

Explanatory Memorandum to the Independent Health Care (Fees) (Wales) Regulations 2011

This Explanatory Memorandum has been prepared by the Department of Health and Social Services and is laid before the National Assembly for Wales in accordance with Standing Order 24.1

Minister's Declaration

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of the Independent Health Care (Fees) (Wales) Regulations 2011. I am satisfied that the benefits outweigh any costs.

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20 January 2011

Description

1. The Independent Health Care (Fees) (Wales) Regulations 2011 prescribe the fees that are required to be paid by private independent hospitals, independent clinics, or independent medical agencies under Part II of the Care Standards Act 2000 ("the Act")

Matters of Special Interest to the Constitutional Affairs Committee

2. None.

Legislative Background

3. Under section 11(1) of the Care Standards Act 2000 ("the Act"), private independent hospitals, independent clinics or independent medical agencies defined in section 2 of the Act must register with the registration authority. Establishments which provide certain techniques or technology requiring registration, are further prescribed in the Private and Voluntary Health Care (Wales) Regulations 2002 ("the Regulations"). In relation to Wales, Welsh Ministers, by virtue of the Government of Wales Act 2006, are designated as the registration authority under the 2000 Act and the registration functions are carried out, on their behalf, by Healthcare Inspectorate Wales (HIW).

4. Private independent hospitals, independent clinics, or independent medical agencies, as defined in section 2 (2) and (3) of the Care Standards Act 2000,

must register with Welsh Ministers, through HIW. The relevant legal powers to impose regulatory fees are powers of the Welsh Ministers, provided in section 8 (4) of the Care Standards Act 2000 and in respect of the following:

- A registration fee (section 12(2) of the Act) - paid when an application to register is made.
- A variation fee (section 15(3) of the Act) - paid when an application to vary or remove a condition or conditions of registration is made.
- An annual fee (section 16(3) of the Act) – paid by registered persons for on-going registrations.
- A fee for changes in the ownership of a body corporate or the identity of its officers (section 22(7)(i) of the Act)

5. This instrument follows the negative resolution procedure.

Purpose and intended effect of the proposed regulations

6. In 2002, when the Care Standards Act 2000 first came into force in Wales, regulatory fees were required from anyone wishing to register to provide independent healthcare services under the Act. In 2006, these regulatory fees were abolished under the Care Standards Act 2000 and the Children Act 1989 (Abolition of Fees) (Wales) Regulations 2006 (“the 2006 Regulations”). At that time, the number of registered independent healthcare providers in Wales was less than 50. A small number of those were providing more critical and / or complex¹ care. Since then, there has been a steady increase in the number of registered providers offering a wider spectrum of care.

7. There are now approximately 100 independent healthcare providers registered with HIW, including:

- independent hospitals (which provide a range of services such as acute care listed services and care for people with a mental health illness and for people with a learning disability)
- independent clinics (which provide private medical services)
- independent medical agencies (who provide private call out services)

8. HIW’s operating costs are funded through its recurring Assembly Government budget. This budget covers HIW’s functions in relation to conducting reviews of ,and investigations into, the provision of NHS health care by and for Welsh NHS bodies (under the Health and Social Care (Community Health and Standards) Act 2003, and also HIW’s functions in relation to the regulation of independent healthcare providers registered with Welsh Ministers, through HIW, under the Care Standards Act 2000.

9. It is proposed to make regulations to introduce fees for:

¹ For example where a general anaesthetic is administered, where specialist clinical equipment is necessary for patients who may require critical care facilities post operatively, or patients who have enduring mental health problems which require them to be cared for in medium secure accommodation, or who are undergoing treatment for a critical illness or condition.

