

Independent Healthcare Inspection (Announced)

Pleasure or Pain Productions

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2020

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Contents

1.	What we did	5
2.	Summary of our inspection	6
3.	What we found	7
	Quality of patient experience	8
	Delivery of safe and effective care	12
	Quality of management and leadership	17
4.	What next?	19
5.	How we inspect independent services	20
	Appendix A – Summary of concerns resolved during the inspection	21
	Appendix B – Improvement plan	22

Healthcare Inspectorate Wales (HIW) is the independent inspectorate and regulator of healthcare in Wales

Our purpose

To check that people in Wales receive good quality healthcare

Our values

We place patients at the heart of what we do. We are:

- **Independent**
- **Objective**
- **Caring**
- **Collaborative**
- **Authoritative**

Our priorities

Through our work we aim to:

Provide assurance:

Provide an independent view on the quality of care

Promote improvement:

Encourage improvement through reporting and sharing of good practice

Influence policy and standards:

Use what we find to influence policy, standards and practice

1. What we did

Healthcare Inspectorate Wales (HIW) completed an announced inspection of Pleasure or Pain Productions on the 04 February 2020.

Our team, for the inspection comprised of two HIW inspectors, one of whom led the inspection.

HIW explored how the service complied with the Care Standards Act 2000, requirements of the Independent Health Care (Wales) Regulations 2011 and met the National Minimum Standards for Independent Health Care Services in Wales.

Further details about how we conduct independent service inspections can be found in Section 5 and on our website.

2. Summary of our inspection

We found that Pleasure or Pain Productions was committed to providing an effective service to patients in an environment that was conducive to providing laser treatments.

Patient notes and records were being maintained to a good standard and supported the clinic to deliver individualised care to patients.

The registered manager had the appropriate skills and relevant knowledge to deliver safe treatment to patients.

Some improvements were needed to help fully protect the safety and well-being of the registered manager and people visiting the premises.

This is what we found the service did well:

- Patients were able to make informed decisions about their treatment
- The clinic sought feedback from patients about their experiences
- Good infection prevention and control arrangements were in place
- Documentation was available to show that the laser machine had been serviced and maintained.

This is what we recommend the service could improve:

- Update its statement of purpose and patients' guide with respect to how patients with mobility issues can access its facilities
- A fire risk assessment of the building needs to be carried out
- A new first aid kit must be purchased
- The clinic must ensure that the local rules in place at the clinic are reviewed by their LPA at least annually.

There were no areas of non-compliance identified at this inspection that required immediate corrective action.

3. What we found

Background of the service

Pleasure or Pain Productions is registered to provide an independent hospital at 26 Cardiff Street, Aberdare, CF44 7DA.

The service was first registered on 9 July 2014 and employs one laser operator, who is also the registered manager¹.

A range of services are provided which include:

- Tattoo removal
- Carbon peel.

¹ A registered manager means a person who is registered under the Independent Health Care (Wales) Regulations 2011 as the manager of the service.

Quality of patient experience

We spoke with patients, their relatives, representatives and/or advocates (where appropriate) to ensure that the patients' perspective is at the centre of our approach to inspection.

We found that patients were very happy with the service provided by the clinic and the registered manager was committed to providing a positive experience for patients.

Suitable arrangements were in place to protect the privacy and dignity of patients during consultation and treatments.

Patients received detailed information pre and post treatment to help them make an informed decision about their treatment.

Prior to the inspection, we invited the service to distribute HIW questionnaires to patients to obtain views on the services provided. A total of 18 questionnaires were completed.

Overall, patient feedback was very positive; every patient who completed a questionnaire rated the care and treatment that they were provided with as excellent. Patient comments included the following:

"Staff are wonderful and my visits here are always a tonic, mental and physically. The staff are great and I feel I am visiting friends"

"Always met with friendly and professional service and made to feel very comfortable during treatment"

"Excellent care and service every time I attend. The room is always clean and reception staff are very helpful and accommodating. Always helpful and explain each service clearly"

Health promotion, protection and improvement

We were told that patients must complete a medical history form at their initial consultation and sign a form at each subsequent treatment session confirming that there have or have not been any changes in their medical history. We saw evidence of completed and signed medical history forms within patient records to confirm this approach. Every patient who completed a HIW questionnaire

also confirmed that they completed a medical history form, or have their medical history checked, before undertaking any treatment.

