

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

The 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 (Wales) Regulations 2011. I am satisfied that the benefits outweigh any costs.

Mrs Edwina Hart AM OStJ MBE

Minister for Health and Social Services

10 March 2011

Description

1. The Independent Health Care (Wales) Regulations 2011 are made under the Care Standards Act 2000 ("the Act") and apply to independent hospitals, independent clinics and independent medical agencies in Wales. The Act provides, in relation to Wales, for the registration and inspection of establishments and agencies by Welsh Ministers through Healthcare Inspectorate Wales (HIW).

Matters of Special Interest to the Constitutional Affairs Committee

2. None

Legislative background

3. Private independent hospitals, independent clinics, or independent medical agencies, as defined in section 2 of the Act must register with the registration authority. Welsh Ministers, by virtue of the Government of Wales Act 2006, are designated as the registration authority under the Act. These registration functions have been transferred to Welsh Ministers by virtue of paragraph 30 of Schedule 11 to the Government of Wales Act 2006. The registration functions are carried out, on their behalf, by Healthcare Inspectorate Wales (HIW). The Private and Voluntary Health Care (Wales) Regulations 2002 (“the PVH Regulations”) set out the regulatory requirements for independent healthcare in Wales.

4. Section 23 of the Act provides for the publishing of statements of National Minimum Standards (NMS) applicable to establishments or agencies and for keeping these national minimum standards under review. Section 23(2) provides that the Welsh Minister shall keep the standards set out in the statements under review and may publish amended statements whenever it is appropriate. Section 23(3) provides that before issuing a statement, or an amended statement which effects a substantial change in the standards, the Welsh Ministers are required to consult such persons as they consider appropriate.

5. The instrument follows the negative resolution procedure

Purpose and intended effect of the proposed regulations

6. The NMS¹ have been in place for approximately eight years. Since then health care practice and provision has continued to develop as a consequence of innovation, research and learning, with new service models continually emerging. Consequently, a review of the NMS and the PVH Regulations was undertaken to ensure that they are fit for purpose.

7. In addition, the opportunity has been taken to align, as far as possible, the NMS with the new Standards for NHS Health Services in Wales, “*Doing Well, Doing Better*”, which came into force on 1 April 2010. These standards provide a consistent framework that enables health services to look across the range of their services in an integrated way to ensure that all that they do is of the highest quality and that they are “doing the right thing, at the right time, for the right patient in the right place and with the right staff”. The alignment of the NMS with the Standards for NHS Health Services in Wales will ensure, as far as possible, that the same standards of care apply to patients treated in independent hospitals, independent clinics or who receive services from independent medical agencies.

8. In reviewing the PVH Regulations, the opportunity was also taken to consolidate the numerous amendments made over the years to these Regulations. It is proposed that the PVH Regulations be revoked and

¹ The National Minimum Standards for Private and Voluntary Healthcare Services in Wales, Welsh Assembly Government 2002

replaced with the new (consolidated) draft Independent Healthcare (Wales) Regulations 2011.

9. The NMS will be replaced with new National Minimum Standards for Independent Health Care Services (2011)

10. The new Independent Health Care (Wales) Regulations 2011 will reduce unnecessary burdens on registered persons - for example:

- Establishments where minor podiatric procedures (for example, nail bed surgery) are provided solely under local anaesthetic are removed from regulation as independent hospitals.
- Establishments which currently require registration as independent hospitals solely by virtue of the provision of oral sedation will no longer be required to register as independent hospitals.
- Certain National Minimum Standards will not apply in relation to registered persons who use Class 3B / 4 Lasers for the provision of a non-surgical cosmetic purpose only.
- Hyperbaric treatment (type 3 hyperbaric chambers) not carried out by, or under the direct supervision or direction of a medical practitioner, is removed from regulation.
- The minimum interval for quality assurance visits by the registered provider to an establishment is reduced.

11. The new Independent Health Care (Wales) Regulations 2011 strengthen patient safety and the quality of treatment - for example:

- New regulations are put in place for blood management, infection control, advice bulletins / patient safety information, safeguarding vulnerable adults and children and monitoring the quality of treatment and services.
- Regulations are strengthened to improve the safekeeping of patient property ; the ordering, recording, administration and supply of medicines to patients ; the arrangements relating to infection control and the arrangements for clinical audit
- Establishments where health care professionals provide male circumcision² (whether for a medical purpose or for religious observance) will be regulated as independent hospitals.
- Where a registered person dies, the period of time that a personal representative can run that the establishment or agency is reduced.
- Registered persons are required to notify HIW of certain events, for example, where patients go absent without leave (for persons detained under the Mental Health Act 1983 (as amended)) and applications made under the Mental Capacity Act 2005 in relation to deprivation of liberty.

Consultation

² The Female Genital Mutilation Act 2003, makes female circumcision illegal.

12. The proposed new draft Independent Health Care (Wales) Regulations 2011 and the supporting new draft National Minimum Standards for Independent Health Care Services were subject to a three month public consultation which closed on 9 September 2010. **Annex 1** details the organisations / individuals who were consulted on the proposals.

13. A total of 22³ responses were received. The respondents are detailed at **Annex 2**. Overall, the response to the consultation was supportive. 88% of respondents agreed with the proposed new regulations; 90% of respondents agreed that the draft National Minimum Standards were clear and straightforward to understand; 84% of respondents agreed with the proposal to align, as far as possible, the National Minimum Standards with the Standards for Health Services in Wales.

