



Independent Healthcare Inspection (Announced) Beauty Within Medi Spa

9 February 2016

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Copies of all reports, when published, will be available on our website or by contacting us:

In writing:

**Communications Manager
Healthcare Inspectorate Wales
Welsh Government
Rhydycar Business Park
Merthyr Tydfil
CF48 1UZ**

Or via

Phone: 0300 062 8163
Email: hiw@wales.gsi.gov.uk
Fax: 0300 062 8387
Website: www.hiw.org.uk

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1. Introduction

Healthcare Inspectorate Wales (HIW) is the independent inspectorate and regulator of all health care in Wales.

HIW's primary focus is on:

- Making a contribution to improving the safety and quality of healthcare services in Wales
- Improving citizens' experience of healthcare in Wales whether as a patient, service user, carer, relative or employee
- Strengthening the voice of patients and the public in the way health services are reviewed
- Ensuring that timely, useful, accessible and relevant information about the safety and quality of healthcare in Wales is made available to all.

HIW inspections of independent healthcare services seek to ensure services comply with the Care Standards Act 2000 and requirements of the Independent Health Care (Wales) Regulations 2011 and establish how services meet the National Minimum Standards (NMS) for Independent Health Care Services in Wales¹.

This report details our findings following the inspection of an independent health care service. HIW is responsible for the registration and inspection of independent healthcare services in Wales. This includes independent hospitals, independent clinics and independent medical agencies.

We publish our findings within our inspection reports under three themes:

- Quality of patient experience
- Delivery of safe and effective care
- Quality of management and leadership.

¹ The National Minimum Standards (NMS) for Independent Health Care Services in Wales were published in April 2011. The intention of the NMS is to ensure patients and people who choose private healthcare are assured of safe, quality services. <http://www.hiw.org.uk/regulate-healthcare-1>

2. Methodology

During the inspection we gather information from a number of sources including:

- Information held by HIW
- Interviews with staff (where appropriate) and registered manager of the service
- Conversations with patients and relatives (where appropriate)
- Examination of a sample of patient records
- Examination of policies and procedures
- Examination of equipment and the environment
- Information within the service's statement of purpose, patient's guide and website (where applicable)
- HIW patient questionnaires completed prior to inspection.

At the end of each inspection, we provide an overview of our main findings to representatives of the service to ensure that they receive appropriate feedback.

Any urgent concerns that may arise from an inspection will be notified to the registered provider of the service via a non-compliance notice². Any such findings will be detailed, along with any other improvements needed, within Appendix A of the inspection report.

Inspections capture a snapshot on the day of the inspection of the extent to which services are meeting essential safety and quality standards and regulations.

² As part of HIW's non-compliance and enforcement process for independent healthcare, a non-compliance notice will be issued where regulatory non-compliance is more serious and relates to poor outcomes and systemic failing. This is where there are poor outcomes for people (adults or children) using the service, and where failures lead to people's rights being compromised. A copy of HIW's compliance process is available upon request.

3. Context

Beauty Within Medi Spa is registered as an independent hospital because it provides Class 3B/4 laser and Intense Pulsed Light Technology (IPL)³ treatments 10 High Street, Cowbridge. The service was first registered in 2003.

The service has a staff team which includes the registered manager and three laser operators who provide laser and IPL treatments. The service is registered to provide the following treatments to patients over the age of 16 years:

Plasmalite IPLS for the following treatments:

- Depilation
- Photo-rejuvenation
- Vascular thread vein removal.

Dornier Diode laser for the following treatments:

- Thread vein removal
- Vascular lesion removal
- Warts and verrucae.

Soprano Diode laser for the following treatments:

- Hair removal.

Harmony multi-application laser for the following treatments:

- Wrinkle reduction
- Acne and acne scarring
- Pigmentation
- Open pore reduction
- Skin tightening

³ IPL is a broad spectrum light source technology and is used by cosmetic and medical practitioners to perform various skin treatments for aesthetic and therapeutic uses.

- Tattoo removal.

4. Summary

We identified a number of areas for improvement and regulatory breaches during this inspection. Further details of these improvements are provided in Appendix A.

