Private and Voluntary Healthcare

Care Standards Act 2000

Regulations and National Minimum Standards
Consultation Document

DH INFORMATION

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Description	The Department plans to make major changes to the way that health and adult social care is regulated and performance managed from a currently planned date of April 2009. The consultation document contains the proposed changes to the regulations governing the independent healthcare and contains the proposed changes to the regulations governing the independent healthcare sector and proposed changes to the associated National Minimum Standards (NMS).	
Cross reference		
Superseded Docs		
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Private and Voluntary Healthcare

Care Standards Act 2000

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Consultation Document

March 2008

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Chapter 1: Introduction

1.1 The Government regulates private and voluntary healthcare in England to ensure that providers in this sector meet appropriate standards of quality and safety when providing services to the public. This consultation contains proposals to amend the regulations govering private and voluntary healthcare in England to:

- remove certain private and voluntary healthcare services from regulation by the Healthcare Commission; and
- ensure that there is clarity about how certain regulations should apply to private and voluntary healthcare.

1.2 Chapter 2 of this document gives details about how private and voluntary healthcare is currently regulated, the rationale for the current proposals for change, and how these proposals relate to the Department of Health's programme of system reform in health and adult social care. Chapter 3 contains the proposals to remove certain private and voluntary healthcare services from Healthcare Commission regulation, and Chapter 4 discusses a range of proposed minor amendments intended to ensure that the regulation of private and voluntary healthcare continues to work as intended. Chapter 5 contains details of how to respond to the consultation.

1.3 Annex 1 contains the proposed draft amendment regulations, and Annex 2 contains suggested revisions and additions to certain national minimum standards (see Chapter 2 for details of the role and purpose of national minimum standards). Finally, Annex 3 contains the draft Partial Impact Assessment, which sets out the costs, benefits and regulatory impact of these proposals.

Chapter 2: The regulation of private and voluntary healthcare

2.1 The Care Standards Act 2000 updated the regulatory framework for care services, including private and voluntary healthcare services in England, and established a new, independent regulatory body in the National Care Standards Commission (NCSC). From April 2004, NCSC's powers in relation to private and voluntary healthcare regulation transferred to the Commission for Healthcare Audit and Inspection (CHAI). CHAI operates under the name of the Healthcare Commission.

2.2 The Act provides the Secretary of State with the power to make regulations to lay down requirements which have to be met by providers of private and voluntary healthcare. The main requirements are set out in the Private and Voluntary Health Care (England) Regulations 2001 (S.I 2001/3968) (the PVH Regulations). Private or voluntary organisations providing healthcare services as defined in the 2000 Act and the PVH Regulations are required to register with the Healthcare Commission and to meet the requirements of the legislation before they can provide services. The Healthcare Commission assesses and inspects all registered providers to ensure that they are complying with the requirements set out in the legislation.

2.3 The Care Standards Act 2000 also provides a power to publish statements of national minimum standards in order to set out the Secretary of State's expectations in more detail. The Healthcare Commission is required to take these national minimum standards into account when determining whether providers are complying with the requirements set out in the PVH Regulations.

Rationale for the proposals for change

2.4 In recent years healthcare has undergone fundamental changes designed to make services better for patients and service users. But more can be done to ensure better services, and we are currently undertaking a major programme of further reform to health and adult social care. This programme will put patients and service users at the forefront of driving forward improvements to services through increased choice and improved commissioning. As part of that programme we plan, subject to the passage of legislation, to replace the current regulatory bodies covering health and social care from April 2009 with a new single regulator the Care Quality Commission which will build on the work of the existing commissions and which will operate an integrated, risk-based, proportionate system of regulation to ensure that providers of he–alth and adult social care services – whether in the private or public sector – meet essential levels of quality and safety in the services which they provide to the public.

2.5 These proposals were first set out in the consultation document "The future regulation of health and adult social care in England"[1] The Department will shortly launch a consultation on the next phase in the development of the new regulatory system. In particular, the forthcoming consultation will seek views on: which health and adult social care activities should require registration with the Care Quality Commission; and what the requirements for registration should be.

2.6 However, it is important that the Department continues to fulfil its responsibility to regulate effectively in the run-up to these changes. Effective regulation is proportionate, risk-based and transparent, and the proposals set out in this consultation will ensure that our regulatory system for independent healthcare continues to deliver assurances of quality and safety for patients while not placing inappropriate or unnecessary burdens on independent sector providers. In addition, the Department believes that the changes proposed in this consultation are consistent with the type of regulatory framework envisaged for 2009 onwards.

1 This document can be obtained from the "consultations library" on the Department of Health's website – the web address is www.dh.gov.uk

Chapter 3: Removal from Healthcare Commission regulation of certain private and voluntary healthcare services

3.1 As mentioned in Chapter 2, the Government's approach to the regulation of businesses calls for proportionate and risk-based regulation. Having considered the private and voluntary healthcare services currently subject to regulation to establish whether all regulation continues to be proportionate and risk-based, the Department of Health believes that the following services do not need to continue to be regulated by the Healthcare Commission in order to ensure the provision of safe and effective services.

Deregulation of Type 3 hyperbaric oxygen chambers

3.2 At present all types of hyperbaric oxygen therapy (HBOT) are prescribed as listed services in regulation 3(1)(e) of the PVH Regulations. The Department categorises hyperbaric oxygen chambers into three types, depending on the level of critical care management provided. While Type 1 and 2 chambers are primarily used for patients who need critical care and whose treatment is supervised by a medical professional, Type 3 chambers are mainly used for the treatment of patients with neurological disorders for which hyperbaric treatment on the NHS is not clinically indicated, and this treatment does not take place under medical supervision. All three types of chamber were regulated due to the perceived risks of fire and oxygen toxicity.

3.3 No adverse incidents of these types have been reported to the Healthcare Commission (or previously the NCSC) since regulation of these establishments began in 2002, or to the Health and Safety Executive. Infection control, which was also perceived as a potential risk that warranted regulation, has not in fact proved to be a serious concern either. We believe that a key reason for this is the range of rigorous, regular inspections of chambers that is needed to satisfy maintenance, insurance and health and safety requirements.

3.4 Given the existence of this range of safety checks, the benefit of registration and regulation by the Healthcare Commission in terms of improved safety of Type 3 chambers is questionable. Therefore, to help relieve the burden on these small establishments it is proposed to deregulate Type 3 hyperbaric chambers with respect to Healthcare Commission registration. Type 1 and 2 chambers would remain in regulation, given the riskier nature of these corresponding treatments.

3.5 Subject to this consultation, we propose to achieve this aim through amending regulation 3(1)(e) of the PVH regulations to provide for HBOT carried out under the supervision of a medical professional to remain in regulation, while removing all other types of HBOT from the category of listed services.

Partial deregulation of in vitro fertilisation techniques

3.6 It is proposed that some providers of in vitro fertilisation (IVF) techniques should be removed from regulation by the Healthcare Commission.

3.7 IVF techniques which require a licence under paragraph 1 of Schedule 2 to the Human Fertilisation and Embryology Act 1990 are prescribed in the current PVH Regulations as listed services, and organisations which provide these services are regulated by the Healthcare Commission. In addition, the Human Fertilisation and Embryology Act 1990 requires these services to be licensed by the Human Fertilisation and Embryology Authority (HFEA). We propose to end this dual regulation by removing these techniques from the definition of listed services. This will mean providers who provide only IVF services which require a licence under the Human Fertilisation and Embryology Act 1990 will only need to be licensed by the Human Fertilisation and Embryology Authority.

3.8 Some providers of IVF treatment also provide other registerable services. These providers will continue to register with the Healthcare Commission and be licensed by the Human Fertilisation and Embryology Authority. Where this is the case, the Commission will work with the HFEA under the principles of the Healthcare Concordat (the system operated by the Healthcare Commission, when working with other bodies, so as to coordinate and streamline their activities such as audits, reviews and inspections) to align their inspection methodologies in order to minimise the burden on providers.

3.9 Subject to this consultation, our aims would be achieved by removing regulation 3(1)(f) and amending regulation 3(2) of the PVH Regulations.

Partial deregulation of lasers and intense pulsed light sources

3.10 Some types of laser and light technologies, when used by private or voluntary sector organisations, are currently prescribed as listed services. These are:

a) Class 3B or Class 4 laser products, as defined in Part I of British Standard EN 60825–1 (Radiation safety of laser products and systems); and

b) an intense pulsed light (IPL), being broadband non-coherent light which is filtered to produce a specified range of wavelengths; such filtered radiation being delivered to the body with the aim of causing thermal, mechanical or chemical damage to structures such as hair follicles and skin blemishes while sparing surrounding tissues.

3.11 The majority of services using these types of equipment are small beauty therapy establishments which do not use them for surgical purposes or in the context of healthcare. There are currently approximately 850 establishments registered with the Healthcare Commission which provide purely cosmetic laser/IPL services.

3.12 The levels of risk involved in the use of lasers/IPL equipment for non-surgical purposes lead us to believe that the current regulatory regime is not proportionate to the risk of harm to patients. It is proposed, subject to the response to this consultation, to remove the requirement for the providers of such services to register with the Healthcare Commission.