14. The response to the consultation also highlighted a number of points for further consideration / clarification including:

- Concerns about the practical effect of the proposal to reduce the timescales from 12 months to 3 months in which a personal representative can run an establishment following the death of a registered person.
- Changing the frequency of employment checks and Criminal Record Bureau (CRB) checks for workers, providers and managers and concerns about the portability of CRB checks.
- The need for further clarity of interpretation of some aspects of the draft regulations including the definition of an independent clinics and clarity of interpretation of the universal applicability of some regulations across all provider settings.
- The need for further guidance to be referenced in a number of specific standards.
- The need for further clarity of interpretation in a number of specific standards

15. As a result of the consultation the following amendments to the Regulations are proposed:

- Regulation 35(4) - in order to minimise any practical difficulties following the death of a registered person, it is proposed that the time period in which a personal representative can run the establishment be extended from 3 months to 6 months.
- Regulations 9, 10, 12, 21 and Schedule 2 (fitness of registered persons and workers and policies and procedures) – in order to address the risks and concerns about portability of CRB checks and the need for providers to have robust arrangements for pre-employment checks, further consultation with HIW, CSSIW and Assembly Government policy leads in NHS Workforce was undertaken in November 2010. As a result of this further consultation the following amendments have been proposed:

³ One response represented the views of 20 independent healthcare providers

- All staff and persons who work in or for the purposes of an establishment or agency must have a fresh CRB check of the appropriate level before they commence working in or for the establishment or agency.
- In relation to staff and persons who work for the registered provider (with the exception of the registered manager and responsible individual), the requirement for these persons to have repeat CRB checks every three years will be removed.
- A new regulation is to be inserted to require registered persons to have in place a robust policy to ensure the safe recruitment of staff, including undertaking checks appropriate to the work that staff are to undertake.

[The current regulation requiring the registered person and any responsible individual to continue to have a repeat CRB check every three years will remain]

- Regulation 3(1)(f) – in response to consultation responses that highlighted that oxygen is not always administered through a mask in hyperbaric chambers, it is proposed that the words “oxygen through a mask” is replaced with a less prescriptive administration of oxygen
- Regulation 9 (3) – in order for the regulatory burden placed upon registered persons to be proportionate to the type of service being provided, it is proposed that an amendment will be made to clarify that this regulation applies having regard to the size of the establishment or agency, the statement of purpose and the number and needs of the patients.

16. The detailed response to the consultation is set out at **Annex 3** and **Annex 4**.

Regulatory Impact Assessment

Options

17. Option 1: Do not introduce new Regulations and the supporting new National Minimum Standards. Failure to introduce the new Regulations and supporting new National Minimum Standards will mean that regulations to strengthen patient safety, quality of treatment and to reduce unnecessary regulatory burdens will not be realised and the current PVH Regulations will remain in place. There are no additional costs imposed on the independent health care sector arising from the introduction of new Regulations and supporting new National Minimum Standards.

18. Option 2: Introduce new Regulations and the supporting new National Minimum Standards. If the new regulations and supporting new national minimum standard are introduced the regulations will strengthen patient safety, the quality of treatment and will reduce unnecessary regulatory burdens on registered persons.

19. The new Independent Health Care (Wales) Regulations 2011 reduce unnecessary burdens on registered persons in the following ways:

- Establishments where minor podiatric procedures (for example, nail bed surgery) are provided solely under local anaesthetic are removed from regulation as independent hospitals.
- Establishments which currently require registration as independent hospitals solely by virtue of the provision of oral sedation will no longer be required to register as independent hospitals.
- Certain National Minimum Standards will not apply in relation to registered persons who use Class 3B / 4 Lasers for the provision of a non-surgical cosmetic purpose only.
- Hyperbaric treatment (type 3 hyperbaric chambers) not carried out by, or under the direct supervision or direction of a medical practitioner, is removed from regulation.
- The minimum interval for quality assurance visits by the registered provider to an establishment is reduced.

20. The new Independent Health Care (Wales) Regulations 2011 strengthen patient safety and the quality of treatment in the following ways:

- New regulations are put in place for blood management, infection control, advice bulletins / patient safety information, safeguarding vulnerable adults and children and monitoring the quality of treatment and services.
- Regulations are strengthened to improve the safekeeping of patient property ; the ordering, recording, administration and supply of medicines to patients ; the arrangements relating to infection control and the arrangements for clinical audit
- Establishments where health care professionals provide male circumcision⁴ (whether for a medical purpose or for religious observance) will be regulated as independent hospitals.
- Where a registered person dies, the period of time that a personal representative can run that the establishment or agency is reduced.
- Registered persons are required to notify HIW of certain events, for example, where patients go absent without leave (for persons detained under the Mental Health Act 1983 (as amended)) and applications made under the Mental Capacity Act 2005 in relation to deprivation of liberty.

21. It is considered that Option 2 (introduce new Regulations and supporting new National Minimum Standards) is the more viable option given the reduction in unnecessary regulatory burdens and strengthened patient safety and the quality of treatment.

Costs and benefits

⁴ The Female Genital Mutilation Act 2003, makes female circumcision illegal.

22. There are no additional costs imposed on HIW or the independent health care providers registered with HIW arising from implementing the new draft Independent Health Care (Wales) Regulations 2011 and the supporting new draft National Minimum Standards for Independent Health Care Services.