Given the findings from this inspection, improvements are needed in the quality assurance and governance arrangements of this service, in accordance with requirements of the regulations and standards. This is important to ensure the safety and effectiveness of the service provided.

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 address these matters, as a failure to do so could result in HIW taking action for non-compliance with regulations.

This is what we found the service did well:

- Patients were provided with enough information to make an informed decision about their treatment
- The service is committed to providing a positive experience for patients
- The service had a system for seeking the views of patients
- The majority of patients who completed the HIW questionnaire told us they were satisfied with their treatment and the service provided.

This is what we found the service needed to improve:

- Updates to the patient's guide and statement of purpose
- Staff training in use of the IPL/laser machines
- Arrangements for the safety of the environment and laser/IPL equipment, including review of local rules, onsite visit by a Laser Protection Advisor and security of the IPL machine when not in use
- Systems for safeguarding children and vulnerable adults
- Arrangements for managing risk and health and safety, including updates to the fire risk assessment
- Updates to policies and procedures
- Systems for governance and monitoring the quality of the service against the requirements of the regulations and standards.

5. Findings

Quality of patient experience

Patient information and consent (Standard 9)

We found evidence to indicate that patients were provided with enough information to make an informed decision about their treatment. We were told that patients were provided with a verbal consultation prior to treatment which included discussion of the risks and benefits of treatment.

We were told that the service provided information for patients to take home and consider their treatment. We saw evidence that patients were asked to provide written consent to treatment and completed medical history forms. We also saw examples of the post-treatment information given to patients to help them with aftercare.

We saw that treatment register was maintained and up-to-date, but we noticed that this did not include space to record any adverse effects.

Improvement needed

Details of any adverse effects should be included within the treatment registers.

Communicating effectively (Standard 18)

A patient's guide document was available in the reception area and included the majority of required information. We noticed that the patient's guide did not include the latest HIW inspection report, which can be found on HIW's website.

Improvement needed

The patient's guide must be updated in accordance with the regulations.

A copy of the patients guide must be provided to HIW.

Although results from the last patient satisfaction survey had been included within the patient's guide, it was unclear how many surveys this was based upon. We also noticed that the guide was very lengthy and would benefit from being consolidated to make it easier for patients to access the relevant information. We advised the registered manager to address this.

A statement of purpose was available and provided relevant information about the service provided, but we found the following updates were needed:

- Relevant qualifications for staff need to include dates of Core of Knowledge⁴ training
- Description of the treatments provided by each staff member need to be updated.

Improvement needed

The statement of purpose must be updated, specifically staff qualifications and treatments provided by each laser operator.

A copy of the statement of purpose must be provided to HIW.

Citizen engagement and feedback (Standard 5)

Before the inspection, the service was asked to give out HIW questionnaires to gain patient views of the service. Nineteen patient questionnaires were completed prior to the date of inspection. The questionnaires showed that the majority of patients were satisfied with the service. Most patients agreed with statements that the service was clean, tidy and that staff were polite, caring, listened and provided enough information about their treatment.

We found that the service had a system for seeking patient feedback. Patient questionnaires were available in the waiting area and we were told that questionnaires were given out to patients on an ad hoc basis. We also saw evidence that the service had analysed patient feedback and this has been included within the patient's guide.

⁴ Core of Knowledge training is intended for operators using lasers and IPL systems for various skin treatments. The training includes information and guidance on the safe use of lasers and IPL systems.

Delivery of safe and effective care

Safe and clinically effective care (Standard 7) and medical devices, equipment and diagnostic systems (Standard 16)

We saw certificates showing that the registered manager and all laser operators had completed up-to-date Core of Knowledge training within the last three years. However, we saw that one of the laser operators did not have documented training records in the use of the laser/IPL machines. We were told that training had been provided by the registered manager rather than the manufacturer of the machine, but this had not been documented. We discussed the suitability of this training and the regulatory requirements for the registered manager to ensure that staff are appropriately trained and have demonstrated understanding of the safe use of the laser/IPL equipment.

Improvement needed

The registered manager must ensure that laser and IPL machines are only used by staff who have undertaken appropriate training and have demonstrated an understanding of the correct and safe use of the equipment, in accordance with Regulation 45.