3.13 All lasers used in surgery would remain in regulation. Subject to the results of this consultation, we intend to achieve our aims by amending regulation 3 of the PVH Regulations to remove paragraph 3(1)(a) and (b), which prescribe Class 3B and 4 lasers and intense lights as listed services, and by modifying section 2(7)(e) of the Care Standards Act 2000 to make it clear that their use for removal of hair roots, skin blemishes and thread veins should not fall within the definition of cosmetic surgery set out in that section.

Consultation questions

Q3.1 Do you agree that Type 3 hyperbaric chambers should be removed from regulation by the Healthcare Commission? If not, please explain why.

Q3.2 Do you agree that providers of IVF services in the private and voluntary sector should not need to be registered with the Healthcare Commission and licensed by the Human Fertilisation and Embryology Authority? If not, please explain why.

Q3.3 Do you agree that the non-surgical use of Class 3B and 4 lasers and intense light sources should no longer be a listed service which require providers to register with the Healthcare Commission as an independent hospital? If not, please explain why.

Q3.4 If you are able to estimate any savings which you may make as a result of no longer needing to comply with this legislation, could you please provide a figure? Could you please list which factors you have included in your estimate and explain your calculation?

Chapter 4: Other amendments to the Private and Voluntary Health Care Regulations

4.1 This chapter contains proposals to make other, relatively minor amendments to the PVH Regulations to ensure that they continue to reflect the Department of Health's policy on the regulation of these services and providers.

Clarification of the regulation of minor procedures

4.2 The Department's intention is to ensure an appropriate level of regulation for the many services which fall within the coverage of the Care Standards Act 2000. We propose to clarify our policy and ensure that services are consistent and proportionate to the level of risk.

4.3 We intend to clarify our policy intention that establishments which provide treatments involving intravenous sedation should be regulated as independent hospitals, and establishments where medical practitioners provide treatment only under oral sedation should be regulated as independent clinics. This will ensure that establishments where services are offered by medical practitioners and which only use oral sedation – for example, to relax a nervous patient during an MRI scan – are not inadvertently subject to a disproportionate regulatory regime.

4.4 We also intend to clarify our intention that establishments where medical practitioners provide minor surgical procedures under local anaesthesia, and establishments where minor podiatric procedures are provided under local anaesthesia, should not be regulated as independent hospitals.

4.5 We intend to achieve these aims by amending regulation 2 of the PVH Regulations to define local anaesthesia and modifying section 2(7)(a) of the Care Standards Act 2000 to insert a reference to intravenous sedation; and by amending regulation 3 of the PVH Regulations (draft regulations 3(3)(i) and (j)) to exempt establishments carrying out minor surgical and podiatric procedures under local anaesthesia from the definition of an independent hospital.

Refractive eye surgery

4.6 Refractive eye surgery currently falls within the definition of listed services set out in section 2(7) of the Care Standards Act 2000 because it is carried out using either anaesthesia and/or laser equipment. Our proposed amendments to regulations 2 and 3 of the PVH Regulations may remove some refractive surgery from the category of

listed services. However, we believe that the risks involved in refractive eye surgery are such that all establishments carrying out this surgery, regardless of the type of technique used, should be registered as independent hospitals. We intend to achieve this through draft regulation 3(1)(aa), which adds refractive eye surgery to the list of prescribed techniques and technologies, and which ensures that establishments which offer this service must continue to register as independent hospitals.

Amendments to limit the "another person" exemption

4.7 Regulations 3(3)(h), 4(1)(b) and 5 of the PVH Regulations currently exempt from registration establishments or agencies which provide treatment only on the basis of arrangements made by the patient's employer or "another person". This provision is designed to ensure that only services which are accessible to the general public are required to register.

4.8 However, as currently drafted, the regulation is potentially unclear about exactly who is exempt, and this has caused confusion. We therefore propose to clarify our policy intention by making it clear that the exemption is only applicable to medical services provided under arrangements made by employers, government departments and insurance companies, and that all other services are required to register. Moreover, the exemption does not apply to healthcare services arranged through private medical insurance. We intend to achieve these aims through amending regulations 3, 4 and 5 of the PVH Regulations as described above.

Unannounced visits

4.9 Regulation 26 of the PVH Regulations requires registered providers to make unannounced visits to their establishments at least once every six months to monitor the quality of service provision. While unannounced visits can be a powerful tool to ensure a "spot check" on provision, and some providers use these visits to good effect, other providers adhere to the letter rather than the spirit of the law, and in these cases visits are less effective.

4.10 We propose to amend regulation 26 of the PVH Regulations to remove the prescriptive requirement to make these unannounced visits every six months and instead allow registered providers to decide for themselves on the frequency of these visits. We hope that, by doing this, we can re-invigorate this provision and can thereby encourage providers to make more effective use of it to quality-assure their services in the future than has been the case in the past.

Consultation questions

Q4.1 Do you think that the proposed amendments to clarify our policy will ensure an appropriate level of regulation is applied to minor procedures? If not, please explain why.

Q4.2 Do you think that the proposed addition of refractive surgery to the list of prescribed techniques and technologies is necessary to preserve patient safety? If not, please explain why.

Q4.3 Do you think that the proposed amendments to limit the "another person" exemption provide sufficient clarity about which services are exempt, and capture all those instances in which medical services are not offered to the general public? If not, please explain why.

Q4.4 Do you think the existing requirement concerning unannounced visits by registered providers is effective? If not, what regulatory requirements do you think are appropriate to ensure adequate quality assurance systems?

Chapter 5: Responding to the consultation

The consultation runs from 18 March to 10 June 2008.

Hard copies of the consultation document can be obtained from:

DH Publications Orderline
PO Box 777
London SE1 6XH

Email: dh@prolog.uk.com
Tel: 08701 555 455
Fax: 01623 724 524

You will need to quote job reference number 280611.

You can respond to this consultation by email or in writing.

Responding by email

If you wish to respond by email, it would be most helpful if you could download a copy of the consultation response forms from:

www.dh.gov.uk/liveconsultations

Once you have completed your response, please email it back to:

regulations.and.standards@dh.gsi.gov.uk questionnaire

Responding in writing

If you wish to respond in writing it would be helpful if you could do so by completing the consultation response forms and sending them to the address below. If you do not want to use the consultation response form or are unable to do so, then please write with your answers and comments to:

Private and Voluntary Healthcare Consultation
Department of Health
Room 330, Wellington House
133–155 Waterloo Road
London SE1 8UG

The consultation criteria

The consultation criteria can be found on the Better Regulation Executive website at:

http://bre.berr.gov.uk/regulation/

This consultation is being conducted in line with the Code of Practice on Consultation issued by the Cabinet Office, and fulfils the following criteria:

- Consult widely throughout the process, allowing a minimum of 12 weeks for written consultation at least once during the development of the policy.
- Be clear about what your proposals are, who may be affected, what questions are being asked and the time scale for responses.
- Ensure that your consultation is clear, concise and widely accessible.
- Give feedback regarding the responses received and how the consultation process influenced the policy.
- Monitor your department's effectiveness at consultation, including through the use of a designated consultations coordinator.
- Ensure your consultation follow better regulation practice, including carrying out a Regulatory Impact Assessment if appropriate.

If you have any complaints or comments about the consultation process (but not responses to the consultation itself), please send them to:

Consultations Coordinator
Department of Health
Room 2N16, Quarry House
Quarry Hill
Leeds LS2 7UE

Email: Mb-dh-consultations-coordinator@dh.gsi.gov.uk

Freedom of information

Information provided in response to this consultation, including personal information, may be published or disclosed in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 and the Environmental Information Regulations 2004).

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, among other things, with obligations of confidence. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information you have provided we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

Annex 1: Draft amendments to the Private and Voluntary Health Care Regulations 2001

CONSULTATION DRAFT

STATUTORY INSTRUMENTS

2008 No.

PUBLIC HEALTH, ENGLAND

Private and Voluntary Health Care (England) Amendment Regulations 2008

Made - - - -	*****
Laid before Parliament	*2008*
Coming into force - -	*1st October 2008*

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 2(4), (7) and (8), 22(1) and (2) and 118(5) to (7) of the Care Standards Act 2000([2]). In accordance with section 22(9) of that Act he has consulted such persons as he considers appropriate.

Citation, commencement, application and interpretation

1.—a. These Regulations may be cited as the Private and Voluntary Health Care (England) Amendment Regulations 2008 and shall come into force on 1st October 2008.

(1) These Regulations apply in relation to England only.

(2) In these Regulations, "the 2001 Regulations" means the Private and Voluntary Health Care (England) Regulations 2001([3]).

Amendment of regulation 2 of the 2001 Regulations

2. In regulation 2 of the 2001 Regulations (interpretation), in paragraph (1), after the definition of "health care professional" insert—

""insurance provider" means—

(a) a person regulated by the Financial Services Authority who sells insurance, or underwrites the risk of such insurance, or

(b) the agent of such a person;

([2]) 2000.c.14. Section 2 has been amended by the Health and Social Care (Community Health and Standards) Act 2003 (c.43) ('the 2003 Act'), section 106 and the National Health Service (Consequential Provisions) Act 2006, section 2 and Schedule 1, paragraphs 198 and 199. Section 2(7) has been modified by S.I. 2001/3968.