- Persons who wish to carry -on or manage an independent hospital, independent clinic, or independent medical agency in Wales and for
 - Persons currently registered with HIW to carry-on an independent hospital, independent clinic, or independent medical agency.
10. The proposed regulatory fees will contribute towards:
- HIW's costs associated with registering the person carrying-on or managing a relevant establishment or agency under the Act. Registration may include HIW obtaining specialist advice, pre-registration meetings with the person seeking registration, and will also include an assessment /review of the application documentation, the suitability of the applicant, and an assessment of whether the premises is fit for purpose. The fee will also cover HIW's general administration costs, including the provision of registration certificates and statutory registration notices etc.
 - HIW's costs of on-going regulation, such as the inspection of the registered establishment, the assessment of any self- assessment information, the preparation of inspection reports, and dealing with any concerns raised about the quality of services

Consultation

11. The proposed regulatory fees were subject to a three-month public consultation which closed on 30 November 2009. The consultees are detailed at **Annex 1**.

12. A total of 13 responses were received. The respondents are detailed at **Annex 2**. Overall, the response has been mixed with almost half of the responses received not supportive of the proposals. The following key issues were highlighted:

- The need for the size and income of a registered provider to be taken into account.
- The ability of small business and charities to pay regulatory fees during the recession and the impact of fees on small businesses.
- Clarity as to why not all charities are exempt from the proposed fees, rather than just hospices.
- Concern about the proposals for managers to be charged the same fee each time they move within Wales from one service to another given that this information will already be known to the regulator.
- Concerns about the proposals to charge fees for type 3 hyperbaric oxygen chambers.
- Clarity as to why an element of the proposed annual fee is based on the number of beds.
- Clarity on how the proposed fees have been costed.

13. The Welsh Assembly Government's response to the consultation, together with the proposed amendments arising from the consultation, is set out in **Annex 3**.

Regulatory Impact Assessment

Options

14. Option 1: Do not introduce regulatory fees. Failure to introduce regulatory fees will mean that HIW will continue to bear the full financial burden of regulation without a financial contribution from the independent healthcare sector. Given HIW's limited financial resources, and the current level of intensity of independent healthcare sector regulation, this is not sustainable.

15. Option 2: Introduce regulatory fees at a level to recover HIW's estimated direct regulatory costs. This level of fee recovery will contribute towards the direct costs of HIW direct costs associated with the registration and on-going inspection of establishments including direct permanent staff costs associated with the registration and on-going inspection of establishments. This level of fee recovery will not, however, contribute towards the costs of other (indirect) management overheads, specialist advice, and reviewer costs which may be required for HIW to inform judgements about the fitness of premises and services.

16. Option 3: Introduce regulatory fees at a level to recover HIW's estimated full-cost of regulation. This level of fee recovery will contribute towards HIW's direct and other indirect costs of regulation, including direct permanent staff costs associated with the registration and on-going inspection of establishments and indirect management overheads, specialist advice, and reviewer costs which may be required to inform judgements about the fitness of premises and services. Adopting full-cost recovery will necessitate the need for HIW to maintain detailed cost schedules for each activity. This could be achieved over time as costs are tracked, and any cross subsidy or increase in regulatory costs could be reflected in future revisions to the regulatory fees. For 2011-12 in the current financial climate, regulatory fees based on full-cost recovery could be problematic, in particular, for some of the smaller independent healthcare providers.

17. It is considered that Option 2 (introduce regulatory fees at a level to recover HIW's estimated direct regulatory costs) is the more viable option at present. It will ensure that there is a fair and reasonable contribution towards HIW costs of regulation. Over time, as actual costs are tracked, it will be appropriate for HIW to revise the regulatory fees in line with this and to consider including both direct and indirect costs.

Costs and Benefits

18. There are no financial implications for Healthcare Inspectorate Wales arising from the proposed regulations. The benefits are outlined against each option.

Risks of not proceeding

19. Failure to introduce regulatory fees will mean that HIW will continue to bear the full financial burden of regulation without a financial contribution from the independent healthcare sector. Given HIW's limited financial resources, and the current level of intensity of independent healthcare sector regulation, this is not sustainable.

Competition Assessment

20. It is anticipated that the level of fees proposed will not adversely impact competition between providers, since they will apply uniformly to all types of services in the market.