Risks of not proceeding

23. If the proposals are not taken forward, improvements to strengthen patient safety, the quality of treatment and reductions in the regulatory burden will not be realised.

Competition Assessment

24. It is anticipated that these proposals will not adversely impact competition between providers, as they will apply uniformly to all types of services in the market.

25. It is considered unlikely that these proposals will act as a restriction on new market entrants. The proposed amendments to the regulations do not substantially favour any particular organisation within the market sector

26. It is considered that the effect of the proposed new NMS and Regulations on economic viability is limited.

Equality Impact Assessment

27. Independent hospitals (which provide a range of services such as acute care, listed services and care for people with a mental illness), independent clinics (which provide private medical services) and independent medical agencies (who provide private call out services) are the relevant establishments and agencies affected by the proposed revised Regulations and NMS.

28. Some treatments provided in these establishments are gender specific and have a religious dimension such as male circumcision performed on religious grounds and gender re-assignments. Care is normally provided in these establishments and by agencies (subject to the particular type of care or treatment being provided), irrespective of race, gender and gender re-assignment (including transgender), age, religion and belief and non belief, sexual orientation and disability. There are no identified issues which disproportionately adversely impact on human rights, in terms of fairness, respect, equality, dignity, and autonomy.

29. Treatment and care is accessible through a variety of funding mechanisms, for example:

- It is paid for by the patient themselves
- It is paid for by a commissioner of the treatment (e.g. a Local Health Board)
- It is paid for by a voluntary or charitable organisation (e.g. a hospice offering palliative care)

List of Organisations / Persons Consulted

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

All independent healthcare providers and managers currently under application for registration through HIW

Welsh Independent Healthcare Advisory Service

Independent Healthcare Advisory Service

Healthcare Inspectorate Wales

Human Fertilisation and Embryology Authority

Care and Social Services Inspectorate Wales

Local Health Boards in Wales

Care Quality Commission

General Medical Council

British Medical Association

Nursing and Midwifery Council

Royal College of Nursing

Velindre NHS Trust

Public Health Wales NHS Trust

The Welsh Ambulance NHS Trust

The Older People's Commissioner for Wales

The Children's Commissioner for Wales.

The Welsh Language Board

Learning Disability Wales

The Learning Disability Implementation Advisory Group

Cartrefi Cymru

Mencap Cymru

The Welsh Therapies Advisory Committee

Wales Council for Voluntary Action

Public Services Ombudsman for Wales

The Society of Chiropodists & Podiatrists

Health Professions Council

Hair and Beauty Industry Authority (HABIA)

Multiple Sclerosis National Therapy Centres

Help the Hospices UK

Health and Safety Executive

National Patient Safety Agency

Medicines and Healthcare products Regulatory Agency

Independent Safeguarding Authority

Department for Children Skills & Families

Equality and Human Rights Commission

Royal Pharmaceutical Council

Information Commission

Royal College of General Practitioners

Royal College of Obstetricians & Gynaecologists

Royal College of Ophthalmologists

Royal College of Physicians

Royal College of Psychiatrists

Royal College of Psychiatrists (Welsh Division)
Royal College of Surgeons of England
Royal Pharmaceutical Society of Great Britain
Welsh Local Government Association
The Association of Directors of Social Services Cymru

List of organisations / persons who responded to the consultation

British Pregnancy Advisory Service (Bpas)
Healthcare Inspectorate Wales
B.ten Ltd
Gresford Skincare Laser Clinic
Natural Health and Fertility Clinic
Royal College of General Practitioners (Wales)
St. Josephs Hospital
Park House Court Ltd
Hywel Dda Health Board
Ludlow St Healthcare
Welsh Language Board
Spire Hospital, Cardiff
Spire Hospital, Wrexham
Society of Chiropodists and Podiatrists
Velindre NHS Trust
Children's Commissioner for Wales
Ty Hafan Children's Hospice
Board of Community Health Councils
Welsh Independent Healthcare Association (WIHA)⁵
Nightingale House Hospice
Aneurin Bevan Health Board
Cardiff and Vale Health Board

⁵ The WIHA represents more than 20 independent healthcare providers (acute and mental health) in Wales operating more than 30 registered establishments.

Analysis of the Response to the Questionnaire

The following is a summary of the response to each of the consultation questions and the Welsh Assembly Government's response.

Question 1 - Are the standards straightforward to understand and is the language clear?

21 responses were received. 19 respondents (90%) agreed that the standards are clear and straightforward to understand. 2 (10%) respondents did not express a view.

Welsh Assembly Government Response

The Welsh Assembly Government notes that the majority of respondents agree that the standards are straightforward to understand and the language is clear.

Question 2 - Are there any revised standards that are not relevant for independent healthcare providers?

18 responses were received. 14 respondents (77%) agreed that the revised standards were relevant for independent healthcare providers. 4 (23%) respondents did not express a view.

Welsh Assembly Government Response

The Welsh Assembly Government notes that the majority of respondents agree that the revised standards are relevant for independent healthcare providers.

Question 3 - Are there any gaps or areas that are not adequately addressed?

