

**Swansea Laser Clinics Limited**  
**4 Castell Close**  
**Swansea Enterprise Park**  
**Phoenix Way**  
**Llansamlet**  
**Swansea**  
**SA7 9FH**

**Inspection Report 2010-2011**

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<b>Inspection Date:</b>	<b>Inspection Managers:</b>
4 April 2011	Mr Ian Dillon & Miss Sarah Lewis

## **Introduction**

Independent healthcare providers in Wales must be registered with Healthcare Inspectorate Wales (HIW). HIW acts as the regulator of healthcare services in Wales on behalf of the Welsh Ministers who, by virtue of the Government of Wales Act 2006, are designated as the registration authority.

To register, they need to demonstrate compliance with the Care Standards Act 2000 and associated regulations. HIW tests providers' compliance by assessing each registered establishment and agency against the *Private and Voluntary Health Care (Wales) Regulations 2002* a set of *National Minimum Standards*, which were published by the Welsh Assembly Government and set out the minimum standards for different types of independent health services. Further information about the standards and regulations can be found on our website at: [www.hiw.org.uk](http://www.hiw.org.uk)

Readers must be aware that this report is intended to reflect the findings of the inspection episode. Readers should not conclude that the circumstances of the service will be the same at all times.

## **Background and Main Findings**

An announced inspection was undertaken at Swansea Laser Clinic on 4 April 2011. The clinic was first registered on 9 November 2009 and is registered to provide a range of treatments using Intense Pulsed Light and Class 4 Laser Technology.

The inspection visit focused upon the analysis of a range of documentation, discussion with the registered manager and examination of patient records.

Details of which standards have/have not been met are provided and a full list of requirements and recommendations are included from pages 10-12.

The main inspection findings are listed below.

### **Patient Information**

A number of patient information leaflets were available detailing the services available at the clinic. However none of the guides included all of the required information as stated in regulation 6 of the Private and Voluntary Health Care (Wales) Regulations 2002.

The clinic maintains a treatment register which included date of treatment, patient name, area treated, shot count, signature authorisation and details of any adverse effects.

Patient records were locked away from the public in fire proof cabinets. Three patient files were viewed which were all legible, signed and dated. Files evidenced that patient consultations had taken place and medical questionnaires had been completed. Also patients sign prior to each session to consent to treatment and to confirm that their medical circumstances have not changed.

Questionnaires are given to patients but due to a lack of response no analysis of returned questionnaires has been undertaken.

### **Policies and Procedures**

Policies and procedures were available along with an index which included formulation and review dates. There was also a declaration signed by staff to show they had read and understood all policies and procedures in place. Policies and procedures in place included:

- Whistle blowing policy should a staff member wish to raise concerns about a colleague
- Complaints policy. There have been no complaints in the past 12 months.
- Confidentiality agreement which has been signed by all members of staff

- Destruction of patient records policy and a procedure was in place should a patient request access to their records
- Recruitment procedure which includes completing application forms and requesting references
- Protection of Vulnerable Adults (POVA) policy and POVA training has also been undertaken.
- Cleaning policy and cleaning schedules are maintained.
- Resuscitation policy, however the policy needs to clearly state exactly what action is to be taken should a patient require resuscitation.

### **Environment Safety**

The Laser Protection Advisor last visited the clinic on 7 October 2010 and an environmental risk assessment has been undertaken within the last year which is compliant.

Fire safety compliance was evidenced. Fire prevention training has been undertaken, fire drills are carried out and a fire log book was available which recorded all fire safety checks.

A five yearly wiring check has been completed; however Portable Appliance Testing (PAT) has not been carried out within the last year which is a requirement.

### **Equipment Safety**

IPL\laser and Core of Knowledge training has been undertaken. All authorised operators have also received CRB checks.

There are three lasers at the clinic and certificates were available to evidence that they had all been serviced and calibrated within the last year in accordance with the regulations.

There is an expert medical protocol in place; however the protocol was not signed by the expert medical practitioner. The expert medical practitioner needs to sign the protocol once it is formulated and also review and sign it every 3 years.

There is a sign on the treatment room door and the door is locked when treatment is being provided. Protective eyewear is used during treatment.

## Registration Types

This registration is granted according to the type of service provided. This report is for the following type of service:

Description
<p><b>Independent hospital providing a listed service using a prescribed technique or prescribed technology:</b></p> <ul style="list-style-type: none"> <li>• <b>Laser or Intense Pulsed Light Source</b></li> </ul>

## Conditions of Registration

This registration is subject to the following conditions. Each condition is inspected for compliance. The judgement is described as Compliant, Not Compliant or Insufficient Assurance.