21. Regulatory fees are currently applied to the independent healthcare providers in England which aim towards full cost recovery. Our understanding is that fees aimed at full cost recovery in England have not adversely impacted the independent healthcare sector in terms of entry barriers. Consequently, the proposed Wales fees, which are lower than those charged in England, should not adversely impact the sector in Wales.

22. It is considered unlikely that these proposals will act as a restriction on new market entrants. The proposed amendments to the regulations do not favour any particular organisation within the independent healthcare sector, with the exception of hospices.

Post Implementation Review

23. The effect of the legislation will be monitored by reviewing the level of annual fees received by HIW.

Consultees

Independent healthcare providers and managers registered by Healthcare Inspectorate Wales (HIW), under the Care Standards Act 2000

Independent healthcare providers and managers currently under application for registration through HIW

Welsh Independent Healthcare Advisory Service

Healthcare Inspectorate Wales

Care and Social Services Inspectorate Wales

Health Commission Wales

Local Health Boards

Care Quality Commission

British Medical Association

Royal College of Nursing

Hair and Beauty Industry Authority (HABIA)

Multiple Sclerosis National Therapy Centres

Help the Hospices UK

Consultation Respondents

Energist Ltd , Swansea

CAIS Ltd

Anonymous Individual

Gresford Skincare Laser Clinic

Beauty within medi spa

Coleg Morgannwg

Mental Health Care (UK) Ltd

Oxygen Therapy Centre Cardigan Ltd

Welsh Independent Healthcare Advisory Services (WIHAS - representing acute and mental hospitals in Wales)

Board of Community Health Councils in Wales

MS Support Centre, Saltney

MS National Therapy Centres (covering Pembroke, Cardigan, Swansea and Saltney)

Destination Skin

Consultation Response

1. Do you agree with the principle of charging fees to contribute towards the cost of regulation? If not, what are your reasons for disagreeing?

Of the 13 respondents², 8 agreed with the proposal and 5 disagreed with the proposal. The reasons for disagreeing were:

- The size and income of a registered provider is not taken into account.
- The ability of small business and charities to pay fees during the recession.
- Charities are reliant on fundraising / donations for existence.
- If hospices are being exempt other charities should be exempt.
- Concern about fees for hyperbaric oxygen chambers.
- Payment of fees should take account of the regulators performance.

Welsh Assembly Government response

(a) Concerns about fees for hyperbaric oxygen chambers, charities being reliant on fundraising / donations for existence, and why only hospices are exempt from regulatory fees.

The proposed fees differentiate between registered service providers in terms of risk and complexity of treatment. For example, the National Minimum Standards (NMS)³ classify hyperbaric oxygen chambers into three types depending on the levels of critical care management provided. Type 1 and Type 2 chambers are for people who may require critical care facilities. A type 3 chamber is only for the provision of hyperbaric oxygen therapy which does not involve any form of critical or complex care and which is intended solely for patients with neurological disorders such as multiple sclerosis or cerebral palsy.

The proposals set out in the consultation for regulatory fees, in the case of hyperbaric oxygen chambers, made a distinction between the level of fees for different types of chambers. For type 3 chambers, it was proposed that registration fees would be significantly discounted, consistent with regulation being proportionate to risk, but still providing assurance on quality and safety. The annual fee proposed in the consultation for a type 3 chamber for the provision of hyperbaric oxygen therapy, was £250. Where hyperbaric oxygen treatment is provided in type 1 or type 2 chambers the proposed fee was £1,500, which recognises that these chambers are for patients who may require critical care facilities and where treatment may be under the direct supervision of a medical practitioner and the consequent regulatory costs borne by HIW are greater.

² Note: one response was on behalf of 28 registered providers

³ National Minimum Standards for Private and Voluntary Health Care Services, Welsh Assembly Government 2002

Given the type of treatment provided in type 3 hyperbaric oxygen therapy chambers, it is proposed to exempt providers who are charities, where the charity solely provides services that are free at the point of delivery and where the treatment is not commissioned by a public body. On this basis, providers of type 3 hyperbaric oxygen chambers will be exempt.