([3]) S.I. 2001/3968.

"local anaesthesia" means any anaesthesia other than general, spinal or epidural anaesthesia, and shall also exclude the administration of a regional nerve block;".

Amendment of regulation 3 of the 2001 Regulations

3. In regulation 3 of the 2001 Regulations (prescribed techniques or technology and exceptions to the definition of independent hospital)—

(a) in paragraph (1)—

"(i) insert before paragraph (a)—

"(aa) refractive eye surgery;",

(ii) omit sub-paragraphs (a), (b) and (f),

(iii) at the end of sub-paragraph (d) insert "and", and

(iv) for sub-paragraph (e), substitute—

"(e) hyperbaric therapy, being the administration of oxygen (whether or not combined with one or more other gases) through a mask to a patient who is in a sealed chamber which is gradually pressurised with compressed air, where such therapy is carried out by or under the supervision or direction of a medical practitioner, except where the primary use of that chamber is—

(i) pursuant to regulation 6(3)(b) of the Diving at Work Regulations 1997([4]) or regulation 8 or 12 of the Work in Compressed Air Regulations 1996([5]); or

(ii) otherwise for the treatment of workers in connection with the work which they perform.";

(b) for paragraph (2), substitute—

"(2) Listed services shall not include in vitro fertilisation techniques, being treatment services for which a licence may be granted under paragraph 1 of Schedule 2 to the Human Fertilisation and Embryology Act 1990([6]).";

(c) in paragraph (3)—

(i) at the end of sub-paragraph (g), omit "and",

(ii) for sub-paragraph (h) substitute—

"(h) a surgery or consulting room (which is not part of a hospital) in which a medical practitioner provides medical services only under arrangements made on behalf of the patients by—

(i) their employer,

(ii) a government department or any executive agency of a government department,

(iii) a prison or other establishment in which the patients are held in custody, other than pursuant to any provision of the Mental Health Act 1983([7]), or

(iv) an insurance provider with whom the patients hold an insurance policy, other than an insurance policy which is solely or primarily intended to provide benefits in connection with the diagnosis or treatment of physical or mental illness, disability or infirmity;", and

(iii) after sub-paragraph (h) insert—

"(i) an establishment which is a hospital by virtue of section 2(7)(a) of the Act solely because it provides—

(i) nail surgery,

([4]) S.I. 1997/2776.
([5]) S.I. 1996/1656.
([6]) 1990 c.37.
([7]) 1983 c.20.

(ii) nail bed procedures, or

(iii) curettage, cautery or the cryocautery of warts, verrucae or other skin lesions,

on any area of the foot and uses local anaesthesia during that procedure; and

(j) an establishment which is a hospital by virtue of section 2(7)(a) of the Act solely because a medical practitioner provides curettage, cautery or the cryocautery of warts, verrucae or other skin lesions and uses local anaesthesia during that procedure.";

(d) omit paragraph (4); and

(e) at the end, insert—

"(5) Subsection (7) of section 2 of the 2000 Act([8]) shall be modified by—

(a) inserting the word "intravenously administered" before "sedation" in paragraph (a); and

(b) substituting for paragraph (e)(a) (cosmetic surgery) the following—

"(a) other than—

(i) ear and body piercing;

(ii) tattooing;

(iii) the subcutaneous injection of a substance or substances into the skin for cosmetic purposes;

(iv) the removal of hair roots or small blemishes on the skin by the application of heat using an electric current; and

(v) the use of—

(aa) a Class 3B or Class 4 laser product, as defined in Part I of British Standard EN 60825-1 (Radiation safety of laser products and systems)([9]); or

(bb) an intense light, being broadband non-coherent light which is filtered to produce a specified range of wavelengths,

with the aim of removing hair roots, skin blemishes or thread veins.".

Amendment of regulation 4 of the 2001 Regulations

4. In regulation 4 of the 2001 Regulations (meaning of independent clinic)—

(a) in paragraph (1), for sub-paragraph (b) substitute—

"(b) unless paragraph (1A) applies, a surgery or consulting room in which a medical practitioner who provides no services in pursuance of the NHS Act provides medical services of any kind (including psychiatric treatment)."; and

(b) after paragraph (1), insert—

"(1A) Paragraph (1)(b) does not apply if the medical services are provided only under arrangements made on behalf of the patients by—

(a) their employer;

(b) a government department or any executive agency of a government department;

(c) a prison or other establishment in which the patients are held in custody, other than pursuant to any provision of the Mental Health Act 1983; or

([8]) Section 2(7) was amended by S.I. 2001/3968.

([9]) Copies of BS EN 60825-1 may be obtained from BSI Customer Services, 389 Chiswick High Road, London W4 4AL.

(d) an insurance provider with whom the patients hold an insurance policy, other than an insurance policy which is solely or primarily intended to provide benefits in connection with the diagnosis or treatment of physical or mental illness, disability or infirmity.".

Amendment of regulation 5 of the 2001 Regulations

5. For regulation 5 of the 2001 Regulations (exception of undertaking from the definition of independent medical agency), substitute—

"**5.** For the purposes of the Act, any undertaking which consists of the provision of medical services by a medical practitioner only under arrangements made on behalf of the patients by—

(a) their employer;

(b) a government department or any executive agency of a government department;

(c) a prison or other establishment in which the patients are held in custody, other than pursuant to any provision of the Mental Health Act 1983; or

(d) an insurance company with whom the patients hold an insurance policy, other than an insurance policy which is solely or primarily intended to provide benefits in connection with the diagnosis or treatment of physical or mental illness, disability or infirmity,

is to be excepted from being an independent medical agency.".

Amendment of regulation 26 of the 2001 Regulations

6. In regulation 26 of the 2001 Regulations (visits by registered provider), in paragraph (3), for the words "at least once every six months" substitute "from time to time".

Signed by authority of the Secretary of State for Health

[*Name*]
Minister of State
Department of Health

[ ] 2008

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made under the Care Standards Act 2000 ("the Act") and they amend the Private and Voluntary Health Care (England) Regulations 2001 ("the 2001 Regulations"): they apply to England only.

Regulation 2 amends regulation 2 of the 2001 Regulations to insert new definitions into the 2001 Regulations.

Regulation 3 amends regulation 3 of the 2001 Regulations to amend what is a "listed service" for the purposes of section 2 of the Act and to except certain establishments from being independent hospitals: it has the effect of changing what establishments are independent hospitals for the purposes of the Act and the 2001 Regulations. In particular, certain treatments involving the use of lasers are removed from the definition of "listed services" (regulation 3(a)(ii)), although refractive eye surgery (which also involves the use of lasers) is retained as a listed service (regulation 3(a)(i)). Fertility treatments that are already regulated under the Human Fertilisation and Embryology Act 1990 are removed from the definition of "listed services" (regulation 3(a)(ii) and (b)). An amendment is made to one of the existing categories of establishment excepted from

being an independent hospital that concerns certain establishments to which the general public does not have access (regulation 3(c)(ii)); certain procedures carried out under local anaesthesia (minor surgery on the foot and minor surgery carried out by medical practitioners) have been added to the list of establishments excepted from being "independent hospitals" (regulation 3(c)(iii)). Section 2(7) of the Act has also been modified which further changes the definition of "listed services" for the purposes of the Act and the Regulations (regulation 3(e)).

Regulations 4 and 5 amend regulations 4 and 5 of the 2001 Regulations respectively: the amendments have the effect of changing the meaning of "independent clinic" and "independent medical agency" for the purposes of the Act and the 2001 Regulations by amending a current exemption from the definition of "independent clinic" and "independent medical agency" that concerns certain establishments to which the general public does not have access.

Regulation 6 amends regulation 26 of the 2001 Regulations to change the frequency at which the registered provider must undertake unannounced visits to an establishment or agency.

Annex 2: National minimum standards – proposed amendments to existing standards and proposed new standards

This annex describes proposed changes to the main statement of national minimum standards (NMS) and should be read in conjunction with it. This main statement of NMS can be downloaded from the Department of Health's website.[10]

Prescribed techniques and technologies

We propose to make a number of changes to the regulation governing prescribed techniques and technologies (regulation 3 of the PVH Regulations). These proposed changes are:

- the removal of IVF treatment from regulation by the Healthcare Commission;
- the removal of class 3B and 4 lasers, and IPL equipment, from regulation by the Healthcare Commission; and
- the amendment of regulation 3 so that only hyperbaric oxygen therapy which is carried out under the supervision of a medical practitioner remains within regulation by the Healthcare Commission.

Chapter 14 of the main statement of NMS sets out the standards for prescribed techniques and technologies. We propose that standards P1, P2 and P3 covering class 3B and 4 lasers, and standards P12, P13, P14, P15 and P16, should be removed from Chapter 14, and that the remains of the chapter should be drafted as shown at Appendix A.

While the use of class 3B and 4 lasers will no longer be a prescribed technique or technology, some establishments will continue to use lasers, principally for cosmetic and other surgical procedures, and we feel it is important that these establishments should continue to use this equipment safely. We therefore propose that those standards on lasers removed from Chapter 14 of the NMS should be added to Chapter 9, which covers acute hospitals. We propose to amend the introduction to Chapter 9 to include an additional section on lasers and lights at the end, after the section on cancer services, and to introduce additional standards A49–A51. These proposed changes are set out at Appendix B.