Any in-house training provided to staff must be documented and the suitability of this must be discussed with the Laser Protection Advisor.

We looked at the local rules, which detail the safe operation of the equipment. We could not be assured that the local rules had been reviewed annually by the Laser Protection Advisor in accordance with the conditions of HIW registration. This is because the local rules had not been signed and dated by the Laser Protection Advisor and there was no reference to the review of local rules within the latest report provided by the Laser Protection Advisor.

Improvement needed

The registered manager must ensure that the local rules are reviewed at least annually by the Laser Protection Advisor.

Eye protection was available for patients and the laser operator, but we noticed that two pairs of eye protection were damaged and needed to be replaced. We highlighted this to the registered manager. Following the inspection, the registered manager confirmed that alternative eye protection could be used while new glasses arrived.

We discussed the arrangements the service had in place with a Laser Protection Advisor. The service had been in contact with a Laser Protection Advisor within the last year. However, we were told this had been through remote self-assessments rather than an onsite visit to the service. An onsite Laser Protection Advisor visit had not been conducted since 2011. Overall, we could not be assured that the self-assessment arrangements with the Laser Protection Advisor were sufficient to help ensure that the safety of the environment, equipment (including eye protection) and patients at the service.

Improvement needed

Patient safety and welfare must be protected. Specifically, an onsite assessment of the safety of the equipment and environment at the service must be conducted by a Laser Protection Advisor.

A copy of the Laser Protection Advisor visit report must be provided to HIW.

We saw evidence that the laser/IPL machines had been regularly serviced. There was a light and sign outside the treatment room to indicate when the laser machine is in use. The registered manager also confirmed that the treatment room doors were locked when in use, in order to prevent unauthorised access. We saw that the activation keys for the laser machines were stored securely. However, the IPL machine did not have activation keys to prevent unauthorised use.

Improvement needed

The registered manager must consider the security arrangements for the IPL machine when it is not in use.

Safeguarding children and vulnerable adults (Standard 11)

The service is registered to treat children over the age of 16 years.

We found that improvements were needed to the arrangements for safeguarding both children and vulnerable adults. The following areas needed to be addressed:

- Training in both the protection of children and vulnerable adults had not been completed by the registered manager and laser operators
- The information and arrangements for parental and child consent to treatment need to be carefully considered and updated
- The child protection policy needed to be reviewed and updated to include details of the procedure for staff to follow in the event of a safeguarding concern, including local safeguarding contacts

- The policy for the protection of vulnerable adults needed to be reviewed to clearly state the procedure for staff to follow in the event of a safeguarding concern.

Improvement needed

Robust processes must be in place to ensure the welfare and safety of children and vulnerable adults who may use the service, including the review of policies, procedures and training for staff.

Infection prevention and control and decontamination (Standard 13)

We saw the service was visibly clean and tidy. An infection control policy was in place, but we found this needed to be updated to include further details of the arrangements for cleaning at the service.

Improvement needed

The infection control policy must be updated with further details of the cleaning arrangements.

Managing risk and health and safety (Standard 22)

We looked at maintenance arrangements at the service. We saw evidence the clinic had conducted a wiring check of the building and a recent gas check certificate was available. No lifts were present at the service.

We saw evidence that Portable Appliance Testing (PAT) testing, to help ensure that small electrical appliances were safe to use, had been recently conducted. We noticed that this had been conducted by the registered manager who told us they were qualified to do this. We advised the registered manager to discuss this with their Laser Protection Advisor.

We noticed that the service used materials/substances that are classified under the Control of Substances Hazardous to Health (COSHH)⁵ Regulations. We were told that safety data sheets were kept for all substances, but these did not include comprehensive risk assessments. We advised the registered manager to consult the guidance provided by the Health and Safety Executive.

⁵ COSHH is the law that requires employers to control substances that are hazardous to health. More information can be found on the Health and Safety Executive website via the following link <http://www.hse.gov.uk/coshh/index.htm>

Improvement needed

The registered manager must ensure that comprehensive COSHH risk assessments are completed for all hazardous substances used at the service.

We saw that environmental risk assessments had been provided for each laser machine.