19 responses were received. 10 respondents (53%) agreed that there were no gaps or areas that have not been are not adequately addressed. However, 6 (32%) respondents thought that there were gaps or areas that are not adequately addressed, with 2 responses referring to criminal record bureau checks. 3 (15%) respondents did not express a view

Welsh Assembly Government Response

The Welsh Assembly Government notes that the majority of the respondents agreed that there were no gaps or areas that have not been are not adequately addressed. The Welsh Assembly Government also notes that the issue of criminal record bureau checks has been highlighted as an area which requires further consideration. Our detailed proposals in relation to criminal record bureau checks are set out at question 15.

Question 4 - Do you agree with the proposal to align, as far as possible, the National Minimum Standards with the Healthcare Standards which are applicable for NHS bodies?

19 responses were received. 16 (84%) respondents agreed with the proposal to align, as far as possible, the National Minimum Standards with the Healthcare Standards which are applicable for NHS bodies. Only 1 (5%) respondent did not agree. 2 (11%) respondents did not express a view.

Welsh Assembly Government Response

The Welsh Assembly Government notes that the majority of respondents agree with the proposal to align, as far as possible, the National Minimum Standards with the Healthcare Standards which are applicable for NHS bodies

Question 5 - Do you agree with the proposal to remove from regulation hyperbaric oxygen therapy which is not carried out by or under the supervision or direction of, a medical practitioner?

18 responses were received. 6 (33%) respondents agreed with the proposal to remove from regulation hyperbaric oxygen therapy which is not carried out by or under the supervision or direction of, a medical practitioner. Only 1 (5%) respondent did not agree with the proposal. 11 (62%) respondents did not express a view.

Welsh Assembly Government Response

The Welsh Assembly Government notes that a third of respondents agreed with the proposal to remove from regulation hyperbaric oxygen therapy which is not carried out by or under the supervision or direction of, a medical practitioner and that only 1 respondent disagreed with the proposal.

Question 6 - Do you agree with the proposal to continue to regulate Lasers and Intense Pulsed Light Sources?

17 responses were received. 12 (70%) respondents agreed with the proposal to continue to regulate Lasers and Intense Pulsed Light Sources. Only 1 (6%) respondent did not agree with the proposal. 4 (24%) respondents did not express a view.

Welsh Assembly Government Response

The Welsh Assembly Government notes that the majority of respondents agree with the proposal to continue to regulate Lasers and Intense Pulsed Light Sources and that only 1 respondent disagreed with the proposal.

Question 7 - Do you agree with the proposal to apply fewer NMS (ie have a lighter touch) in relation to lasers and intense pulsed light sources used solely for non-surgical cosmetic treatments?

17 responses were received. 9 (53%) respondents agreed with the proposal to apply fewer NMS (i.e. have a lighter touch) in relation to lasers and intense

pulsed light sources used solely for non-surgical cosmetic treatments. Only 1(6%) respondent did not agree with the proposal. 7 (41%) respondents did not express a view.

Welsh Assembly Government Response

The Welsh Assembly Government notes that the majority of respondents agreed with the proposal to apply fewer NMS (i.e. have a lighter touch) in relation to lasers and intense pulsed light sources used solely for non-surgical cosmetic treatments and that only 1 respondent disagreed with the proposal.

Question 8 - Do you think that the proposed amendments in relation to minor podiatric procedures [ie that providing this technique does not trigger the need to register as an independent hospital] will ensure an appropriate level of regulation is applied to these minor procedures?

18 responses were received. 11(61%) agreed with the proposed amendments in relation to minor podiatric procedures. Only 1(5%) respondent did not agree with the proposal. 6 (34%) respondents did not express a view.

Welsh Assembly Government Response

The Welsh Assembly Government notes that the majority of respondents agreed with the proposed amendments in relation to minor podiatric procedures and that only 1 respondent disagreed with the proposal.

Question 9 - Do you agree with the proposed changes to the regulations which amend certain previous requirements in relation to the death of a registered person?

19 responses were received. 11(58%) agreed with the proposed changes to the regulations, but some concerns were expressed about the proposed timescales where the period in which a personal representative can run the establishment being reduced from 12 months to 3 months. 3 months was considered too short a period and 6 months was considered to be more realistic. One responder also suggested that all providers could be required to nominate a second individual at registration and ongoing but this would be too onerous on a small provider. 3 (16%) respondents did not agree with the proposal. 5 (26%) respondents did not express a view.

Welsh Assembly Government Response

The Welsh Assembly Government notes that although the majority of respondents agreed with the proposed changes to the regulations amending previous requirements in relation to the death of a registered person, some concerns were raised about the practical implications of the effect of reducing the period from 12 months to 3 months in which a personal representative can run the establishment. The Welsh Assembly Government recognises the practical concerns and proposes that the draft Regulation 34 be amended from 3 months to 6 months.

Question 10 - Do you agree with the proposal to make events notifiable to HIW, where patients detained under the Mental Health Act 1983 go

absent without leave and where applications are made under the Mental Capacity Act 2005 in relation to deprivations of liberty?

19 responses were received. 11(58%) agreed with the proposal under draft Regulation 30 to make events notifiable to HIW where patients detained under the Mental Health Act 1983 go absent without leave, and where applications are made under the Mental Capacity Act 2005 in relation to deprivations of liberty – but some concern that the requirement to notify HIW of any application made to the court, in relation to depriving a patient of their liberty, was unnecessary. 1(5%) respondent did not agree with the proposal. 7 (37%) respondents did not express a view.