10 www.dh.gov.uk/en/Policyandguidance/Healthandsocialcaretopics/Socialcare/Regulationstandardsandinspection/DH_072530

Appendix A: Proposed new Chapter 14 – Prescribed techniques and technologies

Introduction to Standards P1 to P16

Section 2(7)(f) ensures that establishments in which treatments are provided using certain techniques and technologies are regulated. These are techniques or technologies – such as dialysis – that require expertise in delivery, the use of appropriate equipment, and for the establishment to have certain measures in place in order for the treatment to be delivered safely.

This appendix describes these techniques and technologies in more detail, including the risks they can pose, and sets out the standards for each technique or technology.

Dialysis

Haemodialysis and peritoneal dialysis are carried out in the independent sector in a range of settings. These are, typically, acute hospitals, holiday sites (for example Butlin's and Scout Association Holiday Homes) and private satellite units where dialysis is provided under contract to the NHS. The standards do not apply to dialysis that takes place in the patient's home.

Where the NHS uses private satellite units to provide dialysis to NHS patients, these units are required to join the Renal Registry, in association with the main unit to which they are linked. The purpose of the Renal Registry is to monitor the quantity and quality of renal care in the UK. The attached standards provide added quality assurance to that process and are needed to ensure that providers in private and voluntary healthcare and adult social care meet appropriate standards of quality and safety when providing services to the public.

See also, in particular, regulation 3 of the Private and Voluntary Health Care (PVH) Regulations, which relates to prescribed techniques or technologies and exceptions to the definition of an independent hospital.

Endoscopy

Endoscopes are medical devices inserted into the body for diagnostic or surgical purposes. There are two types of endoscope, flexible and rigid:

- Flexible endoscopy uses natural body orifices (eg the mouth, anus or nose) to introduce into the body a long flexible device. The inserted end of the device has a camera, operated remotely by the practitioner, which is used to view

the internal organs. Procedures of this kind usually include upper and lower gastroscopy, bronchoscopy, laryngoscopy, cystoscopy and hysteroscopy. Most acute hospitals have an endoscopy department (sometimes within the day surgery centre) where flexible endoscopy is undertaken, but it may also take place in other healthcare establishments.

- Rigid endoscopy is where a rigid endoscope with a surgical instrument at the inserted end is introduced through the skin. It is also known as minimally invasive surgery or keyhole surgery and includes arthroscopy, laparoscopy, hysteroscopy and cystoscopy, among others. Rigid endoscopy usually takes place in hospital operating departments.

Endoscopes are subject to standards for medical devices and, where they are reusable, for decontamination. Standards relating to medical devices and decontamination are to be found in both the core standards and those for acute hospitals, and are therefore not duplicated here.

See also, in particular, regulation 3 of the PVH Regulations, which relates to prescribed techniques or technologies and exceptions to the definition of an independent hospital.

Dialysis standards

Arrangements for dialysis

Outcome – patients undergo dialysis in accordance with safe and appropriate procedures.

Standard P1

P1.1 There are written criteria for the selection and assessment of patients undergoing dialysis.

P1.2 The criteria and processes for the selection of suitable patients are monitored and reported to an appropriate body.

P1.3 Local protocols for the management of patients, including standards of care to be achieved, are developed and agreed locally by all professionals, on the basis of national guidelines.

P1.4 Where patients are being treated outside hospital, there are explicit arrangements in place for rapid transfer to specialist hospital facilities for unforeseen complications.

P1.5 Staff are made aware of these changes, which are regularly audited and reviewed.

Facilities for dialysis

Outcome – the environment in which dialysis is undertaken is safe and appropriate.

Standard P2

P2.1 There is space around each bed/chair to allow nursing practice to take place and reduce the risk of cross-infection.

P2.2 Screening is provided for each bed space to ensure privacy for patients.

P2.3 There is safe storage of clinical waste in line with new waste disposal regulations.

P2.4 There is safe storage of chemical substances, all of which are fully labelled.

P2.5 There are hand hygiene facilities for staff in all clinical areas.

P2.6 If hepatitis B-infected patients are treated, isolation procedures are available and used following a risk assessment of the patient.

P2.7 Department of Health guidelines on the prevention of blood-borne virus infection in renal dialysis units are followed.

P2.8 Where haemodialysis is given, the specific standards for water quality for haemodialysis, set out in the latest version of the Renal Association's standards document *Treatment for Adult Patients with Renal Failure*, and the appropriate test schedules therein, are complied with.

Staffing for dialysis

Outcome – patients receive dialysis from staff with the relevant expertise.

Standard P3

P3.1 Supervision of nursing care is undertaken by a registered nurse with a current post-registration qualification in dialysis that is recognised as such by the NMC.

P3.2 All staff who come into contact with patients are offered vaccination against hepatitis B.

Hyperbaric oxygen therapy – under the supervision or direction of a medical practitioner

Hyperbaric oxygen therapy (HBOT) involves specialised equipment and experienced personnel delivering oxygen at higher than atmospheric pressures under the supervision

or direction of a medical practitioner. It is used for a number of conditions that well-established research has demonstrated to benefit, including:

- air or gas embolism
- decompression illness
- carbon monoxide poisoning
- gas gangrene
- necrotising fasciitis
- post-radiotherapy tissue damage
- preparation for surgery in previously irradiated tissue
- crush injury
- severe haemorrhagic anaemia
- selected problem wounds
- compromised skin flaps and grafts
- refractory osteomyelitis
- osteoradionecrosis
- thermal burns
- intracranial abscess.

HBOT poses safety risks if chambers are incorrectly operated. Excessive oxygen levels will increase the risk of fire and strict control is needed to minimise the presence of flammable materials. There have been isolated fire and explosion incidents worldwide, both in single occupancy chambers in private use and multiplace chambers under medical supervision. In addition, oxygen breathed under pressure can be toxic, with subsequent ill effects.

Chambers regulated by the Healthcare Commission are those which are used for therapeutic treatments under the supervision of a medical practitioner.

Chambers regulated by the Healthcare Commission will be classified as Type 1 or Type 2 depending on the level of critical care management provided, as defined in the Department of Health's document *Comprehensive Critical Care* which classifies levels from level 0 (the least critical care required) to level 3 (the most critical care required):

- Type 1 chambers are able to accept patients who need critical care of level 2 or above.

- Type 2 chambers are unable to accept patients who need critical care of level 2 or above at the time of referral, or who are thought likely to deteriorate to that level during hyperbaric treatment.

Certain Type 1 and Type 2 hyperbaric chambers where treatment is provided by a medical practitioner will be exempted in the regulations from registering with the Healthcare Commission. These include those run by the armed forces for the treatment of their own staff; and those where the primary purpose of the chamber is pursuant to regulation 6(3)(b) of the Diving at Work Regulations 1997 or regulation 8 or 12 of the Work in Compressed Air Regulations 1996. These chambers are not to be available for use by the general public.

Any hyperbaric chambers not classified as Type 1 or Type 2 do not qualify for registration with the Healthcare Commission.

See also, in particular, regulation 3 of the PVH Regulations, which relates to prescribed techniques or technologies, and exceptions to the definition of an independent hospital.

Hyperbaric oxygen therapy standards

Arrangements for hyperbaric oxygen therapy

Outcome – patients receive hyperbaric therapy safely and in accordance with appropriate procedures.

Standard P4

P4.1 Recommendations in appropriate guidance, for example those of the British Hyperbaric Association, are complied with.

P4.2 The hyperbaric unit works to a set of standard operating procedures (the local rules), which are clearly set out available to and complied with by all staff.

P4.3 These written operating procedures cover:

- the potential hazards associated with hyperbaric chambers;
- methods of safe working;
- safety checks;
- normal operating procedures;
- personal protective equipment;
- adverse incident procedures; and
- hand hygiene.

P4.4 Personnel involved with providing hyperbaric therapy are trained and assessed as being competent in:

- equipment management and cleaning;
- safety management;
- minimising risks;
- basic resuscitation skills;
- action to be taken in the event of an adverse incident; and
- hand hygiene.

P4.5 All staff involved in the provision of hyperbaric therapy have regular, documented update training on the techniques and equipment used.

P4.6 There is equipment available to initiate resuscitation outside the chamber, and this is in line with the current recommendations of the European Resuscitation Council.

Staff qualifications and training

Outcome – patients receive therapy in hyperbaric chambers from competent operators.

Standard P5

P5.1 The hyperbaric unit operates under the clinical responsibility of a medical director who is a medical practitioner and possesses clinical experience in hyperbaric and diving medicine.

P5.2 The medical director ensures that the theoretical and practical training requirements of staff are met and that regular refresher courses are undertaken.

P5.3 The nursing and technical staff should hold appropriate qualifications, eg CHRN, CHT or equivalent.

P5.4 When children under 12 years old are treated, a qualified children's nurse (registered sick children's nurse or registered nurse child branch certificated) accompanies the patient at all times, with the exception of a) attendance inside the hyperbaric chamber, if not appropriate, or b) where delay of treatment could affect the outcome.