We looked at some of the arrangements for fire safety. We saw evidence that fire extinguishers were serviced annually and fire exits had been signposted. A fire risk assessment had been completed, however, we saw this had been conducted prior to the introduction of The Regulatory Reform (Fire Safety) Order 2005 and needed to be updated.

Improvement needed

The registered manager must ensure that all appropriate measures and precautions must be in place to protect the health and safety of patients and staff at this service. Specifically, the registered manager should re-conduct a fire risk assessment using the latest guidance and fire regulations.

Quality of management and leadership

We looked at a sample of the policies and procedures in place at the service. We saw evidence that they had been recently reviewed. However, due to the updates needed to the safeguarding and infection control policies, we recommended the registered manager review the rest of their policies and procedures to ensure these were in line with the requirements of the standards and regulations.

Improvement needed

The registered manager must ensure that the policies and procedures in place meet the requirements of the regulations and standards.

Dealing with concerns and managing incidents (Standard 23)

A complaints policy was in place, but we found that updates were needed. The policy also made misleading references to “clinicians” and referred patients to the “General Medical Council”. Since no staff members at the service are qualified clinical or medical professionals, we told the registered manager to remove these references.

Improvement needed

The complaints policy must be updated.

Incorrect references to medical professionals and bodies must be removed.

Complaints were recorded within a file, together with correspondence sent by the service. We were told that verbal/informal complaints were recorded. We advised that a summary sheet for complaints would assist in identifying any themes emerging as a way of monitoring the quality of the service provided.

Records management (Standard 20)

We were told that patient notes were kept securely, within a locked area.

Workforce recruitment and employment practices (Standard 24)

At the time of our inspection, the registered manager had a Disclosure and Barring Service (DBS) check dated within the last three years in line with the regulations. However, the laser operators needed to update their DBS checks.

Improvement needed

All laser operators must have a DBS check dated within the last three years.

The registered manager confirmed that staff received annual appraisals and new staff had an induction which included the review of policies, procedures and use of the equipment. We were told that weekly staff meetings were held and any updates to policies and procedures would be discussed at these meetings.

Given the findings from this inspection, improvements are needed in the quality assurance and governance arrangements of this service, in accordance with requirements of the regulations and standards. It was also evident that the registered manager needed to improve their knowledge and understanding of these requirements.

The operation of sound quality assurance and governance arrangements and a registered provider's timely response to remedy issues of concern are important indicators of a provider's ability to run their service with sufficient care, competence and skill. There is an expectation, therefore, that the registered provider takes meaningful action to address these matters, as a failure to do so could result in HIW taking action for non-compliance with regulations.

Improvement needed

There must be effective management and quality assurance systems in place to ensure compliance with the standards and regulations, as a means to meeting the legal obligations to provide safe and effective laser treatments to patients.

6. Next Steps

This inspection has resulted in the need for the service to complete an improvement plan in respect of improvements identified within this report. The details of this can be seen within Appendix A of this report.

The improvement plan should clearly state how the improvement identified at Beauty Within Medi Spa will be addressed, including timescales.

The improvement plan, once agreed, will be published on HIW's website and will be evaluated as part of the ongoing inspection process.

Appendix A

Improvement Plan

Service: Beauty Within Medi Spa

Date of Inspection: 9 February 2016

Page Number	Improvement Needed	Regulation / Standard	Service Action	Responsible Officer	Timescale
Quality of Patient Experience					
7	Details of any adverse effects should be included within the treatment registers.	Regulation 23 (1) & 45 (2)	Update all 6 treatment logs	Neil Moaksom	1 month
7	The patient's guide must be updated in accordance with the regulations. A copy of the patients guide must be provided to HIW.	Regulation 7	Update patients Guide and Provide to Regulator	Neil Moaksom	2 months
8	The statement of purpose must be updated, specifically staff qualifications and treatments provided by each laser operator. A copy of the statement of purpose must be provided to HIW.	Regulation 6 (1) and Schedule 1	Update Statement of Purpose and supply to Regulator	Neil Moaksom	2 months