Welsh Assembly Government Response

The Welsh Assembly Government notes that the majority of respondents agreed with the proposals to make events notifiable to HIW where patients detained under the Mental Health Act 1983 go absent without leave and where applications are made under the Mental Capacity Act 2005 in relation to deprivations of liberty. In relation to the concern expressed about duplication of notification, informing HIW of any application made under the Mental Capacity Act 2005 will enable HIW to monitor the frequency of, and reasons for, these applications. HIW will also update their downloadable notification form to include this new requirement. This proposed regulatory requirement also mirrors the requirements in England, under regulation 18 of the Care Quality Commission (Registration) Regulations 2009 No. 3112.

Question 11 – Do you think that the proposed amendments to clarify our policy in relation to the circumcision of male children are appropriate?

20 responses were received. 13 (65%) respondents agreed with the proposed amendments to clarify the policy in relation to the circumcision of male children as being appropriate. 7 (35%) respondents did not express a view.

Welsh Assembly Government Response

The Welsh Assembly Government notes that the majority of respondents agree with the proposal to clarify in the regulations that male circumcision, undertaken by a healthcare professional for medical or religious purposes will be subject to regulation under the Act from April 2011.

Question 12 - Overall, do you agree with the new regulations and / or sub sections that are proposed?

17 responses were received. 15 (88%) respondents agreed, overall, with the the new regulations and / or sub sections. 2 (12%) respondents did not express a view. One response questioned whether the proposed new requirement for an 'annual return' could be incorporated into HIWs annual self assessment methodology and not be an additional burden over and above this.

Welsh Assembly Government Response

The Welsh Assembly Government notes that the majority of respondents, overall, agree with the new regulations and / or sub sections that are proposed. It is also proposed that the 'annual return' is a self assessment against the standards and regulations (and so will not be an additional bureaucratic burden) which will be submitted to HIW to inform its ongoing regulation of the service. It is anticipated that HIW will provide the template for this assessment and, if possible, make it available online.

Question 13 - Are there any services that are not currently regulated by HIW under the Care Standards Act 2000 that should be?

19 responses were received. 4 (21%) respondents felt that there were some services that not currently regulated by HIW under the Care Standards Act 2000 that should be, including the regulation of all NHS providers in line with the Care Quality Commission in England, regulation of injectable cosmetics and fillers, and the reclassification of care homes that provide highly specialised interventions supported by multi disciplinary teams. 6 (32%) respondents felt that there were no services not currently regulated by HIW under the Care Standards Act 2000 which should be. 9 (47%) respondents did not express a view.

Welsh Assembly Government Response

The Welsh Assembly Government notes that approximately a third of respondents agreed that there were no services that are not currently regulated by HIW under the Care Standards Act 2000 that should be. In relation to non-surgical cosmetic treatments, including injectable cosmetics and dermal fillers, the Welsh Assembly Government supports a voluntary registration scheme such as the Independent Healthcare Advisory Services (IHAS) model to encourage the public to seek treatment from a safe, reputable provider.

Question 14 - Are there any comments on the aspects of equality, diversity and human rights within the standards that you wish to make?

18 responses were received. 12 (68%) respondents did not express a view. 3 (16%) respondents commented that there was no mention of religious or spiritual choices at death and that the UN Rights of the Child was not referenced in Standard 10 in relation to privacy and dignity. 3 (16%) respondents did not express a view.

Welsh Assembly Government Response

The Welsh Assembly Government notes that the majority of respondents did not have any comments in relation to aspects of equality, diversity and human rights within the standards. The comments in relation to UN Rights of the Child will be referenced in Standard 10 in relation to privacy and dignity.

Question 15 - What are your views on employment checks and CRB checks for workers, providers and managers?

20 responses were received. 1 respondent did not express a view.

All 19 respondents who expressed a view indicated that CRB checks were important. 10 (53%) respondents did not highlight any proposed change with the current regulatory requirements. 2 (11%) respondents suggested that CRB checks should be portable. 7 (36%) respondents proposed an alternative approach to CRB checks (The current regulatory requirements mean that registered persons must obtain a fresh CRB check, of the relevant level⁶, every three years, for each member of staff or person who works in or for the purposes of the establishment or agency. 5 respondents suggested that the need to repeat the check every three years was not necessary and 1 respondent suggested applying the same CRB rules as the NHS.)

Welsh Assembly Government Response

In relation to the issue of portability, the CRB have developed guidance⁷ about the re-use of CRB checks, known as 'portability'. The CRB guidance sets out how portability may work but also the risks, limitations and legal obligations regarding CRB information.

The current regulations permit a registered person to accept a CRB in respect of which no more than 3 years have lapsed since it was issued. It is accepted that this approach does not fit well with safeguarding because other pre - employment checks may not highlight problems or concerns, or criminal records, cautions and relevant information held by police forces.

In order to address the risks and concerns about portability, and the need for providers to have robust arrangements for pre-employment checks, it is accepted that undertaking a fresh CRB, as opposed to one which may have been issued almost three years previously, will enable providers to have up to date information about any criminal records which might impact on their decision to employ someone. The regulations as drafted seek to balance the need for robust safeguarding provisions against a provider's obligation to have sufficient qualified and skilled staff in place. As such, the draft regulations do permit a person to start work at an establishment or agency if a CRB certificate has been applied for but not received, provided that a number of other safeguards are in place and other vetting has taken place.