P5.5 If the unit treats children there are formal links with a paediatrician to provide advice to the unit.

Facilities for treatment

Outcome – patients receive HBOT in a safe environment.

Standard P6

P6.1 The unit holds the range of equipment and appropriate drugs required for effective resuscitation attempts.

P6.2 Clinical equipment available for use both inside and outside the chamber includes indirect blood pressure equipment, stethoscope, auroscope/ophthalmoscope, thermometer and equipment for neurological assessment, and there are appropriate cleaning procedures in place for all equipment.

P6.3 Equipment for urinary catheterisation, intravenous cannulation and pneumothorax drainage is also available.

P6.4 Multiplace chambers must have at least two compartments (ie an airlock) to allow access and egress of healthcare professionals and equipment while maintaining pressure.

Patient Care

Outcome – appropriate arrangements for patient care are in place.

Standard P7

P7.1 The initial referral is a key point in treatment of patients, and all relevant information is recorded in a standard format.

P7.2 The clinical status of a patient is clearly established by the duty medical officer before a referral is accepted, and the means of transfer is agreed, along with an estimated time of arrival.

P7.3 Wherever possible, the transfer arrangements after treatment, such as return to hospital, an intensive care unit or home, are agreed at the time of referral.

P7.4 The unit assesses the patient medically before treatment starts.

Critical Care in Type 1 Chambers

Outcome – patients are assured that where level 2 or 3 critical care is provided, as appropriate, within the hyperbaric chamber, it is done so effectively.

Standard P8

P8.1 Patients requiring level 2 or 3 critical care receive it either within the hyperbaric chamber, or are transferred immediately to the nearest available facility that provides it.

P8.2 Where level 2 or 3 critical care is provided within the hyperbaric chamber:

- there is a written operational policy and protocols for critical care management in the chamber;
- staff are briefed on the policy and protocols so that they are aware of what they should do in specific circumstances; and
- the duty medical officer is experienced to specialist registrar standards in either anaesthetics or intensive care medicine.

P8.3 Monitoring equipment available for both inside and outside the chamber includes ECG, pulse oximetry, capnography and invasive blood pressure equipment.

P8.4 Arrangements are in place to transfer patients to critical care facilities where necessary, and are agreed in advance with the local critical care network, or the hospital most likely to receive such patients.

P8.5 The unit provides equipment to enable the safe transfer of patients to critical care facilities.

P8.6 The unit has arrangements with a local hospital for radiographic and laboratory investigations.

Appendix B: Proposed Amendments to Chapter 9

Introduction to Chapter 9

Class 3B and 4 Lasers and/or Intense Pulsed Light Sources (standards A49 – A51)

The standards cover both Class 3B and 4 lasers and intense pulsed lights, as both types of equipment share similar features.

Class 3B lasers are concentrated energy sources used for physiotherapy, eg to relieve chronic pain and backache by 'massaging' the tissue by pulsing the beam through it; for acupuncture; and for wound healing, for instance pressure sores, venous and diabetic ulcers, and for softening scar tissue.

Class 4 lasers and intense pulsed light sources are used in a variety of settings and for a variety of therapeutic purposes. Class 4 lasers and intense pulsed lights are powerful devices which, if faulty or used incorrectly, have the potential to cause serious injury to those operating them, recipients of the treatment and other persons in the vicinity, and to ignite flammable materials.

It is essential, therefore, that all establishments that provide medical or surgical treatment which would fall within the definition of section 2(3) or 2(7) of the Care Standards Act 2000 using Class 3B or 4 lasers or intense pulsed light sources are regulated so as to ensure that this equipment is used safely. We regard that the key elements in ensuring that lasers and intense pulsed lights sources are used safely centre around:

- clear lines of responsibility within the registered establishments on the use of lasers and intense pulsed lights, including a clear understanding by all users of the personal responsibility that using lasers and intense pulsed lights entails;
- clear policies and procedures on the use and maintenance of lasers and intense pulsed lights;
- users of laser and intense pulsed lights undergoing specialised training;
- learning, maintaining and updating an effective core of knowledge about the use and impact of lasers and intense pulsed lights;
- effective record keeping;
- safe working areas;
- protective eyewear and other risk-avoidance measures;

- hand hygiene;
- cleaning of equipment;
- cleaning of areas.

Standards A49 – A51 reflect these principles.

Standards

Class 3B and 4 Lasers and/or Intense Pulsed Light Sources

Procedures for Use of Lasers and Intense Pulsed Lights

Outcome – Patients receive treatment using lasers and intense pulsed lights from competent operators and in accordance with appropriate procedures.

Standard A49

A49.1 A protocol produced by an expert medical or dental practitioner is followed which sets out the necessary pre-treatment checks and tests, the manner in which the procedure is to be applied, the acceptable variations in the settings used, and when to abort a treatment. In particular, the protocol addresses:

- contraindications;
- technique;
- pre-treatment tests;
- post-treatment care;
- recognition of treatment-related problems;
- procedure if anything goes wrong with treatment;
- permitted variation on machine variables;
- procedure in the event of equipment failure.

A49.2 The protocol is supported by written procedures for the use of devices, including when they are being used on a trial or demonstration basis, and these cover:

- the potential hazards associated with lasers and/or intense lights;
- controlled and safe access;
- authorised users' responsibilities;
- methods of safe working;
- safety checks;

- normal operating procedures;
- personal protective equipment;
- prevention of use by unauthorised persons;
- adverse incident procedures.

A49.3 There is a register of persons authorised to use lasers and intense lights. Authorised users sign to indicate that they accept and understand the procedures drawn up for the use of lasers and intense lights in the registered establishment (the Local Rules).

A49.4 Laser and intense light users have access to safety advice from a certificated laser protection adviser.

A49.5 A person with overall on-site responsibility for lasers and intense lights is appointed and properly trained to perform this role.

A49.6 Records are maintained every time the laser or intense light is operated, including:

- the name of the person treated;
- the date;
- the operator;
- the treatment given;
- any accidents or adverse effects.

Training for Staff using Lasers and Intense Pulsed Lights

Outcome – Patients receive treatment from appropriately trained operators.

Standard A50

A50.1 All laser and intense pulsed light users have training, which is recorded and covers the following:

- characteristic features of light from lasers and intense pulsed light sources;
- hazards from device malfunction;
- equipment management;
- effects of light on the eye, skin and body tissues;
- safety management, including Local Rules and controlled areas;

- minimising risks;
- action to be taken in the event of an adverse incident.

A50.2 All staff using lasers and intense pulsed lights have regular update training, both planned and in reaction to relevant technological and medical developments.

A50.3 All operators of lasers and intense pulsed light sources use them only for treatments for which they have been trained and, where appropriate, hold qualifications.

Safe Operation of Lasers and Safe Operation of Lasers and Intense Pulsed Lights

Outcome – The environment in which lasers and intense pulsed lights are used is safe.

Standard A51

A51.1 The area around working lasers and intense pulsed light sources is controlled to protect other persons while treatment is in progress. The controlled area is clearly defined and not used for other purposes, or as access to areas, when treatment is being carried out.

A51.2 While the equipment is being operated, the authorised user is responsible for the safety of all persons in the controlled area. No other laser or intense pulsed light source is in use in the same controlled area at the same time.

A51.3 All lasers and intense pulsed light sources have labels identifying them, their wavelength or range of wavelengths, and maximum output power of radiation emitted.

A51.4 In establishments with class 4 lasers, warning signs as specified in EN 60825-1 are displayed on the equipment and on the outside of doors to the controlled area.

A51.5 Protective eyewear is worn by everyone within the controlled area whenever there is a risk of exposure to hazardous levels of laser or intense pulsed light radiation.

A51.6 Operators ensure patient safety by:

- checking with patients if they have any medical condition or treatment for which laser or intense pulsed light treatment would be a contraindication;
- where appropriate, covering the skin outside the area being treated;
- where appropriate, checking the skin type and pigmentation prior to treatment;
- hand hygiene;
- cleaning of equipment.

A51.7 For all lasers and intense pulsed light sources with a key switch, formal arrangements exist for the safe custody of the key, separate from the equipment. Only authorised users have access to the key. The key is not left unattended with the equipment.

A51.8 Lasers and intense pulsed light sources are regularly serviced and maintained to ensure they are operating within their design specification. A record of servicing and repairs is kept.

Annex 3: Draft Partial Impact Assessment

Starts on page 37.

Summary: Intervention & Options

Department /Agency:	Title:	
Department of Health	Impact Assessment of Amendment to the Private and Voluntary Health care (England) 2007 Regulations and Amendments the NMS	
Stage: Consultation	**Version:** 1	**Date:** 6 March 2008
Related Publications:		

Available to view or download at:

http://www.dh.gov.uk/liveconsultations

Contact for enquiries: Judith Hind **Telephone:** 020 7972 1290

What is the problem under consideration? Why is government intervention necessary?

Regulation should be proportionate to costs and risks - we propose to consult on the deregulation of some independent healthcare services in which, we believe, risk no longer needs to be managed via regulation by the Healthcare Commission.

What are the policy objectives and the intended effects?

Objective: To deregulate certain independent healthcare services and clarify certain regulations.

