



Independent Healthcare Inspection (Announced)

ReThink the Ink

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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 ReThink the Ink on the 08 July 2019.

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

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 were assured that ReThink the Ink was providing an effective service to its patients in an environment suitable for providing laser treatments.

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

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

Patient feedback was very positive with the majority of patients rating the care and treatment that they were provided with as excellent.

This is what we found the service did well:

- Patients were able to make informed decisions about their treatment
- Systems were in place to ensure patients were being treated as safely as possible
- Patient notes and records were maintained to a good standard
- The registered manager had up to date training on how to use the laser machine appropriately
- Effective arrangements were in place for infection prevention and control.

This is what we recommend the service could improve:

- The patients' guide needs to be updated to include more information about the service
- The registered manager needs to undertake appropriate child protection training
- Out of date materials in the first aid kit need to be replaced
- One pair of eye protection glasses needs to be replaced.

There were no areas of non compliance identified at this inspection.

3. What we found

Background of the service

ReThink the Ink is registered to provide the following treatments at The Precinct, Station Hill, 9-15 New Road, Porthcawl, CF36 5DL using a Starlight Picosecond laser:

- Tattoo removal
- Birthmarks
- Skin pigment removal.

The service was first registered with HIW in March 2015 and employs one laser operator who is also the registered manager.

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 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 to help them make an informed decision about their treatment.

Some updates were needed to the patients' guide in accordance with the regulations.

Prior to the inspection, we invited the service to distribute HIW questionnaires to patients to obtain views on the services provided. A total of 30 questionnaires were completed.

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

"Fantastic 5 star treatment, very happy with the overall service"

"Excellent service and very friendly on every appointment"

"The service provided is great. Staff are professional and friendly. Makes the process as enjoyable as it can be"

"I have used other providers before and they don't compare to this establishment. A very good practitioner"

Health promotion, protection and improvement

We were told that patients complete a medical history form at their initial consultation and must sign a form at each subsequent treatment confirming that

there have or have not been any changes in their medical history. This follows best practice guidance and helps ensure treatment is safe and suitable for each patient.

We saw evidence of completed and signed medical history forms within patient records to confirm this approach. Each patient that completed a questionnaire also confirmed that they always complete a medical history form, or have their medical history checked, before undertaking any treatment.

Dignity and respect

Every patient who completed a questionnaire agreed that they had been treated with dignity and respect by the registered manager, and felt that they were always able to maintain their own privacy, dignity and modesty during their appointments.

The registered manager told us that lockable changing facilities are available and that the door to the treatment room is always locked during treatment to maintain the patient's dignity before and during treatment.

Consultations with patients take place in a separate consultation room to ensure that confidential and personal information can be disclosed without being overheard.

The registered manager confirmed that patients are entitled to have a family member, friend or a formal chaperone present for support during consultations and treatment sessions.

Patient information and consent

We were assured that patients were able to make an informed decision about their treatment. This is because patients are provided with a face-to-face consultation prior to laser treatment and all patients that completed a 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.

Every patient who completed a questionnaire confirmed that they were required to sign a consent form to evidence that they understood the associated benefits and risks before undertaking any treatment.

Communicating effectively

All of the patients who completed a questionnaire said that they were always able to speak to the registered manager in their preferred language.

All patients who completed a questionnaire also told us that the registered manager 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 detailed statement of purpose¹ was provided to us by the registered manager which we found contained the essential information as required by the regulations.

Copies of a patients' guide were available in the consultation room. We recommend the patients' guide is updated to inform patients how they can pay for their treatment.

Improvement needed

The service must update its patients' guide to include information on the methods of payment available for patients to pay for their treatment, and provide a copy to HIW.

Care planning and provision

The registered manager told us that prior to treatment, patients must agree to undergo a patch test to determine a safe and effective setting of the laser for their skin and hair type. All but one of the patients that completed a questionnaire confirmed that they had been given a patch test before they received treatment.

All of the patients that completed a questionnaire told us that they had been given aftercare instructions about how to prevent infection and aid healing after their treatment.

¹ A statement of purpose is a legally required document that includes a standard set of information about a provider's service.

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

Equality, diversity and human rights

ReThink the Ink is situated on the first floor and is not easily accessible to patients with mobility issues. These accessibility issues are made clear in the statement of purpose however we recommend that these issues are also made clear to patients in the patients' guide.

Improvement needed

The service must update its patients' guide with respect to how patients with mobility issues can access its facilities, and provide a copy to HIW.