In order to provide on-going safeguarding assurance, providers must ensure that they do not employ someone who is barred from 'regulated or controlled activity' under the Safeguarding Vulnerable Groups Act 2006. In addition, when the Independent Safeguarding Authority (ISA) commences registration under the Scheme's phasing in arrangements, workers will be required to be registered with the ISA.

In order to address these risks and concerns, the following amendments are proposed to the draft regulations:

⁶ Standard or Enhanced level

⁷ <http://www.crb.homeoffice.gov.uk/faqs/portability.aspx>

- All staff and persons who work in or for the purposes of an establishment or agency must have a fresh CRB check of the appropriate level before they commence working in or for the establishment or agency. This addresses the risk about portability.
- In relation to staff and persons who work for the registered provider (with the exception of the registered manager and responsible individual), the requirement for these persons to have repeat CRB checks every three years will be removed. [This approach is in line with the other UK countries].
- A new regulation is to be inserted to require registered persons to have in place a robust policy to ensure the safe recruitment of staff, including undertaking checks appropriate to the work that staff are to undertake

The current regulation requiring the registered persons and any responsible individual to continue to have a repeat CRB check every 3 years will remain unchanged.

Question 16 – Other comments

Clarity was sought as to whether podiatrists, who comply with the Society of Podiatry Accreditation scheme and who need to register under the Act, require HIW inspections

Welsh Assembly Government Response

Establishments where minor podiatric procedures, (for example, nail surgery) are provided under local anaesthesia only, will not be subject to regulation as an independent hospital. Podiatric procedures provided under general anaesthesia will be subject to regulation. Subject to HIW being able to meet its statutory regulatory obligations, inspection intervals are at the discretion of HIW. To assist HIW gain assurance that a provider is complying with their statutory obligations under the Act, a registered person may choose to submit evidence to HIW of how they have met the Society of Podiatrists Accreditation Scheme, where this maps to a relevant NMS or regulatory requirement.

Clarity was sought as to whether the Hellenic Clinical Indicators and Data Management Programme would be acknowledged by HIW

Welsh Assembly Government Response

Registered providers can choose to refer HIW to *The Hellenic Clinical Indicator and Data Management Programme* as supporting evidence of their compliance with a specific NMS.

An amendment to Regulation 3(1) (f), was proposed. It was suggested that the words “oxygen through a mask” is replaced with a less prescriptive administration of oxygen

Welsh Assembly Government Response

The Welsh Assembly Government agrees that the current drafting is too prescriptive. It is proposed that regulation 3(1) (f) will be amended.

Clarity was sought as to whether Regulation 9 (2) - which sets out a requirement for the preparation and implementation of a written policy setting out how disturbed behaviour exhibited by a patient is managed - is universally applied or whether it applies only to relevant settings

Welsh Assembly Government Response

The Welsh Assembly Government accepts that this regulation should be interpreted having regard to the size of the establishment, the statement of purpose and the number and needs of the patients. It is proposed that regulation 9 will be amended to reflect this.

Responses received in relation to the draft National Minimum Standards for Independent Health Care Services in Wales

NMS Comment

- 1 None received
- 2 Reference to the Children’s Commissioner for Wales should be included within the supporting information and guidance section.

In relation to mental health, reference to restraint should be included. Also, reference to the requirement for detailed policies in relation to the explanation of rights (right to withdraw consent, right to appeal against detention etc as specified in MHA Code of Practice for Wales) for detained patients and checking they have been understood. Also, there is need to include a statement to the effect that restrictions placed upon a person should be the minimum necessary to manage the risks identified for that individual.

WAG Response

Reference to the Children’s Commissioner for Wales will be included within the supporting information and guidance section. Reference will be made to restraint in the section covering mental health.

- 3 None received
- 4 Reference to the need for an uninterrupted supply (or back up arrangements) is rewritten to cover secure MH units as well.
Need links to NPSA / MHRA

WAG Response

Reference to the need for an uninterrupted supply (or back up arrangements) will include secure mental health units. Reference will be made to NPSA / MHRA within the supporting information and guidance section.

- 5 Reference is made to the need for patient satisfaction surveys to be used to inform developments and improvements. Reference should also be made to the importance of such processes feeding into governance processes

WAG Response

Reference will be made linking the patient satisfaction surveys improvement processes with the governance.

- 6 For independent sector this should be more orientated toward quality improvement rather than harm reduction.

Reference to regulation 15 should be included. In relation to policies and procedures, reference should be made to regulation 9. In relation to notifications reference should be made to regulation 30 and not regulation 28. DOLS reporting is a duplication

WAG Response

In relation to notifications the regulation numbers are 29 and 30.

7 None received

8 'Care Planning and Provision' is all-important in the context of ensuring the consistency and quality of bilingual care across disciplines and sectors. There is an opportunity to make reference to bilingual provision in line with the requirements of partnership and contracting with the public sector.

Mental health - this section should be reworded to included reference to: An evaluation of the clinical history, including identification of risks to themselves or to others, including suicidal tendencies.

WAG Response

Reference to bilingual provision is made in standard 9 which sets out the need for information to be provided in a language and format appropriate to the level of the understanding of the service user. The section relating to mental health will be amended to include a risk to themselves or to others.

9 It is important to note that as provided by Article 12 of the UNCRC the child who is capable of forming his or her own views has the right to express those views freely in all matters affecting the child, the views of the child being given due weight in accordance with the age and maturity of the child. Additionally Article 13 of the UNCRC provides the child with the right to freedom of expression; this right shall include freedom to seek, receive and impart information and ideas of all kinds, regardless of frontiers, either orally, in writing or in print, in the form of art, or through any other media of the child's choice. We would suggest that the UNCRC could be usefully referenced within the Supporting information and guidance section for Standard 9.

