do so.
- 1.4 Nueterra's business model relies on the active participation of consultants in the ownership and management of our healthcare facilities. In our view, this model makes for good and innovative management, improves quality and efficiency, and leads to better outcomes for patients and their PMIs in terms of price. If Nueterra is not able to secure the active participation of consultants, it is much less likely to invest in the UK.
- 1.5 The Provisional Findings, in which the Commission has indicated that it has concerns as to *all* types of equity participation model, save in limited circumstances, including the one upon which Nueterra's business plans are based, therefore causes us considerable concern. Further, if a remedy of the breadth and uncertainty set out in the Remedies Notice was introduced, this could have profound implications for our plans to enter the UK market.
- 1.6 Nueterra therefore considers it necessary to address this important issue by way of this submission and would welcome the opportunity to discuss these issues in more detail with the Commission.

2. BACKGROUND ON NUETERRA

- 2.1 Nueterra was established 17 years ago in the USA and currently operates 79 healthcare facilities in 27 of the American states, comprising:
- 34 ambulatory service centres (equivalent to "day surgeries" in the UK);
 - 6 surgical (acute in-patient) hospitals;
 - 8 endoscopic ambulatory care centres;
 - 2 community hospitals (serving medical and surgical patients); and
 - 29 physical therapy centres.
- 2.2 Through these facilities, Nueterra currently is in partnership with over 2,500 consultants and party to 15 ventures with several well established healthcare providers.

The Nueterra Healthcare Philosophy and Approach

- 2.3 Nueterra's approach is based on entering into partnerships with consultants and hospital providers so that all parties' interests are aligned and focused on the key objective – the delivery of the finest quality healthcare for patients at an appropriate price. We operate in a highly competitive market place in the US and need to work with our consultants and investors constantly to improve quality to attract patients. The active participation of consultants facilitates our ability to deliver the efficiencies necessary to enable us to compete in a clinical sense, and also aligns their interests most directly with both patients and the facilities in which their patients are treated.
- 2.4 At the heart of our business model is the relationship with our consultant partners who are invited to make a financial investment in a medical facility. Our experience confirms that consultants who have made this financial and emotional commitment to the operation of "their" hospital are focused on the long term success of the project. We see this as an extension of the consultant's practice.
- 2.5 It is Nueterra's expectation that a consultant will refer all potential suitable patients to the facility in which the consultant invests but there is no obligation to do so, nor any direct financial reward by reference to the number of referrals. The only requirement is that the consultant is a practising consultant at the facility in which he/she invests; if a consultant stops practising at the facility for whatever reason, the joint venture company has a right to buy back the shareholding. Nueterra's joint venture arrangements in the US also include a restriction on the consultant which limits his/her ability to take an ownership interest in another facility within a certain geographical area, but this does not limit in any way the consultant's ability to practise at and/or refer patients to a competing facility.
- 2.6 Nueterra intends that its Consultant Ownership model in the UK would be based on the following principles, similar to the equity joint venture model which Aspen supports in its submission to the Commission dated 25 May 2013:
- Nueterra owns the majority stake in a facility and consultants are eligible to own up to 49% (consultants will each have a very small shareholding of 1-3%, possibly up to 5% but this is unusual);
 - All shares are priced at the outset based on the capital needs of the venture and all parties (consultants and non-consultants) pay the same price per share, up front, in cash. All participating consultants therefore pay a fair market price for their shareholding. No consultant is ever "gifted" shares on the basis of a commitment to make referrals (which appears to be the Circle model), and referrals are not required as a condition to ownership;
 - After start up, the price of the shares is based on the financial performance of the venture;
 - When profits are available they are distributed on a pro rata basis (in accordance with a pre-determined formula) linked to the proportion of the consultant's interest and not to the revenue which the consultant brings to the hospital. Losses are shared in a similar fashion. Through this model, all risks and rewards are therefore shared equally by all equity investors;
 - There is no direct financial reward linked to the number of referrals made;
 - Consultant owners are involved in the management of the facility at every level of the organisation. Consultants act as Board Directors and chair clinically focussed Board committees e.g. Medical Executive Committees;
 - Consultants would be expected to make referrals based on what is in the best interests of their patients. In our US facilities, consultants are required

to exercise a duty of care towards their patients by the by-laws of each facility and a consultant can, in any event, refer a patient to a facility only if it meets the needs of the patient. This is consistent with the requirements of the UK General Medical Council to always act in the best interests of the patient¹, with the potential for disciplinary action; and

- The arrangement is transparent to patients. In the US, it is a legal requirement that consultants must inform patients of their investment at the time any referral is made to a facility. The consultant's interest is also disclosed on the medical consent form which the patient is required to sign before he/she receives treatment. Nueterra would impose similar requirements on consultant owners in the UK and such requirements could form part of the Commission's transparency remedies.