Condition number	Condition of Registration	Judgement
1.	No services are to be provided except using a NLite class 4 laser, a class 4 Lumenis Ultra Pulse CO2 Laser and a Lumenis 1 diode/Nd, YAG/Intense Pulsed Light System within the meaning of regulation 3 (1) (a) & (b) of the Private and Voluntary Healthcare (Wales) Regulations 2002.	Compliant
2.	Only the nominated persons, as referered to in your local rules (as varied from time to time) are authorised to use the equipment listed in (1) above for the following treatments only:	Compliant

Condition number	Condition of Registration	Judgement
	<p>(a) skin lesions/wrinkles  (b) active acne  (c) scars  (d) leg veins  (e) spider naevi  (f) telangiectasia  (g) red scar  (h) port wine stains</p> <p>The above treatments (a) – (h) must only be provided using the NLites class 4 laser</p> <p>(i) wrinkles  (j) scars including acne  (k) moles  (l) skin rejuvenation</p> <p>The above treatments (i) – (l) must only be provided using the class 4 Lumenis Ultra Pulse CO2 laser</p> <p>(m) hair removal  (n) vascular lesions  (o) skin pigmentation</p> <p>The above treatments (m) – (o) must only be provided using the Lumensis 1 diode/Nd YAG/Intense Pulsed Light System.</p>	
3.	No treatment is provided to persons under the age of 18 (eighteen) years.	Compliant
4.	No overnight accommodation is provided.	Compliant

## Assessments

Healthcare Inspectorate Wales (HIW) carries out on site inspections to make assessments of standards. If we identify areas where the provider is not meeting the minimum standards or complying with regulations or we do not have sufficient evidence that the required level of performance is being achieved, the registered person is advised of this through this inspection report. There may also be occasions when more serious or urgent failures are identified and the registered

person may additionally have been informed by letter of the findings and action to be taken but those issues will also be reflected in this inspection report. HIW makes a judgment about the frequency and need to inspect the establishment based on information received from and about the provider, since the last inspection was carried out. Before undertaking an inspection, the Healthcare Inspectorate Wales will consider the information it has about a registered person. This might include: a self assessment against the standards; the previous inspection report findings and any action plan submitted; provider visits reports; the Statement of Purpose for the establishment or agency and any complaints or concerning information about the registered person and services.

In assessing each standard we use four outcome statements:

Standard met	No shortfalls: achieving the required levels of performance
Standard almost met	Minor shortfalls: no major deficiencies and required levels of performance seem achievable without extensive extra activity
Standard not met	Major shortfalls: significant action is needed to achieve the required levels of performance
Standard not inspected	This is either because the standard was not applicable, or because, following an assessment of the information received from and about the establishment or agency, no risks were identified and therefore it was decided that there was no need for the standard to be further checked at this inspection

## Assessments and Requirements

The assessments are grouped under the following headings and each standard shows its reference number.



- Core standards
- Service specific standards

Standards Abbreviations:

C = Core standards

A = Acute standards

MH = Mental health standards

H = Hospice standards

MC = Maternity standards

TP = Termination of pregnancy standards

P = Prescribed techniques and technology standards

PD = Private doctors' standards

We have set out our findings below and specified from pages 10-12 what recommendations / requirements if any, the registered provider must take to bring the establishment in line to comply fully with the minimum standards and regulations. Failure to comply with a regulation may be an offence. Readers must be aware that the report is intended to reflect the findings of the inspector at the particular inspection episode. Readers should not conclude that the circumstances of the service will be the same at all times; sometimes services improve and conversely sometimes they deteriorate.

## Core Standards

Number	Standard Topic	Assessment
C1	Patients receive clear and accurate information about their treatment.	Standard almost met
C2	The treatment and care provided are patient – centred.	Standard met
C3	Treatment provided to patients is in line with relevant clinical guidelines.	Standard met
C4	Patients are assured that monitoring of the quality of treatment and care takes place.	Standard met
C5	The terminal care and death of patients is handled appropriately and sensitively.	Standard not applicable
C6	Patients views are obtained by the establishment and used to inform the provision of treatment and care, and prospective patients.	Standard almost met
C7	Appropriate policies and procedures are in place to help ensure the quality of treatment and services.	Standard met
C8	Patients are assured that the establishment or agency is run by a fit person/organisation and that there is a clear line of accountability for the delivery of services.	Standard met
C9	Patients receive care from appropriately recruited, trained and qualified staff.	Standard met
C10	Patients receive care from appropriately registered nurses who have the relevant skills knowledge and expertise to deliver patient care safely and effectively.	Standard not applicable
C11	Patients receive treatment from appropriately recruited, trained and qualified practitioners.	Standard not applicable
C12	Patients are treated by healthcare professionals who comply with their professional codes of practice.	Standard not applicable
C13	Patients and personnel are not infected with blood borne viruses.	Standard not applicable
C14	Children receiving treatment are protected effectively from abuse.	Standard not applicable
C15	Adults receiving care are protected effectively from abuse.	Standard met
C16	Patients have access to an effective complaints process.	Standard met
C17	Patients receive appropriate information about how to make a complaint.	Standard met
C18	Staff and personnel have a duty to express concerns about questionable or poor practice.	Standard met
C19	Patients receive treatment in premises that are safe and appropriate for that treatment. Where children are admitted or attend for treatment, it is to a child friendly environment.	Standard almost met
C20	Patients receive treatment using equipment and supplies that are safe and in good condition.	Standard met