Effects: To reduce inappropriate burdens placed on business, and to reduce the running costs to the Healthcare Commission.

What policy options have been considered? Please justify any preferred option.

1. Take no action until April 2010, part of the fundamental review of health and adult social care.

2. Take action from October 2008 and amend regulations to reduce inappropriate burdens.

Our preferred option is Option 2. This will ensure that businesses and the Healthcare Commission can benefit from our deregulatory and clarification proposals.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects? The policy will be reviewed as part of the work on the more fundamental changes to the health and social care systems.

Ministerial Sign-off For SELECT STAGE Impact Assessments:

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister:

..... Date: 12 MAR 2008

Summary: Analysis & Evidence

Policy Option: 1 **Description: take no action now and consider action as part of the fundamental review of health and adult social care**

COSTS

ANNUAL COSTS	
One-off (Transition) **Yrs**	Description and scale of **key monetised costs** by 'main affected groups' Taking no action now will not incur a change in baseline costs. If the fundamental review results in pursuing changes as detailed in option 2 then costs would mirror, perhaps not exactly, those mentioned under option 2, but would be incurred a year later.(no need for discounting).
£ 0	
Average Annual Cost (excluding one-off)	**Total Cost** (PV) **£ 0**
£ 0	

Other **key non-monetised costs** by 'main affected groups' HCC needs to plan on a reduced budget from April 2008 and a delay will make orderly budget planning very difficult.

BENEFITS

ANNUAL BENEFITS	
One-off **Yrs**	Description and scale of **key monetised benefits** by 'main affected groups' Taking no action now will not result in a change in baseline benefits. If the fundamental review results in pursuing changes as detailed in option 2 then benefits would mirror those mentioned under option 2 but would kick in one year later.
£ 0	
Average Annual Benefit (excluding one-off)	**Total Benefit** (PV) **£ 0**
£ 0	

Other **key non-monetised benefits** by 'main affected groups' Provide stability until proposed wider system reform changes are implemented.

Key Assumptions/Sensitivities/Risks

Price Base Year 2007	Time Period Years	**Net Benefit Range** (NPV) **£ 0**	**NET BENEFIT** (NPV Best estimate) **£ 0**

What is the geographic coverage of the policy/option?			England	
On what date will the policy be implemented?			N/A	
Which organisation(s) will enforce the policy?			HCC	
What is the total annual cost of enforcement for these organisations?			£ baseline	
Does enforcement comply with Hampton principles?			Yes/No	
Will implementation go beyond minimum EU requirements?			Yes/No	
What is the value of the proposed offsetting measure per year?			£ no offsetting	
What is the value of changes in greenhouse gas emissions?			£ none	
Will the proposal have a significant impact on competition?			No	
Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium	Large
Are any of these organisations exempt?	No	No	N/A	N/A

Impact on Admin Burdens Baseline (2005 Prices) (Increase – Decrease)

Increase of £ 0 Decrease of £ 0 **Net Impact** **£ 0**

Key: **Annual costs and benefits: Constant Prices** **(Net) Present Value**

Summary: Analysis & Evidence

Policy Option: 2

Description: Take action from October 2008 to deregulate certain independent healthcare services and clarify certain existing regulations.

COSTS

ANNUAL COSTS	
One-off (Transition) **Yrs**	Description and scale of **key monetised costs** by 'main affected groups' Net savings derived from reduction in admin burdens on service providers, reduction in costs to HCC (this equals the financial savings in fees to providers and is not counted twice) minus the increased costs in treating an assumed incease in adverse incidents from deregulation.
£ 0	
Average Annual Cost (excluding one-off)	**Total Cost** (PV) **£ -9.6m**
£ -9.6m	

Other **key non-monetised costs** by 'main affected groups'

BENEFITS

ANNUAL BENEFITS	
One-off **Yrs**	Description and scale of **key monetised benefits** by 'main affected groups' Benefit to HCC – savings from deregulation help to plan within reuced budget from 2008.
£ 0	
Average Annual Benefit (excluding one-off)	**Total Benefit** (PV) **£ 0**
£ 0	

Other **key non-monetised benefits** by 'main affected groups' The proposals make the regulatory framework better fit for purpose, removing inappropriate burdens and making the existing regulations more transparent and targeted, in line with two of the five principles of better regulation.

Key Assumptions/Sensitivities/Risks Assumptions have been made about the increased incidence of adverse events from deregulation of lasers and lights. Mitigation of these risks have been considered in the proposals. Further work required to firm up estimate on admin burden reduction.

Price Base Year 2007	Time Period Years	**Net Benefit Range** (NPV) **£ -**	**NET BENEFIT** (NPV Best estimate) **£ not quantified**

What is the geographic coverage of the policy/option?			England	
On what date will the policy be implemented?			1.10.2008	
Which organisation(s) will enforce the policy?			HCC	
What is the total annual cost of enforcement for these organisations?			£ -1.3m	
Does enforcement comply with Hampton principles?			Yes	
Will implementation go beyond minimum EU requirements?			No	
What is the value of the proposed offsetting measure per year?			£ is offsetting	
What is the value of changes in greenhouse gas emissions?			£ none	
Will the proposal have a significant impact on competition?			No	
Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium	Large
Are any of these organisations exempt?	No	No	N/A	N/A

Impact on Admin Burdens Baseline (2005 Prices) (Increase – Decrease)

Increase of £ 0 Decrease of £ 9.6m(est) **Net Impact** **£** -9.6m

	Annual costs and benefits: Constant Prices	(Net) Present Value	

Evidence Base (for summary sheets)

[Use this space (with a recommended maximum of 30 pages) to set out the evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Ensure that the information is organised in such a way as to explain clearly the summary information on the preceding pages of this form.]

Amendments to The Private and Voluntary Health Care (England) Regulations 2007 and amendments to the National Minimum Standards

Background

1. The Department of Health (the Department) regulates independent healthcare providers via the Care Standards Act 2000 and the Private and Voluntary Health Care (England) Regulations 2001 (S.I. 2001/3968)(PVH Regulations). Further guidance on how the legislative requirements may be met is set out in the National Minimum Standards (NMS). The NMS were first published in 2002, and the Healthcare Commission are obliged to take them into account when assessing independent healthcare providers.

2. The Department plans to make major changes to the way that health and adult social care is regulated and performance managed from a currently planned date of April 2009 onwards. These plans were first outlined in The future regulation of health and adult social care in England consultation, which ran from November 2006 to February 2007. The Department plans to consult further on this developing programme.

Objective

3. The Government has a responsibility to ensure that the regulatory systems it sets up are fit for purpose. The regulatory regime must be focused on activities that have the potential to cause harm. Furthermore, the regulatory regime must be proportionate to the nature and frequency of the risks involved, and transparent and consistent with the original policy intent.

4. Against this background the Department ensures that the services and establishments it regulates are kept under constant review. After assessing the types of service currently in regulation, the Department believes that there is a need to reduce the burden on providers through the removal of certain services from Healthcare Commission regulation and reduce the Healthcare Commission's running costs, and to clarify some existing regulations by revising them to make clear the original policy intent .

5. In considering the changes proposed in this partial Impact Assessment, the Department has put forward proposals which we believe will support the wider system reform changes planned for introduction from April 2009, subject to Parliamentary approval.

Description of Proposals

Introduction

6. We have examined the obligations placed on the independent healthcare sector by the current regulations to determine whether it is still necessary to impose these obligations.

7. In addition, in line with the requirements of the review of Arms Length Bodies to reduce the cost of regulation, we have asked the Healthcare Commission to achieve a reduction in its running costs as soon as possible before April 2009. We have been working closely with the Healthcare Commission to identify ways to reduce the regulatory burden currently placed on both the Commission and providers.

8. We propose that certain treatments should no longer be regulated by the Healthcare Commission. These treatments are:

   - The non-surgical use of Class 3B and 4 lasers and intense pulsed light equipment;
   - in vitro fertilisation techniques which are licensed under the Human Fertilisation and Embryology Act 1990;
   - type 3 Hyperbaric Oxygen Therapy.

Options Considered

A. Take no action now, but review these services as part of the wider programme of changes planned for 2010

9. This option would ensure stability for the independent healthcare sector in the run-up to a major regulatory change, but would mean that some independent healthcare sector businesses would face regulatory burdens that the Department now believes are inappropriate. In addition, this option does not help the obligation on the Healthcare Commission to operate within a reduced budget from as soon as possible before April 2009.

   Costs – baseline costs would not change until the wider review.

Benefits – baseline benefits would not change until the wider review, except for there being stability prior to a wider programme review. However, there would be the disbenefit of continuing a regulatory regime that was now thought to be inappropriate. The disbenefits would mirror the costs/savings determined under the next option.

B. Deregulate these services from 1 October 2008

10. *IVF treatment*. In addition to registering with the Healthcare Commission, IVF services are also required to obtain a license from the Human Fertilisation and Embryology Authority (HFEA) under the Human Fertilisation and Embryology Act 1990.