Our philosophy for success

2.7 Nueterra seeks to operate in the spirit of true partnership, sharing risks and rewards based on a pro-rata equity investment and active clinical management, to provide better quality and value for patients. We partner with hospital providers and their consultants in a framework that enables all the parties to deliver:

- Better clinical outcomes and higher levels of patient safety;
- World class standards of patient experience and satisfaction;
- Increased operational efficiency; and
- Better care at a lower cost.

Hospital Development Expertise and Resources

2.8 Nueterra has a proven track record in the development and operation of new stand-alone healthcare facilities over the last 17 years in the US that deliver quality healthcare at competitive prices in mature healthcare economies. We have a dedicated team of in-house experts, along with extensive resources, to manage the complexity implicit in the development, financing and operation of new hospitals. Nueterra is an investor of its own equity/ risk capital in all its projects.

International Strategy

2.9 Nueterra is now applying its experience and principles internationally to deliver borderless healthcare. All our facilities will share clinical knowledge, ideas and investment capital, facilitating interaction between consultants around the world.

2.10 In the UK and in Europe we plan to develop new hospital and day surgery centres based on the partnership model described above. We are also planning to purchase existing facilities in areas where we believe we can compete by delivering better value for patients through the provision of better care and lower prices. We do not, as yet, have any operational units in Europe but we are in the advance stages of development of a number of projects.

3. KEY ISSUES

3.1 Nueterra wishes to respond to the Commission's provisional findings specifically in so far as they relate to clinician incentives and, in particular, to make the following key points:

¹ GMC *Good Medical Practice (2013)*, including the requirement at paragraph 78: "You must not allow any [financial] interests you have to affect the way you prescribe for, treat, refer or commission services for patients".

- Nueterra supports the Commission's provisional findings that short term incentives, by way of cash or kind, given to consultants to encourage the referral of patients to a particular hospital and which motivate directly based on the value or volume of referrals made (which can be used as a barrier to entry by incumbent operators) are unethical and should be prohibited, as they are in the US.
- As to long term incentives, we are concerned that the Commission has not sufficiently distinguished between the "gift" of an equity interest to a consultant in exchange for a binding contract to refer patients to the relevant facility and the cash investment by a consultant into a partnership, with others, to develop and operate a private hospital ("the Consultant Ownership model").
- Based on our experience in the USA, we wish to demonstrate that our Consultant Ownership model is pro-competitive as it creates cost efficiencies and promotes a higher quality of service and facility and represents an additional successful business model that, if adopted more widely in the UK, would increase competition and choice in the private hospital market.

4. CONSULTANT INCENTIVES

- 4.1 The Commission has examined a range of incentives offered by private hospitals to consultants to encourage referrals or treatments at their facilities and sets out its provisional conclusions in respect of their competitive effects. A distinction is drawn between short term or direct incentive schemes where the value of the incentives is dependent on the number or value of referrals made by an individual consultant, and long term or indirect incentive schemes where the value of the incentives depends on the conduct of a number of the scheme's participants, including equity participation schemes.
- 4.2 The examples of direct incentives given by the Commission in its report are rewards for referrals, either in cash, equity or 'kind', eg subsidised consulting rooms, the provision of nursing staff, administrative support etc, the provision of which is explicitly or implicitly linked to hospital income generated by consultants.
- 4.3 In comparison, indirect incentives are referred to as usually taking the "*form of equity or some other form of profit-sharing where the incentive effect arises from the fact that directing a patient to a particular hospital is likely to increase the profits of that hospital in the longer term.*" A number of examples of such arrangements are referred to in the report, for example the Partner/consultant model employed by Circle when setting up its private hospital in Bath. Pursuant to this business model, in return for committing to undertake a certain proportion of their work at a Circle facility, consultants are entitled to an equity stake in the Circle partnership and a role in managing and organising the delivery of services². In terms of equity participation schemes, the Commission also refers to the joint venture arrangements involving Aspen³ and some joint venture and co-investment vehicles involving BMI⁴.
- 4.4 The Commission acknowledges that the incentive effect of indirect incentive schemes is likely to be lower than, e.g. fee for referral schemes, as the percentage share of total profit accruing to the individual consultant is likely to be low and less immediate. However, the Commission considers competitive harm may arise from *both* direct and indirect incentive schemes as they incentivise consultants to refer patients to, or treat patients at, a hospital that they otherwise would not have selected had their decisions