This approach follows best practice guidance and helps to ensure treatment is safe and suitable for each patient.

Dignity and respect

Consultations with patients take place in private to ensure that confidential and personal information can be disclosed without being overheard. The registered manager told us that patients are able to change in a separate room if necessary and confirmed that the door is locked during treatments in order to maintain the patient's dignity at all times.

Every patient who completed a HIW questionnaire said that they had been treated with dignity and respect by the staff at the clinic and felt that they were always able to maintain their own privacy, dignity and modesty during their appointments.

Patients are able to have a family member, friend or a formal chaperone present for support during consultations and treatment sessions.

Patient information and consent

The registered manager described how they would assess the capacity of patients to consent to treatment and we were assured that patients would be able to make their own informed decision to consent to treatment. Patients receive a face-to-face consultation prior to treatment to help them understand the options available to them and the risks and benefits associated with each treatment option. Each patient that completed a HIW questionnaire agreed that they had been given enough information to help them understand the treatment options available to them and the risks and benefits associated with each treatment option. Patients also told us that the cost of any treatment was always made clear to them before they received the treatment.

All of the patients who completed a HIW questionnaire said that they had to sign a consent form before receiving any new treatment. We saw evidence of consent forms within patient records that had been signed by the patient and countersigned by the laser operator to confirm this approach.

Communicating effectively

Every patient who completed a HIW questionnaire said that they were always able to speak to staff in their preferred language. Patients also told us that staff

listened to them during their appointment and felt that they had been involved as much as they wanted to be in decisions about their treatment.

A patients' guide was available for patients in the downstairs waiting area and a statement of purpose² was provided to us by the registered manager. We found both documents contained all the relevant information required by the regulations.

Care planning and provision

The registered manager described suitable pre-treatment checks that are performed on patients to help determine a safe and effective setting of the laser for their skin and hair type. Patients are required to undergo a patch test on a small area of their skin before receiving treatment; all of the patients who completed a HIW questionnaire said that they had been given a patch test before they received treatment to confirm this approach.

We saw a copy of the aftercare advice leaflet that is provided to patients to ensure they understand how to prevent infection and aid healing after their treatment.

We examined a sample of patient records and found evidence that they were being maintained to a high standard meaning care was being planned and delivered with patients' safety, wellbeing and individual needs in mind.

Equality, diversity and human rights

The clinic is located on the first floor up some steep stairs and is therefore not accessible for people with mobility difficulties. We recommend that these accessibility issues are made clear to patients in the statement of purpose and the patients' guide.

² A statement of purpose is a legally required document that includes a standard set of information about a provider's service.

Improvement needed

The service must update its statement of purpose and patients' guide to inform patients with mobility difficulties of the accessibility issues at the clinic, and provide a copy to HIW.

Citizen engagement and feedback

Patient feedback is predominantly obtained by the clinic through the completion of online reviews through social media such as Facebook and Instagram. The transparency of the online reviews ensures current and prospective patients are informed about the quality of care being delivered by the clinic.

The registered manager told us that they were also in the process of designing a patient satisfaction questionnaire for those who did not wish to leave an online review. We encouraged this approach and advised that best practice would be to enable patients to provide their views anonymously and to inform patients of any changes made to demonstrate that feedback is being listened to and acted upon.

The majority of patients who completed a HIW questionnaire said that they were aware of being asked for their views about the service provided at the clinic.

Delivery of safe and effective care

We considered the extent to which services provide high quality, safe and reliable care centred on individual patients.

We found evidence that patients were receiving focussed individualised care that was documented in well maintained patient records.

Clinical facilities were in good condition and the laser machine had been regularly serviced to help ensure patients were being treated as safely as possible.

The service must ensure that they comply with their conditions of registration with HIW at all times.

Managing risk and health and safety

We looked at the arrangements in place to protect the safety and well-being of the staff and people visiting the premises.

We saw certification that gas safety checks and Portable Appliance Testing (PAT) had been carried out annually. The registered manager could not provide evidence during the inspection that an electrical wiring check of the premises had been completed. We informed the clinic that we required this evidence to be provided to HIW as part of their completed improvement plan in Appendix C.