Standard 9 deals with patients receiving *"the right information, at the right time, provided by the right people, in a way they can understand"* in order to consent to treatment in a manner which is clinically safe and once more reference must be made to what is stated in paragraph 5 above i.e. the question of whether some patients can be assessed and treated clinically safely and effectively in English if Welsh is their main language? Providers should give due attention to the linguistic needs of the patients in their care and the supporting guidance should refer to.

Include MHA and MCA relevant links in supporting guidance.

WAG Response

Reference to UNCRC, MHA and MCA will be made within the supporting

information and guidance section. Reference to due linguistic needs of the patient will be made.

- 10 We welcome the fact that Standard 10 refers to respect for the linguistic needs of patients in the context of dignity and respect and we believe that it would be appropriate to give providers guidance by referring them to good practice, to language legislation and to the work and resources of the Welsh Language Board.

The rights of the child is not included. There is no reference to religious and spiritual choices.

WAG Response

Reference to religious and spiritual choices will be made. Reference to bilingual provision is made in standard 9 which sets out the need for information to be provided in a language and format appropriate to the level of the understanding of the service user. In relation to rights of the child, reference is made in standard 2 to the rights of children, safeguarding is covered in standard 11 and the children's environment is covered in standard 12.

- 11 With regard to Standard 11 Safeguarding Children and Safeguarding Vulnerable Adults, Regulation 16, provides that "abuse", in relation to a patient, means—
- (a) sexual abuse;
 - (b) physical or psychological ill-treatment;
 - (c) theft, misuse or misappropriation of money or property; or
 - (d) neglect and acts of omission which cause harm or place at risk of harm

We would question whether this definition is in line with the All Wales Child Protection Procedures and the four definitions of abuse therein which are: Physical, emotional, sexual and neglect.

Should reference to regulations 38 & 46 be made?

Also the Registration of Social Care and independent health Care (Wales) Regulations 2002 makes reference to what has to be in place for registration in Schedule 1 Part II – you may wish to make reference to this. Mental health

Suggest a bullet point also covers the content of regulation 46.

What is meant by corporate and local lead for POVA ?

WAG Response

The definition as drafted is consistent with the All Wales Child Protection Procedures. Reference will be made to regulations 38 & 46. The corporate lead will be a designated senior officer of the organisation. The local lead

will be a designated person in the care establishment.

- 12 Refers to Environment which once again places patient experience at the centre of all the standards. We would like to note in addition that an environment which respects the patient's dignity and identity and which empowers the patient to use his/her language of choice without feeling uncomfortable by normalising the Welsh language and offering positive support is vital to the wellbeing of Welsh speaking patients.

WAG Response

The environment in this context, relates to the physical environment. Standard 10 makes reference to the linguistic needs of the patients.

- 13 No comments received

- 14 For the vast majority of independent sector providers in Wales, breastfeeding is probably not relevant – suggest this is removed from the definition, but may be added as a guidance under service specific section

Should reference to regulation 18 also be made?

It is unclear how the bullet point about patients accommodated/treated for obesity will be interpreted. Does it apply to any service that happens to be treating / caring for a person who is obese?

Is it the expectation that the second point about specialist knowledge of obesity management and nutritional needs apply to slimming clinics? If so could the wording be made clearer?

WAG Response

Reference will be made to breastfeeding only applying where mothers who are breast feeding are treated (e.g. a mother and baby unit in a mental health unit.)The bullet point relating to patients who accommodated and/ or treated for obesity will not apply to all patients who are being treated for different conditions but who are also obese. Reference will be made to independent clinics (which includes slimming clinics) who treat patients for obesity to have a specialist knowledge in obesity management and nutritional needs, relevant to their role.

- 15 Should reference to regulations 39 & 40 also be made?

Does it need to be made clear that those organisations holding and administering controlled drugs need to have Home Office License?

Make sure clear that when medicines supplied to patients provided with manufacturers information but only for OPDs (difference between 'dispensed' and 'administered')

WAG Response

Reference to regulations 39 & 40 is not necessary. HIW do not regulate the

Medicines Act or Home Office licensing. The following link will be inserted as supporting guidance -

<http://www.homeoffice.gov.uk/drugs/licensing/domestic-licences>

Clarification that when medicines supplied to patients provided with manufacturers information but only for OPDs (difference between 'dispensed' and 'administered' will be made in NMS 15 (p52)

16 No comments received

17 No comments received

18 Should reference to regulation 18 also be included

We welcome the fact that standard 18 'communicating effectively' addresses linguistic considerations. We believe that reference should be made to the Welsh Language Board website in the section on supporting guidance so that providers can access information on best practice regarding bilingual provision.

WAG Response

Reference has been made to the Welsh Language Board website in the section on supporting guidance

19 Should reference to regulation 9 also be included?

WAG Response

Reference to regulation 9 will be included.

20 There is some duplication in the text of this standard, which causes some confusion – also the drive to create a single patient record is not always in the best interests of patient safety where consultations are conducted in different locations. Much of the text may be better dropped into a guidance document rather than being stipulated in the Standard itself.

Clarify 'single' or 'comprehensive'.