² Paragraphs 8.73 to 8.77 of the Provisional Findings. The consultants holding the equity interests do not have to pay for the shares up front on allotment, only when they wish to sell them. The consultant may terminate his/her commitment with 12 months' notice at any time following the first anniversary of the relevant facility's opening (Appendix 6.1 to CC's report).

³ Paragraphs 8.87 to 8.90 of the Provisional Findings.

⁴ The precise terms of the BMI arrangements are not disclosed in the report.

been based on price and quality considerations alone. The Commission considers that this could lead to hospital operators choosing to compete with each other over rewards to consultants rather than on the basis of quality or price and, as such, this distorts competition.

- 4.5 While the Commission provisionally concludes that both types of incentive schemes can have an adverse effect on competition, it acknowledges that some long term incentive schemes can sometimes have pro-competitive effects that outweigh any anti-competitive effects. This conclusion is based on the evidence, referred to in the report, to the effect that the success of the few private hospital operators who have successfully entered the market in the last five years has been largely due to their offering of equity participation schemes to consultants. These schemes incentivised consultants to commit in advance to working at the new hospital which commitments, in turn, strengthened the viability of the hospital's business plan and its ability to obtain financial backing.
- 4.6 The Commission's proposed remedy is to prohibit private hospital operators from offering to consultants *any* incentives, in cash or kind, which are intended to or have the effect of encouraging consultants to refer patients to or treat them at its hospitals. Equity participation schemes will also be prohibited unless it can be demonstrated that *"such ownership results in a reduction in barriers to entry that is likely to be at least as beneficial to competition as any distortion is harmful."*
- 4.7 There are aspects of the Commission's analysis that we endorse. Nevertheless, we are concerned that any and all forms of arrangements with consultants appear to be captured under the "umbrella of concern" set out by the Commission with only a very vague and uncertain caveat where *"equity ownership results in a reduction in barriers to entry that is likely to be at least as beneficial to competition as any distortion is harmful."*⁵
- 4.8 We believe that there are important distinctions between the types of arrangements addressed by the Commission's provisional findings. It is one thing for a hospital to give a consultant free office space or to pay a consultant for referring patients to the hospital; but it is quite another for a consultant to make an investment in a hospital facility that is subject to risk of loss with no referral requirement. We believe that if all arrangements between consultants and hospitals are eliminated then competition, quality of service, price and efficiency will suffer. As a result, the Commission's proposed remedy is disproportionate and insufficiently targeted on the issues of genuine concern.

5. THE CONSULTANT OWNERSHIP MODEL IS PRO-COMPETITIVE

- 5.1 The Commission's provisional finding that all types of consultant incentive schemes (potentially including the Consultant Ownership model) are capable of having an adverse effect on competition appears to stem from two main theories of competitive harm:
- First, that consultants might be inclined to refer patients to or treat patients at a hospital they would not otherwise have chosen on the grounds of either quality or of price, exploiting an information asymmetry between patient and clinician; and
 - Second, consultants might be induced to increase the number of referrals leading to over-treatment and over-diagnosis. The Commission recognised, however, that incidents of over-treatment are likely to be few and far between; incentives to conduct unnecessary diagnostic tests or consultations were more likely to have an effect on consultants' behaviour.

⁵ Paragraph 8.134 of the Provisional Findings.

Anti-competitive incentive structures

- 5.2 We would agree that short-term incentives offered to consultants specifically to reward referrals to a particular facility and which may increase in line with the number of referrals, could have such negative effects. Indeed, we do not support equity participation schemes which are based on "gifted" shares which also require referrals to the facility, as these are also capable of having the negative effects outlined by the Commission to the detriment of patients. In our opinion, these arrangements are inappropriate as they amount to an incentive in its purest form and are unethical.
- 5.3 In fact, these types of schemes – either the gifting of shares or the imposition of referral requirements – are already illegal in the US. In the US, an investment by a consultant in a healthcare facility must be for cash and the hospital cannot lend money to a potential investor. We therefore support the prohibition of such short-term incentives in line with the approach in the United States (which is described in more detail below).