In relation to the point made about charities being reliant on fundraising / donations for existence, it is acknowledged that many charities rely solely on fundraising activities and donations to fund their operations. However, if a service is being commissioned from the charity, for example, from a public body, it would be reasonable for the charity to charge a fee to the commissioner of this service to help defray the costs of the proposed regulatory fee

(b) Concerns about the ability of small business and charities to pay fees during the recession.

It is proposed that the coming into force date of the proposed regulations is 1 April 2011. This recognises the difficulties of the current economic climate and allows registered providers, particularly smaller businesses, to plan for the introduction of fees.

(c) Linking regulators performance to fees

HIW will ensure that the costs of regulation are reasonable and this will include ensuring that efficient and effective regulatory / administrative systems are in place.

2. Do you agree with the proposal to charge registration fees? If not, what are your reasons for disagreeing?

Of the 13 respondents, 7 agreed with this proposal and 6 disagreed with the proposals. The reasons for disagreeing were:

- Registration in England will be abolished from 2010 for providers offering laser and intense pulse lights treatments.
- Small businesses have overheads and are further penalised
- May deter small businesses from registering.
- Managers should not be charged the same fee each time they move within Wales from one service to another as the information is already known to the regulator. A reduced fee should apply.
- Clarification on why hospices are not subject to fees and who will pay for this regulation
- Type 3 Hyperbaric oxygen therapy services are deregulated in line with England
- If in the future an independent treatment centre is set up and commissioned to provide totally NHS care, would they pay fees.
- Concern about the impact on small charities to pay fees.

Welsh Assembly Government response

(a) The issues highlighted about Type 3 Hyperbaric oxygen chamber services, the concern about the impact on small charities to pay fees, and why hospices are not subject to fees have been responded to in Question 1.

(b) The regulation of providers of laser and intense pulse lights treatments, this is a matter which will be considered as part of the review currently being undertaken of the PVH Healthcare (Wales) Regulations and National Minimum Standards made under the Care Standards Act 2000. The proposal in the consultation on the revision of the standards and regulations for independent healthcare addresses will be that all providers using prescribed technologies such as Class 3B/4 lasers or IPLS will remain regulated by HIW under the Care Standards Act 2000, and there will be proposals for those providers who are using these devices solely for a non-surgical cosmetic purpose (e.g. hair removal) that they will be subject to 'lighter touch' regulation.

(c) In relation to the concerns raised about managers to be charged a fee each time they move within Wales from one service to another, it is proposed that the requirement for managers to be charged a fee if they move within Wales, consecutively and without a gap, from one service to another is excluded. It is accepted that the information already available to HIW can be relied on where managers move within Wales consecutively and without a gap.

3. Do you agree with the proposal to charge an annual fee? If not, what are your reasons for disagreeing?

Of the 13 respondents, 7 agreed with this proposal and 6 disagreed with the proposal. The reasons for disagreeing were:

- Concern about the impact on small businesses
- Charities should be supported, not penalised, for bringing relief to MS sufferers.
- Annual fees should be based on the number of beds

Welsh Assembly Government response

(a) The concerns about the impact of fees on small businesses and charities has been responded to in Question 1

(b) In relation to the issue raised about the calculation of annual fees, in addition to a flat fee rate, which is payable in all cases and which is set at different levels for different categories of provider, an element of the annual fee is based on the number of beds. This is proposed because larger

establishments may provide a wider range of services and may require more specialist input to inspection⁴. This will be reviewed annually.

4. Do you agree with the proposal to have a fee for variation or removal of registration conditions? If not, what are your reasons for disagreeing?