We saw evidence that fire extinguishers throughout the premises had been serviced annually to ensure they worked properly and fire exits were signposted. Fire alarm tests were carried out by the business located on the ground floor of the premises. We could not be assured that a fire risk assessment of the premises had been undertaken to mitigate against potential fire hazards and risks. We recommend that this is carried out in line with the Regulatory Reform (Fire Safety) Order 2005.

The registered manager described suitable procedures to follow in the event of an emergency such as patient collapse and confirmed that they had undertaken first aid training. However, as the first aid training was not recent, we advised the registered manager to consider undertaking a first aid refresher course.

We were told that a first aid kit was available from the business located downstairs. However, we recommend that the clinic purchases its own first aid kit in line with the Health and Safety (First-Aid) Regulations 1981.

Improvement needed

Evidence that an electrical wiring check has been undertaken on the premises within the last five years must be sent to HIW.

The clinic must arrange for a fire risk assessment of the building to be carried out.

A new first aid kit must be purchased and subsequently checked regularly by staff to ensure all items are present and in date.

Infection prevention and control (IPC) and decontamination

We found the premises to be in good condition and the treatment room was clean and clutter free. There were no concerns given by patients over the cleanliness of the setting; all of the patients that completed a HIW questionnaire felt that, in their opinion, the premises were very clean.

The registered manager described suitable infection control arrangements at the clinic which included ensuring good hand hygiene and the completion of cleaning schedule checklists to document the cleaning undertaken of the treatment room and laser equipment. We found these arrangements were consistent with those outlined in the clinic's infection control policy.

Safeguarding children and safeguarding vulnerable adults

The registered manager confirmed that the service complies with their condition of registration to only treat patients over the age of 18 years old. Any children accompanying adults at appointments are not permitted into the treatment room when treatment is taking place for their safety.

We saw that a vulnerable adults policy was in place which outlined the procedures to follow in the event of any safeguarding concerns. The policy included the contact details of relevant local adult safeguarding agencies to ensure any concerns can be reported appropriately and in a timely manner.

We saw certification that the registered manager had undertaken safeguarding training to improve their knowledge and awareness relating to the protection of vulnerable adults who may be at risk.

Medical devices, equipment and diagnostic systems

During the inspection we looked at the arrangements that were in place at the clinic to protect the safety of patients when using the laser machine. We saw evidence that the laser machine had been regularly serviced and calibrated to help ensure it performs consistently and as expected.

A medical treatment protocol that set out the procedures to follow to ensure treatment is delivered safely to patients was also in place which had been overseen by an expert medical practitioner as required by the regulations.

A contract was in place with a Laser Protection Adviser (LPA) to provide expert advice on the safety and day to day operational use of the laser machine. We saw that the local rules in place at the clinic, which govern the safe use of the laser machine, had recently been reviewed by the LPA. However, we saw that prior to this, the LPA had reviewed the local rules every 18 months. This is not in keeping with the clinic's conditions of registration with HIW which require the local rules to be reviewed at least annually by a relevant expert in the field of laser or intense pulsed light [an LPA].

Whilst this has not resulted in the issue of a non-compliance notice, there is an expectation that the registered manager takes meaningful action to comply with the clinic's conditions of registration going forward.

The registered manager must also complete and sign the register of authorised users contained within the latest version of the local rules to evidence their awareness and agreement to follow these rules. The register must be updated with the names and signatures of any new laser operators that are employed by the clinic before they begin to undertake treatment with patients.

Improvement needed

The clinic must ensure that the local rules in place at the clinic are reviewed by their LPA at least annually.

The registered manager must ensure that the register of authorised users contained within the local rules is kept up to date each year.

Safe and clinically effective care

We saw evidence that the registered manager met Medicines and Healthcare products Regulatory Agency (MHRA) requirements³ to be a competent user of the laser machine having completed both Core of Knowledge⁴ training and training by the laser machine manufacturer on how to operate it safely.

A range of protective eyewear was available for patients and the laser operator. We saw that the glasses and goggles had been kept in good condition and the registered manager confirmed that they were checked regularly for any damage.