The benefits of the Consultant Ownership model

- 5.4 In our view, the Consultant Ownership model creates benefits for patients and PMIs and is pro-competitive because:
- (i) ***The incentive to refer is based on the facility being suited to and equipped for the consultant's requirements:***
- The consultant does not receive any direct financial benefit from referring a patient to the facility and is under no obligation to do so⁶. The value of the consultant's interest in the facility and his/her share of the profits are not related to the number of referrals made by that consultant. The decision to refer to the facility will therefore be made on the basis that it is the best facility for that consultant to perform the relevant procedure. The facility will have been designed or chosen to meet the requirements of that consultant (acting as an extension of his/her practice) and will be under on-going management by the consultant. It follows that if the facility is best placed for the consultant to treat the patient, it is usually the best place for the patient to be treated. In this sense, the interests of the consultant and the patient are aligned.
- (ii) ***The interests of the hospital and the consultant are aligned in terms of driving efficiencies and providing a high quality service:***
- Our experience confirms that consultants who have an equity interest in a hospital also have an emotional commitment to its operation and are focused on the long term success of the hospital. This success is achieved by delivering better quality and better value healthcare. As co-owners, consultants have the right and the responsibility to participate in the management of the facility and in the care of its patients. Consultants act as board directors and chair clinically focused board committees. This direct involvement of the consultants in the management and operation of their hospitals is testimony of the aligned interest; there is a mutual desire to drive efficiency and lower costs leading to better value services and improved quality of care. Consultants have an on-going incentive to ensure that the facility in which they practice is efficient and of a high quality as this the basis for long-term success and profitability.

⁶ The only requirement is that the consultant will be obliged to sell his/her shares if he/she stops practising in the facility altogether and he/she may also be restricted from investing in a competing facility in the same geographical area, as mentioned above.

- The success of the Consultant Ownership model is supported by consumer survey results and the US Government's own report on quality outcomes, which place consultant-owned facilities in the top tier categories for quality and consumer satisfaction⁷.

(iii) *The arrangements are transparent. The patient is made aware of the consultant's interest and is able to make an informed choice:*

- As described above, it is a requirement of US law that the patient is informed up front about the consultant's interest in the facility before any referral and Nueterra would propose to impose similar requirements in the UK. Although the patient's choice may be based (as in the UK) on the consultant's preference (as to the best facility for him/her to perform the procedure), the US patient is nevertheless likely be aware of, and to consider, competing options in the market. It is fair to say that the US patient is probably "savvier" in this sense than the UK patient due to the (privatised) nature of the US system and the prevalence of such ownership models. However, this is something to be encouraged in the UK; the patient should be made aware of his/her "buyer" power in the decision-making process.

(iv) *We are not aware of a link between over-treatment or over-diagnosis and consultant ownership schemes:*

- The Commission acknowledges in its provisional findings that examples of over treatment as a result of consultant incentives is low thereby acknowledging that, in general, consultants will act in the best interests of their patients which we would take as a given. The Commission suggests however that there may be an incentive to over-refer for diagnostic testing, particularly where the diagnostic equipment has been purchased by a group of consultants. In the US, there have been a number of studies to examine the possibility that consultant owned hospitals in the US increase utilisation and there is no clear evidence that this is the case.
- In our view, even if there were such an incentive towards greater utilisation, this is constrained by the PMIs. A PMI will generally agree to cover a certain number of tests or will pay a bundled fee which relates to the overall treatment of a patient (this is part of a general increasing trend towards "payment for outcomes") such that any additional tests would be at the cost of the healthcare provider and, therefore, there would be a positive disincentive to over-treat or test.

(v) *The Consultant Ownership model is an important investment model which facilitates entry and therefore increases competition and choice in the market, to the benefit of patients and PMIs:*

- The purchase of equity interests in healthcare facilities by consultants enables the facility to raise additional capital to help overcome the significant cost barriers to entry, which the Commission acknowledges in its provisional findings, while simultaneously generating consultant commitment to the new facility. As the Commission acknowledges, the costs involved in developing a new hospital act as a significant barrier to entry. Equity participation schemes are one of the ways of encouraging consultants to support a new