Last 2 bullet points redundant

Suggest reference is made to the MHA Code of Practice for Wales.

May benefit by changing much of this into guidance rather than a standard. Careful consideration is also required when recommending a drive for a single patient record as there are instances when it may not be the most suitable or safest approach, such as taking account of multi-location treatments and consultations.

WAG Response

The standard requires professional notes to be integrated into a single patient record and this includes consultations in different locations. The last

two bullet points are considered relevant. Reference will be made to the MHA Code of Practice for Wales

- 21 It may be helpful to provide a definition of Research vs Audit – the one being pro-active/real time patient involvement and the other being a retrospective review/monitoring of past activity or outcomes. Reference to the Integrated Research Application System may not be relevant for the independent sector, unless it is accessible for non NHS organisations.

It might be helpful to make reference to the Mental Capacity Act in the bullet point about processes for obtaining consent as there is specific detail in the Act in relation to consent as part of research.

Would benefit from defining what is meant by Research and Audit to avoid confusion as the two are different processes with different outcomes. WIHA is not clear that independent sector organisations can access the Integrated Research Application System. This being the case its inclusion would not be so relevant.

WAG Response

Clarification will be made in relation to the Integrated Research Application System and Ethics Committee approval. Reference will be made to the Mental Capacity Act in relation to the processes for obtaining consent.

- 22 Should also link to Regulation 26 and should include more consistent references to other H & S legislation, if these are to be referenced at all here.

As part of the CPA all care and treatment plans should be based on a comprehensive risk assessment of the individual. It would be useful to include a reference to this requirement.

Further, it needs to be made clear that medium and low secure MH services should set out their arrangements for adequately and appropriately addressing environmental, relational and procedural security as these should be appropriate to the risk that patients pose and should ensure that the restrictions placed on patients are proportionate to the risk.

Should also link to regulation 26 and ensure there are consistent references to Health and Safety if they are to be included.

Change management of staff absenteeism to impact of staff absenteeism.

WAG Response

Reference will be made to Regulation 26. Reference will be made to medium and low secure mental health services.

- 23 Dealing with Concerns and Managing Incidents, we recognise the importance of having systems that are able to respond to concerns that may be raised by staff and service users alike. We would reinforce the

importance of ensuring that children and young people receive information in formats that are accessible and understandable to them. It is vital that children and young people are confident that adults will take their concerns seriously and that responses to issues that children raise are timely. Children and young people may not always wish to use formal complaints procedures and it is important that providers consider how they gather the views of children and young people on an ongoing formative basis in ways that are accessible and child friendly.

Should also make reference to the MOU between WIHA and HIW as a reference/guidance source.

Inconsistent language (incidents; near misses; adverse incidents; errors; critical incidents.)

WAG Response

The glossary will be amended to clarify inconsistent language in relation to incidents; near misses; adverse incidents; errors; critical incidents etc. Reference will be made to the MOU between WIHA and HIW as a reference/guidance source. Reference will be made for the need to ensure that children and young people receive information in formats that are accessible and understandable to them.

24 Should reference be made to regulation 21 and not 20?

Re-word bullet re referral to the ISA, frequency of CRB needs to be addressed.

Relevance of RSCN in a mental health unit? Need to clarify settings and appropriate experience.

WAG Response

Reference should be made to regulation 20 and not regulation 21. Reference has been made to CRB checks. In relation to children further clarity has been made in relation service specific elements.

25 Mental health practitioners are not RMOs, they are responsible clinicians or medical practitioners.

Look at wording of training and induction – make relevant to role

Take out – ‘until competence is achieved’.

It would be very useful to see a reference to the Welsh Language Board’s advice document, Recruitment and the Welsh Language, in the context of standards 24 and 25, as the planning, recruitment and deployment of a bilingual workforce is vital to delivering the quality of services fully in Wales. We trust that you will incorporate the necessary references to

- the need to consider the linguistic needs of patients and users in order to provide a quality service which is clinically effective

- national and European language policy and legislation
- the Welsh Assembly Government's vision of effective bilingual healthcare services
- a link to the Welsh Language Board's website and resources in order to provide further advice and guidance for providers.

WAG Response

Reference to bilingual provision is made in standard 9 which sets out the need for information to be provided in a language and format appropriate to the level of the understanding of the service user. Changes have been made to make relevant to their role. Reference to Resident Medical Officers (RMO) has been removed and reference to on going training relevant to their role has been included.

Glossary comments

Suggest you also include reference to

- HFEA – or whatever replaces them
- IPL
- Classes of lasers and operation by health care professionals

Same sex accommodation- a statement about persons who have successfully been reassigned their gender would be helpful.

WAG response

This has been addressed. Once a person is legally reassigned they are of that gender but not until then.

Introduction comments

A number of suggestions were made including making reference to the use of blood; making reference to cancer standards; clarity as to what are the requirements when children are admitted for only one night; making reference to European Directives in relation to diagnostic services; in relation to pharmacy making reference to the need for a license from the Home Office for possession and supply of controlled drugs ; reflecting changes in relation to the future of the the HFEA; and explaining what are the circumstances that exclude an hospice from the need for registration; clarity as to whether medico legal work falls into or outside of regulation.

WAG Response

Changes have been made to pharmacy services making reference to the need for a license from the Home Office for possession and supply of controlled drugs. The use of blood, cancer standards and reference to European Directives are covered in the relevant standards. HIW can address queries in relation to registration.