11. We will consult on our proposal to end this dual regulation by removing IVF from the list of prescribed techniques and technologies in the 2001 Regulations. The effect will be that providers who solely provide IVF services will only need to obtain a licence from the HFEA, and this would mean that 46 IVF providers currently registered with the Healthcare Commission would no longer need to register. Establishments that provide other services requiring registration will still be required to register with both the Healthcare Commission and obtain a licence from the HFEA. Where this is the case, the Commission will work with HFEA to align their inspection methodologies in order to minimise the effects on providers.

12. We do not judge that removing this dual regulation will result in any change to the standard of care offered to patients, and no additional costs will be incurred by the HFEA.

13. *Type 3 Hyperbaric Oxygen Therapy chambers (HBOT3).* Hyperbaric oxygen therapy involves the administration of pure oxygen to patients in pressurised chambers. Chambers regulated by the Healthcare Commission are classified as Type 1, 2, or 3 depending on the levels of critical care management provided as defined in the Department of Health's May 2000 document *Comprehensive Critical Care*. Type 3 chambers are those chambers used only for the treatment of patients with neurological and other disorders and for which NHS hyperbaric treatment is not clinically appropriate.

14. There is no accepted evidence as to the medical benefits of HBOT3 and the National Institute of Health and Clinical Excellence did not recommend their use. The reason for including HBOT3 within the Commission's remit was the possible risk of fire and oxygen toxicity. However, no incidents involving hyperbaric oxygen therapy have ever been reported to the Commission or its predecessors, and the Multiple Sclerosis National Therapy Association, which provide most of the HBOT3 treatments

available in England, have put in place training, peer review and other measures to support their members' good practice in compliance with the regulations and NMS. In addition, the obligations required under the insurance policies held by HBOT3 services incorporate adequate safeguards to ensure patient safety.

15. As there is no recognised health benefit from HBOT3, and as patient safety can be assured through other means, we will consult on whether HBOT3 services should no longer be subject to regulation by the Healthcare Commission. For reasons given earlier, we do not expect that removal of these chambers from regulation will change the standard of care offered to patients.

16. *Class 3B and 4 lasers and intense pulsed light (IPL) treatments.* These treatments are currently regulated by the Healthcare Commission. They are used to provide the following services:

- cosmetic procedures such as hair removal, photo-rejuvenation, skin resurfacing and reduction of thread veins;
- treatments which can straddle definitions of cosmetic services and dermatology, such as reduction of port wine stains and birth marks, wound and scar reduction;
- dental treatments such as teeth whitening;
- surgery and refractive surgery (laser-eye treatments).

Refractive eye surgery currently falls within the definition of listed services set out in section 2(7) of the Care Standards Act 2000 because it is carried out either using anaesthesia and/or laser equipment. Our proposed amendments to regulations 2 and 3 of the PVH Regulations may remove some refractive surgery from the category of listed services. However, we believe that the risks involved in refractive eye surgery are such that all establishments carrying out this surgery, regardless of the type of technique used, should be registered as independent hospitals. We intend to achieve this through draft regulation 3(1)(aa), which adds refractive eye surgery into the list of prescribed techniques and technologies, and which ensures that establishments which offer this service must continue to register as independent hospitals.

17. There are currently approximately 850 establishments registered with the Healthcare Commission who provide purely cosmetic laser/IPL services. This represents 45% of all registrations, and there is evidence that the sector is growing (see remarks under Competition Assessment). In view of the need to reduce the Healthcare Commission's budget and to do so in a way that allows the Commission to concentrate on its core business of regulating healthcare, we have considered whether the Healthcare Commission should still have a role to play in regulating non-surgical laser treatments.

18. We would wish to distinguish between those uses of lasers and lights that can rightly be categorised as providing a healthcare need and those non-surgical cosmetic treatments that cannot be so regarded and which also pose less potential risk and harm. The former should continue to be regulated by the Healthcare Commission. On the other hand, there is a need to question whether the latter should fall within the Healthcare Commission's remit. We therefore propose to consult on whether light-based treatments used for non-surgical purposes should remain in Healthcare Commission regulation. This would leave providers of cosmetic laser and light treatments operating in an environment where the only regulation would be via the byelaws of certain local authorities which have the powers to register these treatments and have opted to do so – although establishments would of course need to adhere to Trading Standards and Health and Safety legislation, which will provide opportunities for redress in cases where a person is unhappy with their treatment. People who seek these cosmetic treatments will therefore need to take additional steps to satisfy themselves of the training, skills and experience of their treatment provider. The Department's cosmetic surgery website would make clear that such establishments were no longer regulated and we believe that there is a sufficiently developed competitive market for those seeking these treatments that they will to be able to find an establishment that satisfies them regarding standards.

19. Nevertheless, it would be realistic to assume that deregulation of these laser and light establishments might result in a greater incidence of adverse events in some parts of this market. In turn it is likely that the NHS will have to pick up and treat this increased number of complications.

Cost and benefits

Policy Savings for the Healthcare Commission

20. We estimate that this option will provide total annual savings to the Healthcare Commission of £1.33m, with the deregulation of lasers and lights alone providing £1.2m of the savings. These figures have been arrived at by determining the total full cost recovery regulatory fees currently charged to providers of the relevant establishments.

Financial savings to providers and reductions in admin burdens on providers

21. Removal of Healthcare Commission regulation will remove a barrier on entry to this market. There will be financial savings for providers because they will no longer have to pay regulatory fees to the Healthcare Commission. These savings will mirror exactly the savings calculated above for the Healthcare Commission. Therefore there will be total annual financial savings of £1.33m. In addition there will be a reduction in the administrative burden on these establishments. A detailed exercise to calculate this reduction using the 2005 administrative burdens database has not yet been

undertaken but will be carried out during the consultation. However a rough and ready estimate can be provided by considering that the total administrative burden reported in 2005 for private and voluntary healthcare was approximately £50m. The total amount spent by the Healthcare Commission in regulating the private and voluntary healthcare sector was around £8m. This produces an aggregate ratio showing that for every £1 spent by the Healthcare Commission on PVH regulation, £6.25 of administrative burdens are generated for healthcare providers. Assuming that this ratio applies to the deregulated establishments being considered under this option, we have a total reduction in administrative burdens of £8.3m (6.25 * 1.33m).

Benefits and disbenefits from degulation

22. There are good grounds for believing that standards of care will not change if and when dual registration changes and HBOT3 treatments are deregulated. It is unlikely that the same can be said about the deregulation of lasers and lights. Appendix A explores what might be the implications and the conclusions are that the direct costs from having to treat the increase in adverse incidents, possibly all falling on the NHS, will be between £900,000 and £1.8m. These figures must be treated with an appropriate degree of caution. Quality of life detriments or other effects have not been considered.

Preferred Option

23. Our preferred option is Option B, which allows for the deregulation of these services from 1 October 2008. On balance we consider that it is important for the regulatory framework to be fit for purpose and where we believe inappropriate burdens are being imposed then they should addressed with immediate effect. In addition, the Healthcare Commission needs to operate within a reduced budget. We believe that any potential decline in the standards of laser and light treatments can be mitigated by those seeking such treatments being aware that these services are no longer regulated and taking a slightly greater role in satisfying themselves that their treatment provider is providing treatments of an appropriate standard of quality and safety. The market is sufficiently developed to respond to consumer expectations. The Department's cosmetic surgery website for patients at www.dh.gov.uk/cosmeticsurgery would be updated to signal very clearly any change in regulation.

Clarification

Introduction

24. Currently, healthcare providers are exempt from regulation if they only provide treatment on the basis of arrangements made by the patient's employer or "another person". This provision is designed primarily to ensure that medical services to which

the general public does not have access – such as occupational health services – do not need to register with the Healthcare Commission.

25. However, as currently drafted, the regulation does not specify exactly which services are exempt under the "another person" provision, and this has caused confusion. Enquiries have been made about whether an organisation would need to register with the Commission if they structured their services to separate the referral and treatment functions – and only provided medical services to patients through their own referral service, which would be "another person".

26. In addition, some uncertainty has arisen over our intentions with regard to the regulation of clinics which undertake minor surgical procedures, and in particular, whether we intended that these clinics should be regulated on the same basis as independent hospitals.

Options Considered

C. Do nothing

27. This option would do nothing to resolve the uncertainties that have arisen about our policy intentions. The existing regulations will continue to fall short in terms of being transparent and targeted, which are two of the five principles of better regulation.

    Costs – none.

    Benefits – none.

D. Clarification of certain regulations as soon as possible before April 2009

28. As stated above, we intended the "another person" exemption should principally apply to those medical services that could not be accessed by the general public. We therefore propose to amend the regulations to clarify that the exemption only applies when medical services are provided under arrangements made by:

    - a person's employer;
    - a Government department or executive agency of a Government department;
    - a prison or other establishment where patients are held in custody;
    - an insurance company (but not health insurance companies).

29. We also intend to amend the regulations to clarify our policy intention with regard to the regulation of clinics that undertake minor procedures. We intend to amend the regulations to make it clear that establishments where medical practitioners provide

minor surgical procedures, or establishments where minor podiatric procedures are provided, are not regulated as independent hospitals. This should ensure that an appropriate level of regulation is applied to these smaller establishments which carry out less risky procedures. This should not result in a change in standards of care.

Costs – none.

Benefits – greater clarity for providers and a reduction in enquiries as to what the regulations mean.