⁷ See attached to this Submission: (i) A list of 2012 award winning facilities in a Press Ganey poll of consumer satisfaction and note that, although consultant owned hospitals make up less than 10% of all hospitals in the US, they make up more than half of the winners in this poll; and (ii) The results of a report on hospital value-based purchasing released by the Centres for Medicare & Medicaid Services in December 2012, which shows that when the Federal Government sorted through the clinical information it was using to reward hospitals for providing higher-quality care, 9 out of 10 of the top 10 performing hospitals were consultant-owned, as were 48 of the top 100, again, bearing in mind that consultant-owned facilities represent less than 10% of all hospitals in the US, this demonstrates the fact that they generally provide higher quality care.

entrant, thereby facilitating entry and increasing competition. Any restriction on the use of the Consultant Ownership model in the UK in the form adopted by Nueterra would unnecessarily increase barriers to entry and reduce the potential for a more competitive private healthcare market with improved choice and quality and downward pressure on price;

- The fact that equity ownership can greatly lower entry barriers, benefit competition and improve the quality of healthcare services was the conclusion of a 2004 study commissioned by the United States Department of Justice and the Federal Trade Commission titled "*Improving Health Care: A Dose of Competition*". The study broadly examined the state of the health care marketplace and the role of competition, antitrust and consumer protection in satisfying preferences for high-quality, cost-effective healthcare. The report discusses the anticompetitive potential of state imposed regulations and restrictions, including their "chilling effect" and concludes that equity ownership can greatly lower entry barriers, benefit competition and improve the quality of the healthcare services provided⁸.

5.5 For the reasons set out above, it is Nueterra's view that the Consultant Ownership model, although it may create an indirect incentive for consultants to refer business to the facility, is overall pro-competitive in that it creates direct benefits for patients and represents an additional successful business model that, if adopted more widely in the UK, will increase competition and choice in the private hospital market.

6. THE COMMISSION'S PROPOSED REMEDY 4

6.1 The Commission has proposed a remedy (Remedy 4) preventing private hospital operators from offering to consultants any incentives, in cash or kind, which are intended to or have the effect of encouraging consultants to refer patients to or treat them at its hospitals except where such ownership results in a reduction in barriers to entry that is likely to be at least as beneficial to competition as any distortion is harmful.

6.2 For the reasons set out above, because consultant ownership schemes are essentially pro-competitive, we believe that they should be excluded from the application of this remedy. Other measures which are designed to address potential information asymmetries for patients would further mitigate any perceived risks in this respect.

6.3 Moreover, we believe that a remedy in the terms set out by reference to such a vague criterion which prohibits all schemes "*except where such ownership results in a reduction in barriers to entry*" would be difficult to enforce and would lead to considerable uncertainty, dampening incentives to invest in the UK private healthcare market. To avoid this risk, we consider that Consultant Ownership models should be excluded from the remedy provided that:

- Consultants pay fair market value for their shares (at start up stage reflecting the level of their capital investment);
- Profits and losses are distributed on a pro-rata basis, i.e. based on the level of ownership interest, not on the level of referrals;
- Consultants are not contractually bound to make referrals to the facility and there are no short term financial rewards linked to referrals; and

⁸ The conclusions in the study were based on: 27 days of Joint Hearings from February to October 2003; a Commission-sponsored workshop in September 2002; and independent research. The Hearings gathered testimony from approximately 250 panelists, including representatives of various provider groups, insurers, employers, lawyers, patient advocates, and leading scholars on subjects ranging from antitrust and economics to health care quality and informed consent. The Hearings and Workshop elicited 62 written submissions from interested parties.

- The consultant is obliged to disclose his/her interest to all patients (and possibly also on some central system which can be accessed by all).

6.4 We have set out below our initial views in response to the Commission's specific questions in relation to Remedy 4. We may make further comments on these points as the procedure unfolds.

(a) Is the remedy practicable? What framework of rules could be used to determine reasonably and practically whether the benefits of an incentive scheme in terms of lowering barriers to entry, outweighed the distortions created? What degree of oversight would be required to monitor compliance and who should fund it and exercise monitoring? How could the 'fair market price' test be monitored and enforced and who would be responsible for doing so?

6.5 We consider this remedy is not practicable as suggested. Any remedy which involves a benefit-burden analysis would be too subjective, difficult to apply and overly burdensome and, as such, could have a chilling effect on new entry using such models, which we understand is not the Commission's intention. However, a remedy could be put in place using a simple framework of rules which excludes the Consultant Ownership model as described above and other arrangements involving payments to reflect an amount that parties would pay if there was no referral relationship between them (that is, a "fair market price"). For those relying on protected fair market price arrangements, the level of oversight would not have to be substantial. For example, if a consultant fails to pay a fair market price, it could lose the right to practise. This should be easy enough to self-assess (based on the level of investment, relationship to cost, industry benchmarks etc) and to monitor if the relevant body has the ability to request evidence (in response to complaints, for example). A consultant could be required to disclose on a periodic basis the existence of any such relationships to relevant regulatory bodies and/or to patients (as part of the proposed transparency remedies).