Number	Standard Topic	Assessment
C21	Patients receive appropriate catering services.	Standard not applicable
C22	Patients, staff and anyone visiting the registered premises are assured that all risks connected with the establishment, treatment and services are identified, assessed and managed appropriately.	Standard met
C23	The appropriate health and safety measures are in place.	Standard not inspected
C24	Measures are in place to ensure the safe management and secure handling of medicines.	Standard not applicable
C25	Medicines, dressings and medical gases are handled in a safe and secure manner.	Standard not applicable
C26	Controlled drugs are stored, administered and destroyed appropriately.	Standard not applicable
C27	The risk of patients, staff and visitors acquiring a hospital acquired infection is minimised.	Standard met
C28	Patients are not treated with contaminated medical devices.	Standard met
C29	Patients are resuscitated appropriately and effectively.	Standard met
C30	Contracts ensure that patients receive goods and services of the appropriate quality.	Standard not applicable
C31	Records are created, maintained and stored to standards which meet legal and regulatory compliance and professional practice recommendations.	Standard met
C32	Patients are assured of appropriately completed health records.	Standard met
C33	Patients are assured that all information is managed within the regulated body to ensure patient confidentiality.	Standard met
C34	Any research conducted in the establishment/agency is carried out with appropriate consent and authorisation from any patients involved, in line with published guidance on the conduct of research projects.	Standard not applicable

## Service specific standards - these are specific to the type of establishment inspected

Number	Prescribed Techniques and Technology Standards	Assessment
	Class 3B and 4 Lasers and / or Intense Pulsed Light Sources	
P1	Procedures for use of lasers and intense pulsed lights.	Standard almost met
P2	Training for staff using lasers and intense pulsed lights.	Standard met
P3	Safe operation of lasers and intense pulsed lights.	Standard met

## Schedules of Information

The schedules of information set out the details of what information the registered person must provide, retain or record, in relation to specific records.

Schedule	Detail	Assessment
1	Information to be included in the Statement of Purpose.	Standard met
2	Information required in respect of persons seeking to carry on, manage or work at an establishment.	Standard Met
3 (Part I)	Period for which medical records must be retained.	Standard met
3 (Part II)	Record to be maintained for inspection.	Standard met
4 (Part I)	Details to be recorded in respect of patients receiving obstetric services.	Not applicable
4 (Part II)	Details to be recorded in respect of a child born at an independent hospital.	Not applicable

## Requirements

The requirements below address any non-compliance with The Private and Voluntary Health Care (Wales) Regulations 2002 that were found as a result of assessing the standards shown in the left column and other information which we have received from and about the provider. Requirements are the responsibility of the 'registered person' who, as set out in the legislation, may be either the registered provider or registered manager for the establishment or agency. HIW will request

the registered person to provide an 'action plan' confirming how they intend to put right the required actions and will, if necessary, take enforcement action to ensure compliance with the regulation shown.

Standard	Regulation	Requirement	Time scale/Action
C1	6 (1) (a) (b) (c) (d) (e) (f) (g)	<p><b>Findings</b> No patient guide available with all of the required information.</p> <p><b>Action Required</b> The registered person is required to ensure that a patient guide is produced for the establishment which includes the following information:</p> <ul style="list-style-type: none"> <li>• Summary of statement of purpose</li> <li>• terms and conditions in respect of services to be provided for patients, including the amount and method of payment of charges by patients for all aspects of their treatment</li> <li>• a standard form of contract for the provision of services and facilities by the registered provider to patients</li> <li>• a summary of the complaints procedure established under regulation 22</li> <li>• a summary of the results of the most recent consultation conducted in accordance with regulation 16</li> <li>• the address and telephone number of the appropriate office of the National Assembly</li> <li>• the most recent inspection report published by the National Assembly or information as to how a copy of that report may be obtained.</li> </ul>	An updated copy of Patient guide to be sent to HIW, upon completion of the patient consultation.

Standard	Regulation	Requirement	Time scale/Action
C6	6 (1) (3) & 16 (1) (2) & (3)	<p><b>Findings</b> No analyses of patient feedback has been undertaken.</p> <p><b>Action Required</b> The registered person is required to maintain a system for reviewing at appropriate intervals the quality of treatment provided and a summary of the results must be made available in the patient guide.</p>	A Patient survey is required to be undertaken within 3 months and details of the outcome should be sent to HIW.
C19	24 (2) (d)	<p><b>Findings</b> Portable Appliance Testing (PAT) testing had not been undertaken within the last year.</p> <p><b>Action Required</b> The registered person is required to ensure that PAT testing is carried out and documentation is available to evidence this.</p>	A copy of the PAT testing certificate to be sent to HIW within 28 days of this report.

## Recommendations

Recommendations may relate to aspects of the standards or to national guidance. They are for registered persons to consider but they are not generally enforced.

Standard	Recommendation
C29	Resuscitation policy to clearly state what action is to be taken should a patient require resuscitation.
P1	The expert medical protocol should be reviewed and signed every three years by the expert medical practitioner.

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