Citizen engagement and feedback

Patient feedback is obtained by the clinic through the completion of patient satisfaction questionnaires and the registered manager told us that he encourages patients to complete Facebook or Google reviews to ensure current and prospective patients are informed about the quality of care being delivered by the clinic.

All but one of the patients who completed a questionnaire said that they were aware of being asked for their views about the service provided at the clinic, for example, through patient questionnaires.

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 the clinic to be well run and met the relevant standards and regulations to ensure the health, safety and welfare of patients and people visiting the clinic.

Systems were in place to ensure patients were being treated as safely as possible. The laser machines were maintained in accordance with the manufacturer's guidelines and the registered manager had up to date training on the use of the machines.

The service was committed to providing safe and reliable care, but the registered manager needs to undertake training on the protection of children.

Managing risk and health and safety

Overall, we found suitable maintenance arrangements were in place to protect the safety and well-being of the registered manager and people visiting the premises. A building electrical wiring check had been undertaken within the last five years and annual Portable Appliance Testing (PAT) had been carried out to help to help ensure small electrical appliances were fit for purpose and safe to use.

Appropriate arrangements were in place to adequately protect the registered manager and people visiting the clinic in the event of a fire:

- a fire risk assessment had recently been undertaken and subsequent remedial actions had been implemented by the registered manager
- fire extinguishers throughout the clinic had been serviced within the last twelve months to ensure that the equipment worked properly
- fire alarm tests were carried out monthly and recorded in a logbook.
- fire exits were appropriately signposted.

We saw that a first aid kit was available but found that some of its contents had exceeded their expiry dates and were therefore not fit for purpose. We

recommend the out of date materials in the first aid kit are replaced and that a system is put in place to regularly check for out of date first aid materials in future.

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 advise the registered manager to consider undertaking a first aid refresher course.

Improvement needed

The service must replace any out of date materials in the first aid kit and implement a system to ensure the first aid kit has all contents within their expiry date at all times.

Infection prevention and control (IPC) and decontamination

We found the premises to be visibly clean and tidy. There were no concerns given by patients over the cleanliness of the setting; all of the patients that completed a questionnaire felt that, in their opinion, the premises were very clean.

The registered manager described the infection control arrangements at the clinic which we found to be in line with best practice guidance and consistent with the procedures outlined in their infection control policy.

We saw hazardous (clinical) waste was being stored securely and saw evidence that a contract was in place for the safe transfer and disposal of such hazardous waste.

Safeguarding children and safeguarding vulnerable adults

The registered manager confirmed that the service complies with their conditions of registration to only treat patients aged between 13 and 80 years old. Parental consent is required by the registered manager before undertaking treatment on patients aged under 18 years old to help safeguard children and the clinic.

We saw that a policy for the safeguarding of children and adults was in place which outlined the procedures to follow in the event of any safeguarding concerns. However, we recommend the policy is updated to include the contact details of relevant local children and adult safeguarding agencies to ensure concerns are reported appropriately.

We found that the registered manager had received training in the protection of vulnerable adults but had not received child protection training. While the registered manager told us that they require parents or guardians to be present during treatment of children aged under 18 years old, we would recommend that they undertake child protection training (level 2) to gain an understanding of national guidelines for safeguarding and what constitutes abuse and neglect.

Improvement needed

The safeguarding of children and vulnerable adults policy must be updated to include the contact details of relevant local children and adult safeguarding agencies.

The registered manager must undertake child protection training level 2 and submit evidence of completed training to HIW.

Medical devices, equipment and diagnostic systems

Overall, we found suitable arrangements were in place to protect the safety of patients when using the laser machine at the clinic. This is because:

- the laser machine had been regularly serviced and calibrated in line with the manufacturer's guidelines to help ensure it performs consistently and as expected
- a treatment protocol setting out the procedures to follow to ensure treatment is delivered safely to patients was 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 of the laser installation and day to day operational use
- comprehensive local rules² developed by the LPA that detailed the safe operation of the laser machine were in place and had been

² Local rules (or safe working procedures) should reflect safe working practices and relate to the day-to-day safety management of lasers, IPL systems and LEDs.

signed by the registered manager to evidence their awareness and agreement to follow these rules.

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 the Core of Knowledge⁴ training and training by the laser machine manufacturer on how to operate it safely.