Of the 13 respondents, 6 agreed with this proposal (although 2 of the respondents agreed in principle) and 7 disagreed with the proposal. The following comments were made:

- Supportive only if HIW is required to undertake a visit
- Supportive only if sufficient to cover administration costs

Welsh Assembly Government response

(a) The fee for variation of registration conditions covers HIW's administrative costs, including assessment of application information and where necessary, any visits. A desktop review of information also involves significant input. The fees for a major variation will normally apply where a visit is also required to be made, but a fee for a minor variation will normally apply where no visit is made. Fees will be sufficient to cover administrative costs only in respect of applications to remove a condition of registration.

5. In respect of all fee categories (registration, variation, annual) do you agree with the proposal to have either no fee or a reduced fee for certain types of services? If not, what are your reasons for disagreeing?

Of the 13 respondents, 12 agreed with this proposal. The following comments were made:

- Registered providers of laser and intense pulse lights treatments should not be part of the consultation
- Need to be aware of charities

Welsh Assembly Government response

(a) The points raised about charities and the regulation of Class 3B/4 lasers and intense pulsed light sources have been responded to in Question 1 and 2.

6. With the exception of lasers or IPLs and providers who solely offer Refractive Eye Surgery do you agree with the proposals that where multiple services are provided the higher registration and annual fee level will apply? If not, what are your reasons for disagreeing?

Of the 13 respondents, 5 agreed with this proposal; 8 responses were either not applicable / no comment / did not understand the question.

Welsh Assembly Government response

⁴ Note – inspection includes reviewing information provided from and about the registered provider, preparation, administration, site visit, inspection report.

(a) It is proposed that with the exception of lasers or IPLs and providers who solely offer Refractive Eye Surgery that where multiple services are provided the higher registration and annual fee level will apply

7. Do you agree with the proposal to make a refund of annual fees where the provider voluntarily cancels their registration within six months of the fee being paid? If not, what are your reasons for disagreeing?

Of the 13 respondents, 11 agreed with this proposal; 1 disagreed with the proposal; 1 response was no comment.

Welsh Assembly Government response

(a) It is proposed to make a refund of annual fees where the provider voluntarily cancels their registration within six months of the fee being paid.

8. Do you agree with the proposal that failure to pay the annual fee is a prescribed ground for cancellation of the registration? If not, what are your reasons for disagreeing?

Of the 13 respondents, 5 agreed; 1 agreed, subject to a warning being provided; 4 disagreed; 3 did not comment

Welsh Assembly Government response

(a) It is proposed that failure to pay the annual fee is a prescribed ground for cancellation of the registration.

9. The following additional comments / concerns were highlighted

- There is no evidence to support fees.
- Regulation already takes up too much time.
- There is a need to understand the need/costs of regulation, but need to bear in mind the size of the business.
- Agree with inspection, but fees be passed on to clients
- Clarity is required as to whether 'enforcement' fines are part of the fees consultation?
- Clarity is required on what is meant by a 'multiple registered provider'?
- The issue of 'bed fees' can place a disproportionate cost pressure on smaller facilities with fewer beds.
- There are differentiated fees between those who provide general acute (GA) and those who do not.
- Greater clarity is required on the reasoning of bed fees and how fees have been costed overall.
- The proposed bed fee is higher than the CQC in England

Welsh Assembly Government response

(a) Evidence to support fees

In 2002, when the Care Standards Act 2000 first came into force in Wales, the number of registered independent healthcare providers in Wales was less than 50. Since then, there has been a steady increase in the number of registered providers offering a spectrum of care. There are now approximately 100 independent healthcare providers registered with HIW, including independent hospitals (which provide care a range of services such as acute care listed services and care for people with a mental health illness and for people with a learning disability) ; independent clinics (which provide private medical services) and independent medical agencies (who provide private call out services)

HIW's costs relating to the regulation of independent healthcare providers is currently funded wholly from its recurring Assembly Government budget. Given the potential for HIW's cost of regulating independent providers to increase through new registrations and the current budgetary pressures, the introduction of regulatory fees is considered fair and reasonable. The proposed regulatory fees will contribute towards HIW's costs associated with registering the person carrying-on or managing a relevant establishment or agency under the Act. Registration may include HIW obtaining specialist advice, pre-registration meetings with the person seeking registration, and will also include an assessment /review of the application documentation, the suitability of the applicant, and an assessment of whether the premises is fit for purpose. The fee will also cover HIW's general administration costs, including the provision of registration certificates and statutory registration notices etc. The proposed regulatory fees will contribute towards HIW's costs of on-going regulation, such as the inspection of the registered establishment, the assessment of any self- assessment information, the preparation of inspection reports, and dealing with any complaints.