No patients received treatment on the day of the inspection, but the registered manager described the safety precautions taken when treatment is in progress; a warning sign on the outside of the treatment room door indicates that the laser machine is in use and the treatment room is locked to prevent any unauthorised persons from entering during treatments. We were told that the key to the laser machine is locked away after each appointment to ensure it is kept secure when not in use.

We saw that the LPA had visited the clinic in 2014 when the clinic was first registered with HIW to complete an environmental risk assessment to identify and mitigate for any hazards associated with the use of the laser machine and the environment of the treatment room. Since then, the LPA and registered manager have communicated remotely to confirm that there have been no changes to the environment or layout of the treatment room to ensure it remains safe to provide treatments in.

Participating in quality improvement activities

The registered manager told us that they are in regular contact with patients throughout their course of treatment to understand how their treatment is progressing. This helps the clinic provide individualised care and, along with patient reviews, to monitor the quality of service they provide to patients.

³ [Lasers, intense light source systems and LEDs – guidance for safe use in medical, surgical, dental and aesthetic practices](#)

⁴ Training in the basics of the safe use of laser machines

Records management

We saw evidence that patient records were being maintained in line with best practice and professional guidelines and supported the service to deliver good quality patient care. Patient notes were detailed and of good quality and a comprehensive patient treatment register was being maintained.

We found that patient information was being kept securely. Paper patient records were kept in a locked cabinet to prevent unauthorised access.

Quality of management and leadership

We considered how services are managed and led and whether the workplace and organisational culture supports the provision of safe and effective care. We also considered how the service review and monitor their own performance against the Independent Health Care Regulations and National Minimum Standards.

The registered manager had the appropriate skills and relevant knowledge to deliver safe and effective treatment to patients.

The service had a wide range of policies and procedures which were all updated on an annual basis.

The complaints procedure in place at the clinic would enable patient complaints to be handled effectively and in a timely manner.

Governance and accountability framework

Pleasure or Pain Productions is run by the registered manager who is responsible for the day to day management of the service and is the only employed laser operator.

We found that the clinic had a number of policies in place and saw evidence that they had been reviewed and updated annually.

We saw that the clinic had an up to date liability insurance certificate to protect against compensation claims and associated legal costs.

Dealing with concerns and managing incidents

The service had an appropriate complaints procedure which included the correct contact details of HIW in line with regulatory requirements. A summary of the complaints procedure was included within the statement of purpose and in the patients' guide.

We saw that suitable systems were in place to record and manage any formal or informal complaints and concerns received by the clinic from patients.

Workforce planning, training and organisational development

The registered manager told us that they have an informal agreement with another laser operator who is willing to undertake some sensitive treatments on patients. The laser operator is not formally employed by the clinic but we saw evidence to be assured that they have the appropriate knowledge, skills and experience to provide safe and effective care to patients. They had completed the Core of Knowledge training and had also completed training on how to use the laser machine safely.

The registered manager also confirmed that the laser operator would be required to read the local rules and sign the register of authorised users to evidence their awareness and agreement to adhere to the rules before undertaking any treatment.

The registered manager told us that they hold informal catch ups with the laser operator to ensure they are aware of the policies and employment practices in place at the clinic.

Workforce recruitment and employment practices

We saw evidence that the registered manager had an appropriate Disclosure and Barring Service (DBS) certificate⁵ to help the service comply with the regulatory requirements that staff are of good character and to help protect patients against the risk of inappropriate, or unsafe, care and treatment. We saw evidence that the other laser operator used by the clinic also had an appropriate DBS certificate in place.

⁵ The Disclosure and Barring Service (DBS) helps employers make safer recruitment decisions and prevent unsuitable people from working with vulnerable groups. It replaces the Criminal Records Bureau (CRB) and Independent Safeguarding Authority (ISA).

4. What next?

Where we have identified improvements and immediate concerns during our inspection which require the service to take action, these are detailed in the following ways within the appendices of this report (where these apply):

- Appendix A: Includes a summary of any concerns regarding patient safety which were escalated and resolved during the inspection
- Appendix B: Includes any other improvements identified during the inspection where we require the service to complete an improvement plan telling us about the actions they are taking to address these areas.