We saw that eye protection glasses specific to the strength of the laser machine were available for patients and the laser operator. The registered manager confirmed that the glasses were checked regularly for any damage. However, we noticed that one pair of glasses had a slight crack in one lens. We recommend that this pair of glasses is replaced to reduce the potential risk of causing harm to patients.

No patients were being treated on the day of the inspection, but the registered manager described the safety precautions taken when treatment is in progress; a red light and a warning sign on the outside of the treatment room door informs the public of the risk of lasers being used inside the treatment room. The treatment room is locked to prevent any unauthorised persons from entering during treatments and the machine is kept secure at all times to prevent unauthorised usage.

We saw evidence that the LPA had completed a recent risk assessment to identify any hazards associated with the use of the laser machine and the environment of the treatment room. The risk assessment did not identify any hazards that needed remedial action.

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/474136/Laser_guidance_Oct_2015.pdf.

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

Improvement needed

The service must replace the pair of eye protection glasses that was identified as having a slight crack in one lens.

Participating in quality improvement activities

We found evidence that the registered manager had systems in place to assess and monitor the quality of service provided to patients as required by the regulations. For example, following treatment, the service provided the opportunity for patients to provide feedback through questionnaires and online reviews.

A range of risk assessments had also been undertaken to help protect the health, welfare and safety of patients and others visiting the clinic.

Records management

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

We saw evidence of suitable record keeping processes in place at the clinic, including detailed patient notes that were of good quality and a comprehensive patient treatment register, which supported the service to deliver quality patient care.

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 treatment to patients.

The service had a wide range of policies and procedures which were all updated frequently in line with regulations.

A complaints procedure was in place to ensure any complaints are responded to efficiently and effectively.

Governance and accountability framework

ReThink the Ink is run by the registered manager who is responsible for the day to day management of the service and is the only laser operator.

We found that the service had a number of policies in place which were accessible and saw evidence that they had been reviewed and updated regularly.

We saw that the service had an up to date liability insurance certificate in place to protect the clinic 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.

Workforce planning, training and organisational development

As mentioned earlier within the report, we saw certificates showing that the registered manager, as the only authorised operator of the laser machine, had completed the Core of Knowledge training and had also completed training on how to use the laser machine.

We also noted that the registered manager demonstrated their competency as a laser operator through their qualification to teach other laser operators across the country on how to safely use a Starlight Picosecond laser machine.

Workforce recruitment and employment practices

We saw evidence that the registered manager had an appropriate Disclosure and Barring Service (DBS) certificate in place to satisfy Regulation 19, which requires that patients must be protected against the risks of inappropriate or unsafe care and treatment.

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: ReThink the Ink

Date of inspection: 08 July 2019

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 patients' guide to include information on the methods of payment available for patients to pay for their treatment, and provide a copy to HIW.	The Independent Health Care (Wales) Regulations 2011 Regulation 7	Updated on the 9/7/2019 copy forwarded on	Jon Richardson	Done
The service must update its patients' guide with respect to how patients with mobility issues can access its facilities, and provide a copy to HIW.		Updated on the 9/7/2019 copy forwarded on	Jon Richardson	Done
Delivery of safe and effective care				
The service must replace any out of date materials in the first aid kit and implement a	National Minimum	First aid box replaced in full, shortest expiry date noted on outside of box	Jon Richardson	Done

Improvement needed	Regulation/ Standard	Service action	Responsible officer	Timescale
system to ensure the first aid kit has all contents within their expiry date at all times.	Standards for Independent Health Care Services in Wales Standard 22 Health and Safety (First-Aid) Regulations 1981			
The safeguarding of children and vulnerable adults policy must be updated to include the contact details of relevant local children and adult safeguarding agencies.	The Independent Health Care (Wales) Regulations 2011	Policy has been updated on the 9/7/19	Jon Richardson	Done
The registered manager must undertake child protection training level 2 and submit evidence of completed training to HIW.	Regulation 16 National Minimum Standards for Independent	Course completed on 10/7/19 course providers were high speed training on line course. Also completed the laser safety management course including the core of knowledge	Jon Richardson	Done

Improvement needed	Regulation/ Standard	Service action	Responsible officer	Timescale
	Health Care Services in Wales Standard 11			
The service must replace the pair of eye protection glasses that was identified as having a slight crack in one lens.	The Independent Health Care (Wales) Regulations 2011 Regulation 15(2)	Glasses disposed of and replaced	Jon Richardson	Done

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): Jonathan Richardson

Job role: Registered Manager

Date: 08 August 2019