(b) Is the remedy reasonable? Should certain kinds of arrangement still be permitted and if so which? Should, for example, those with a value of less than a certain amount, be deemed 'de minimis'? If so, what should this figure be?

6.6 We consider the remedy would be reasonable only if it excludes certain arrangements involving equity ownership by consultants – we would suggest those which meet the conditions in paragraph 6.3 above – and any other arrangements under which the consultant pays fair market value for the items or services provided, and provided that healthcare service providers and consultants have an objective method for determining compliance with the remedy.

6.7 It may be helpful to introduce a *de minimis* exclusion for gifts, for example, Christmas bonuses or presents, for a value under £100 for example.

(c) Is the remedy comprehensive? Should it apply to other healthcare service providers such as laboratories or firms supplying diagnostic services such as imaging, for example? Should PMIs be permitted to operate incentive schemes which reward consultants who recommend cheaper treatments or less expensive hospitals?

6.8 We consider that all healthcare service providers should be encouraged to produce better outcomes, and create operational efficiencies which lower costs. For example, a PMI should be permitted to reward consultants who recommend less expensive items, services, treatments, and/or healthcare service providers, to the extent the quality of care provided in connection with the less expensive option is comparable. We believe all stakeholders in the healthcare industry have a duty to control the rising costs of care and to work collaboratively to provide the best outcomes.

(d) Are there regulatory regimes in other jurisdictions that the CC could learn from in the context of remedy specification and implementation? Would, for example, the Stark Law

in the USA, be a useful model as regards restrictions on the commercial relationships between healthcare facilities and clinicians and their introduction?

- 6.9 We believe the Stark law, and another model in the USA, called the Anti-Kickback Statute, are useful models in terms of guidance as to the parameters of any remedy in the UK relating to consultant incentives. Both regimes protect certain arrangements that might otherwise be prohibited.
- 6.10 Under the Stark law, consultant owned facilities are permitted provided that the parties meet the requirements of an exception; if the investment is purchased on the same terms as other non-referring individuals and where the return on the investment is made in proportion to the amount of capital actually invested by the individual. Under the Anti-Kickback Statute, it is prohibited for any person to knowingly and willfully solicit, receive, offer or pay anything of value to induce referrals of items or services payable by a government healthcare program, subject to certain arrangements which fall within a "safe harbor." Meeting a safe harbor is not required, but rather it gives the parties the comfort of knowing the government will not prosecute the arrangement. And failure to meet a safe harbor does not necessarily mean the parties have violated the Anti-Kickback Statute, if they can establish that they did not have an improper intent.
- 6.11 Like the Stark law and Anti-Kickback Statute, the framework of rules under Remedy 4 should provide clear guidelines for determining compliance with the underlying rule and also with the applicable exception and/or safe harbor; permitting certain arrangements involving equity ownership by consultants.

(e) What would be the cost of implementing this remedy, particularly in terms of unwinding existing equity sharing arrangements? Would it be necessary or desirable to 'grandfather' existing arrangements?

- 6.12 We feel strongly that equity sharing arrangements, including existing arrangements, should continue to be allowed if the consultant pays an amount that is equal to fair market value for the equity received. We consider that equity participation schemes which fall within the category of excepted arrangements as described above should be allowed to remain in place. More generally, we do not have a view on how existing arrangements which do not fall within the excepted arrangements should be unwound, but expect that a period of transition should be permitted.

(f) Particularly in the context of market entry and expansion, are any relevant customer benefits likely to arise from equity participation by consultants in hospitals that would not otherwise be available?

- 6.13 As we have described in detail above, our experience confirms that consultants who have an equity interest in a hospital also have an emotional commitment to its operation and are focused on the long term success of the hospital. This success is achieved by delivering better value healthcare. As co-owners, consultants have the right and the responsibility to participate in the management of the facility and in the care of patients. This direct involvement of the consultants in the management and operation of the hospitals ensures patients benefit directly from reduced costs and improved quality of care.

1 October 2013