Page Number	Improvement Needed	Regulation / Standard	Service Action	Responsible Officer	Timescale
Delivery of Safe and Effective Care					
9	<p>The registered manager must ensure that laser and IPL machines are only used by staff who have undertaken appropriate training and have demonstrated an understanding of the correct and safe use of the equipment, in accordance with Regulation 45.</p> <p>Any in-house training provided to staff must be documented and the suitability of this must be discussed with the Laser Protection Advisor.</p>	<p>Regulations 45</p> <p>Standard 25</p>	<p>Document in house laser safety training for Pippa De Klerk.</p> <p>LPA to oversee and endorse</p>	Neil Moaksom	2 months
9	<p>The registered manager must ensure that the local rules are reviewed at least annually by the Laser Protection Advisor.</p>	<p>HIW conditions of registration</p> <p>Regulation 15 (1) & (2)</p> <p>Standard 16</p>	<p>Local Rules to be reviewed and endorsed by LPA. Nb This has been carried by our LPA previous to this inspection but had not been signed for.</p>	Neil Moaksom	2 weeks
10	<p>Patient safety and welfare must be protected. Specifically, an onsite assessment of the safety of the</p>	<p>Regulation 15 (1), (2) & 19(1)(2)</p>	<p>An LPA visit has been arranged and scheduled for the 4th April 2016. A copy of the visit report will be</p>	Neil Moaksom	2 months

Page Number	Improvement Needed	Regulation / Standard	Service Action	Responsible Officer	Timescale
	equipment and environment at the service must be conducted by a Laser Protection Advisor. A copy of the Laser Protection Advisor visit report must be provided to HIW.	Standard 16	forwarded to the HIW.		
10	The registered manager must consider the security arrangements for the IPL machine when it is not in use.	Regulation 15 (2) & 45 (3)	The Plasmalite IPLS was manufactured with no provision for Key operation. The security arrangement for this machine when it is not in use will be reviewed.	Neil Moaksom	1 month
11	Robust processes must be in place to ensure the welfare and safety of children and vulnerable adults who may use the service, including the review of policies, procedures and training for staff.	Regulation 16 Standard 11	Update Child Protection Policy paperwork. Action training for POVA and Safety of children	Neil Moaksom	2 months
11	The infection control policy must be updated with further details of the cleaning arrangements.	Regulation 9 (n)	Infection Control policy update	Neil Moaksom	1 month
12	The registered manager must ensure that comprehensive COSHH risk assessments are completed for all hazardous substances used at the	Regulation 9; 19 (b); 26 (2) (a) Standard 22	Carry out an updated COSHH risk assessment. This has been carried out previous to this inspection but using older guidance material	Neil Moaksom	2 months

Page Number	Improvement Needed	Regulation / Standard	Service Action	Responsible Officer	Timescale
	service.				
12	The registered manager must ensure that all appropriate measures and precautions must be in place to protect the health and safety of patients and staff at this service. Specifically, the registered manager should re-conduct a fire risk assessment using the latest guidance and fire regulations.	Regulation 15 (1),(2); 19(1); 26(5)(b) Standard 22	Re conduct fire risk assessment using the latest guidance. NB Carried out and reviewed previous to this inspection but using older guidance material.	Neil Moaksom	10 weeks
Quality of Management and Leadership					
13	The registered manager must ensure that the policies and procedures in place meet the requirements of the regulations and standards.	Regulation 9	Review all policies and procedures	Neil Moaksom	2 months
13	The complaints policy must be updated. Incorrect references to medical professionals and bodies must be removed.	Regulation 24	Update complaints policy	Neil Moaksom	2 weeks
13	All laser operators must have a DBS check dated within the last three years.	Regulation 12(2) (c) and	DBS check for Neil Moaksom and Amanda Moaksom has now been received.	Neil Moaksom	3 weeks

Page Number	Improvement Needed	Regulation / Standard	Service Action	Responsible Officer	Timescale
		Schedule 2	We are awaiting the DBS Check for Pippa De Klerk		
14	There must be effective management and quality assurance systems in place to ensure compliance with the standards and regulations, as a means to meeting the legal obligations to provide safe and effective laser treatments to patients.	Regulation 19 Standard 1	Review Regulation 19 Standard 1 policies and procedures	Neil Moaksom	2 months

Service Representative:

Name (print): NEIL MOAKSOM

Title: Registered Manager

Date: 17/3/2016