Where we identify any serious regulatory breaches and concerns about the safety and wellbeing of patients using the service, the registered provider of the service will be notified via a [non-compliance notice](#). The issuing of a non compliance notice is a serious matter and is the first step in a process which may lead to civil or criminal proceedings.

The improvement plans should:

- Clearly state when and how the findings identified will be addressed, including timescales
- Ensure actions taken in response to the issues identified are specific, measurable, achievable, realistic and timed
- Include enough detail to provide HIW and the public with assurance that the findings identified will be sufficiently addressed.

As a result of the findings from this inspection the service should:

- Ensure that findings are not systemic across other areas within the wider organisation
- Provide HIW with updates where actions remain outstanding and/or in progress, to confirm when these have been addressed.

The improvement plan, once agreed, will be published on HIW's website.

5. How we inspect independent services

Our inspections of independent services may be announced or unannounced. We will always seek to conduct unannounced inspections because this allows us to see services in the way they usually operate. The service does not receive any advance warning of an unannounced inspection. In some circumstances, we will decide to undertake an announced inspection, meaning that the service will be given up to 12 weeks' notice of the inspection.

Feedback is made available to service representatives at the end of the inspection, in a way which supports learning, development and improvement at both operational and strategic levels.

HIW inspections of independent healthcare services will look at how services:

- Comply with the [Care Standards Act 2000](#)
- Comply with the [Independent Health Care \(Wales\) Regulations 2011](#)
- Meet the [National Minimum Standards](#) for Independent Health Care Services in Wales.

We also consider other professional standards and guidance as applicable.

These inspections capture a snapshot of the standards of care within independent services.

Further detail about [how HIW inspects independent services](#) can be found on our website.

Appendix A – Summary of concerns resolved during the inspection

The table below summaries the concerns identified and escalated during our inspection. Due to the impact/potential impact on patient care and treatment these concerns needed to be addressed straight away, during the inspection.

Immediate concerns identified	Impact/potential impact on patient care and treatment	How HIW escalated the concern	How the concern was resolved
No immediate concerns were identified on this inspection.			

Appendix B – Improvement plan

Service: Pleasure or Pain Productions

Date of inspection: 04 February 2020

The table below includes any other improvements identified during the inspection where we require the service to complete an improvement plan telling us about the actions they are taking to address these areas.

Improvement needed	Regulation/ Standard	Service action	Responsible officer	Timescale
Quality of the patient experience				
The service must update its statement of purpose and patients' guide to inform patients with mobility difficulties of the accessibility issues at the clinic, and provide a copy to HIW.	National Minimum Standards for Independent Health Care Services in Wales Standard 2	Document updated and a copy sent to HIW.	Gareth Wills	Completed.
Delivery of safe and effective care				
Evidence that an electrical wiring check has been undertaken on the premises within the last five years must be sent to HIW.	National Minimum Standards for Independent Health Care Services in Wales	Five year wiring check of the building completed and a copy sent to HIW.	Gareth Wills	Completed.

Improvement needed	Regulation/ Standard	Service action	Responsible officer	Timescale
The clinic must arrange for a fire risk assessment of the building to be carried out.	Standard 22 Health and Safety (First-Aid) Regulations 1981	Fire risk assessment completed and sent to HIW.	Gareth wills	Completed.
A new first aid kit must be purchased and subsequently checked regularly by staff to ensure all items are present and in date.	Independent Health Care (Wales) Regulations 2011 Regulation 26	New first aid kit acquired and on show.	Gareth wills	Completed.
The clinic must ensure that the local rules in place at the clinic are reviewed by their LPA at least annually.	Independent Health Care (Wales) Regulations 2011 Regulation 19	L P A contacted and advised that HIW require a yearly updated certificate.	Gareth wills	Completed.
The registered manager must ensure that the register of authorised users contained within the local rules is kept up to date each year.	National Minimum Standards for Independent Health Care Services in Wales Standard 22	Local rules updated and signed.	Gareth wills	Completed.
Quality of management and leadership				
No recommendations made.				

The following section must be completed by a representative of the service who has overall responsibility and accountability for ensuring the improvement plan is actioned.

Service representative

Name (print): Gareth Wills

Job role: Manager

Date: 24/07/2020