Preferred option

30. Our preferred option is option D, which will allow us to clarify our policy intention with regard to a small but important number of providers.

Impacts

Competition Assessment

Will the proposal have a significant impact on competition?

31. We do not consider that the removal of dual regulation for IVF treatment will affect competition. The proposals for HBOT3 are also considered very unlikely to affect competition or the current 'monopoly' position of the Multiple Sclerosis National Therapy Association that supplies most of these treatments.

32. The deregulation of lasers and lights would be expected to make entry into this market easier and so increase competition. However, the market for cosmetic treatments has already experienced rapid growth over the last few years. In addition, it is hoped that, along with deregulation, consumers will be more individually concerned about standards in a market that already offers a good deal of choice. Against this background it is difficult to say exactly what will be the effect of deregulation.

Small Firms Impact Test

Independent Healthcare

33. We are proposing to remove non-surgical laser and light treatments and HBOT3 treatments from regulation, and many of the establishments offering these treatments are smaller firms. This will remove the current admin burdens and fees paid to the Healthcare Commission.

Legal Aid Impact Test

Will the proposal introduce new criminal sanctions or civil penalties?

34. These proposals will not extend the range of sanctions currently available to the Healthcare Commission.

Other Economic issues

Will the proposal bring receipts or savings to Government?

35. No.

Will it impact on costs, quality or availability goods and services?

36. Given what was said under the competition assessment we consider it unlikely that the availability, quality or price of services will be significantly affected by these proposals.

Will it impact on the public sector, the third sector, consumers?

37. The proposals will mean that people who seek non-surgical laser or intense pulsed light treatments will need to do more to satisfy themselves of the qualifications, skills and experience of their provider.

Will the proposal result in new technologies?

38. No.

Will the proposal result in a change in the investment behaviour both into the UK and UK firms overseas and into particular industries?

39. These proposals are extremely unlikely to result in any changes in investing behaviour.

Carbon and Greenhouse Gas Assessment

Will the proposal lead to change in the emission of Greenhouse Gases?

40. It is unlikely that these proposals will have an effect on greenhouse gas emissions.

Other Environmental issues

Will the proposal be vulnerable to the predicted effects of climate change?

41. No.

Will it lead to a change in the financial costs, environmental and health impacts of waste management?

42. No.

Will it impact significantly on air quality?

43. No.

Will it involve any material change to the appearance of the landscape or townscape?

44. No.

Will it change the degree of water pollution; levels of abstraction of water; exposure to flood risk?

45. No.

Will it disturb or enhance habitat or wildlife?

46. No.

Will it affect the number of people exposed to noise or the levels of exposure?

47. No.

Health Impact Assessment

Will the proposal have an impact on health, wellbeing or health inequalities?

48. No.

Equality Assessment

- Will the proposal have an impact on:
- Race equality
- Gender equality
- Disability Equality
- Human Rights

49. The proposals have not been designed to bring a specific benefit or set of benefits to a specific group or groups, but have instead been designed to apply to the different types of establishment regulated under the Care Standards Act. The changes will have an equal impact on all patients who use these services, and will not affect one group more than another than is currently the case.

Rural Proofing

Will the policy have a different impact in rural areas?

50. No.

Social

- Could the proposal have a differential impact

on:

- Children and young people
- Older people?
- Could the proposal have a differential impact

on:

- Income groups
- Devolved countries
- Particular regions of the UK?

51. These proposals have not been designed to bring a specific benefit or set of benefits to a specific group or groups, or to a particular area of the country, but have instead been designed to apply consistently and transparently to the different types of establishment regulated under the Care Standards Act in England.

Sustainable Development

Have you considered all of the above issues and does the proposal comply with Sustainable Development Principles?

52. We have reviewed the proposals against the five sustainable development principles of:-

- Living with environmental limits;
- Ensuring a strong, healthy and just society;
- Achieving a sustainable economy;
- Promoting good governance; and
- Using sound science responsibly.

53. We are satisfied that our proposals will not undermine or act contrary to any of the five principles of sustainable development.

Consultation and Review

54. We propose to hold a twelve-week public consultation on these proposals. We will actively seek the views of organisations already in regulation and we will also continue discussions with Healthcare Commission to firm up the analysis on costs and benefits that require further attention.

55. We consider these proposals will support the wider and more fundamental changes we propose to make to the regulatory system for health and the adult social area from April 2009 onwards, subject to Parliamentary approval. The development of those proposals will involve input from the independent healthcare sector, and we will seek views on how the proposals outlined in this partial Impact Assessment have worked in practice as part of the Department's continuing responsibility regarding safe and effective practice. A more formal commitment to review and evaluation cannot be made at the present time.

Timescale

57. We hope to bring these changes into effect from 1 October 2008, subject to consultation. The proposals will be implemented by the Healthcare Commission as part of their risk-based assessment and inspection regimes.

Specific Impact Tests: Checklist

Use the table below to demonstrate how broadly you have considered the potential impacts of your policy options.

Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.

Type of testing undertaken	*Results in Evidence Base?*	*Results annexed?*
Competition Assessment	Yes	No
Small Firms Impact Test	Yes	No
Legal Aid	Yes	No
Sustainable Development	Yes	No
Carbon Assessment	Yes	No
Other Environment	Yes	No
Health Impact Assessment	Yes	No
Race Equality	Yes	No
Disability Equality	Yes	No
Gender Equality	Yes	No
Human Rights	Yes	No
Rural Proofing	Yes	No

Appendix A: Deregulation of lasers and lights – possible effect on the number of adverse incidents

The current number of adverse incidents or medical complications arising from treatments in laser and light establishments that would be deregulated under the proposals cannot be estimated directly – nor can a direct estimate be made of the effect that deregulation might have on increasing these numbers. The Healthcare Commission has some limited 'complications' data provided by twenty individual providers of regulated private cosmetic surgery. It reports that rates ranged from 3.7% to 0% with an overall rate of 1.0%. This is a small sample and the case mix is not known.

There is a limited literature on adverse events in medical settings. One of the most comprehensive studies of medical mistakes found that 3.7 per cent of patients suffered an injury that prolonged their stay or resulted in a measurable disability; nearly 14 per cent of these injuries were fatal [Harvard Medical Practice Survey, 1991]. In a UK setting, a smaller scale study [Vincent 1995] found that 7 per cent of hospital patients were the subject of medical mishaps. Vincent concluded that this led to a mean of seven extra days in hospital for those concerned, at a direct cost of £67,000 for 500 cases (other costs for dealing with mishaps were not included, such as dealing with claims and complaints). A later study by Vincent [Vincent et al, 2001], which consisted of a retrospective study of patient records in two English hospitals, found 10.8 per cent of patients experienced an adverse incident, of which around half (5.2 per cent) were judged to have been preventable. These adverse incidents caused permanent impairment in 6 per cent and contributed to death in 8 per cent of cases.

These figures cannot be applied directly to laser and light treatments. Nevertheless, such treatments are potentially harmful and they will generate adverse incidents.

Given the above considerations, a reasonable working assumption of 1% is adopted as the current adverse incident rate for laser and light procedures – this is the average figure provided by the Healthcare Commission statistics quoted above. In addition, a further working assumption is adopted that deregulation by the Healthcare Commission, mitigated by consumers taking more responsibility for ensuring treatments are provided to the correct standard, will increase adverse incidents to a new long-term level of between 1.5 and 2%.

Given there are currently 850 establishments that will be deregulated by the proposals, and assuming each establishment provides on average of 400 treatments per year, this means

that there are 340,000 treatments per year. In turn, deregulation would generate an extra 1700 – 3400 adverse incidents per year.

The main risk from laser and light treatment is burns to the skin. As an average unit cost for treating these adverse incidents, 2005 NHS reference costs have been used [see References for more information on the source of these figures]. In particular, healthcare related groups (HRGs) J37 and J45. These are respectively day case minor skin procedure category 1 w/o cc and day case minor skin infection. These are very similar in cost – £553 and £533 so an average unit cost of £540 is adopted.

Based on the estimate of increasing the number of adverse incidents by between 1700 and 3400 cases this represents a yearly extra cost of treating these cases of between £900,000 and £1.8m. These are the direct costs of treating adverse incidents and are, in the main, likely to fall on the NHS. Other costs, such as the costs of dealing with complaints or pursuing claims and time off work are not included. Also not taken into account is the reduction in pain and suffering in terms of quality adjusted life years (QALYS).

Appendix B: References

- Vincent 1995. C Vincent, Clinical risk management, London 1991: BMJ.
- Vincent et al 2001. Patient safety incidents in British hospitals; preliminary retrospective record review BMJ, March 2001, 322:517 -519.
- Harvard Medical Practice Survey 1991. Two papers. Paper 1 – Brennan T, Leape L, Laird N et al, Incidence of adverse events and negligence in hospitalised patients: the results from the Harvard Medical Malpractice Study I, New England Journal of Medicine, 1991, 324: 370 – 376. Paper 2 – Leape L, Brennan T, Laird N et al, Incidence of adverse events and negligence in hospitalised patients: the results from the Harvard Medical Malpractice Study II, New England Journal of Medicine, 1991, 324: 377- 384.
  NHS/DH reference cost information is on the Dept Health website: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_062884

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