(b) Enforcement Fees are not part of the fees consultation. New regulatory enforcement options conferred on the Care Standards Act 2000, through Schedule 5 of the Health and Social Care Act 2008, provide for Fixed Penalty Offences. Regulations for Fixed Penalty Offences are currently being drafted.

(c) The issue of bed fees has been responded to in Question 3.

(d) The term 'multiple registered provider' relates to a provider who may be registered as an Independent hospital but as part of those hospital services provides treatment under section 2(3)(a)(ii) of the Act .

(e) Clarity on how fees have been costed.

HIW's estimated annual cost of regulation of its private and voluntary healthcare activities is approximately £324,460, detailed as follows:

Estimated direct staff costs	£320,260
Estimated management costs	£4,200

Total estimated costs £324,460

HIW's estimated annual receipt of regulatory fees in relation of its private and voluntary healthcare activities is approximately £249,750, detailed as follows:

Annual Fees

25 mental health hospitals		
• Flat rate fee	£50,000	
• Per bed	£113,750	£163,750
5 acute hospitals		
• Flat rate fee	£10,000	
• Per bed	£33,500	£43,500
1 termination of pregnancy clinic		£1,500
3 small independent hospitals		£1,500
41 Laser / IPL providers		£20,500
3 dental hospitals		£4,500
13 independent clinics		£6,500
Anticipated new registrations and variations		£6,000
Say 2 new mental health hospitals ; 2 new laser providers;		£1,500
Say 3 applications to vary conditions (major)		£500
Say 2 applications to vary conditions (minor)		
Total estimated regulatory fees		£249,750

The estimated receipt of regulatory fees (£249,750) recovers approximately 77% of HIW's estimated costs of regulation (£324,460). HIW will be monitoring its costs of regulation to ensure that fee recovery does not exceed costs.

(f) In relation to the point raised about the regulatory bed fees in Wales being higher than the regulatory bed fees charged by the Care Quality Commission in England, the CQC annual bed fees as highlighted in the 2009 fee scheme are marginally lower than the levels proposed by Wales (in some cases by only £2 per bed lower.) However, the annual flat rate fee is , generally, considerably higher in England when compared to Wales (for example, the flat rate for mental health hospitals or acute hospitals is £5,705 whereas in Wales, the proposed flat rate for mental health hospitals or acute hospitals is £2,000)

As a result of the issues raised during consultation the following is proposed:

- It is proposed that the coming into force date of the proposed regulations is 1 April 2011. This recognises the difficulties of the current economic climate and allows registered providers, particularly smaller businesses, to plan for this charge.

- It is proposed to exclude a charity from the payment of fees where the charity solely provides services that are free at the point of delivery and where the treatment is not commissioned by a public body. This exclusion will mean that charities such as hospices and providers of therapy in a type 3 hyperbaric oxygen treatment chamber (which does not involve any form of critical or complex care and which is intended solely for patients with neurological disorders such as multiple sclerosis or cerebral palsy) will not be subject to regulatory fees
- The requirement for managers to be charged a fee if they move within Wales, consecutively and without a gap of more than 7 days, from one service to another is excluded. It is accepted that the information already available to HIW can be relied on where managers move within Wales consecutively and without a gap of more than 7 days
- It is proposed that for those providers who are using prescribed technologies such as Class 3B/4 lasers or IPLS these devices solely for a non-surgical cosmetic purpose (e.g. hair removal) that they will be subject to 'lighter touch' regulation.