Regulation of Care Act 2013

Independent Medical Agency

The Hyperbaric Chamber

Announced Inspection

Completed on 14/6/17

13.30 – 15.45

Registration and Inspection Unit 3rd Floor, Murray House, Mount Havelock Douglas, Isle of Man, IM1 2SF
Completing and returning your report

To complete your report form, enter text by clicking on the box see the instructions below.

Use the tab key to move to the next box.

1. Provider’s action plan
   a. Add details of your actions to complete the requirements/recommendations (if applicable)

2. Provider’s comments/response
   a. Confirm you have read and agree/disagree the contents of the report by clicking on the appropriate box
   b. State any factual inaccuracies found, add comments (if applicable)
   c. Sign (type name when returning electronically) and date

3. Return your report to randi@gov.im within 4 weeks

4. Do not use any other method e.g. links to Cloud or other file sharing services

This report and grades represent our assessment of the quality of the areas of performance which were examined during this inspection.

Part 1: Service information

Part 2: Descriptors of performance against Standards

Part 3: Inspection Information

Part 4: Inspection Outcomes and Evidence and Requirements

When making decisions the Registration and Inspection Unit have regard as to how well the service meets the Independent Medical Agencies (August 2015). Providers of services are required, as part of their conditions of registration, to fully comply with the minimum standards.

This report identifies strengths and areas of good practice as well as areas where, in order to meet the minimum standards, improvement is required. It also summarises the findings of an inspection of the service and any requirements and recommendations made. It will form the basis for decisions by the Registration and Inspection Unit regarding registration, any variation of registration conditions and any enforcement action.

Standard 1 - Premises and Equipment
Standard 2 - Introduction and Assessment
Standard 3 - Quality of Treatment and Care
Standard 4 - Treatment Records
Part 5: Provider's comment/response

<table>
<thead>
<tr>
<th>Part 1 - Service Information</th>
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<tbody>
<tr>
<td>Name of Service</td>
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<tr>
<td>The Hyperbaric Chamber</td>
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</tbody>
</table>

Care Service Number

ROCA/P/0237A

Address
The Hyperbaric Chamber
Scholl Building
Fire Headquarters
Peel Road
Douglas
IM1 5ED

Registered company name: Kevin Gray Memorial Trust (The Hyperbaric Chamber)

Email Address: hyperbaric@manx.net

Name of Responsible Person
David Downie

Name of Registered Manager
David Downie

Manager Registration number ROCA/M/0149

Date of latest registration certificate
3/10/16

Date of latest manager certificate
3/10/16

Date of any additional regulatory action in the last inspection year (i.e. improvement measures or additional monitoring).
First inspection

Date of previous inspection
First inspection

Person in charge at the time of the inspection
David Downie - manager
Name of Inspector(s)
Kevin West

Part 2 - Descriptors of Performance against Standards
Inspection reports will describe how a service has performed in each of the standards inspected. Compliance statements by inspectors will follow the framework as set out below.

Compliant
Arrangements for compliance were demonstrated during the inspection. There are appropriate systems in place for regular monitoring, review and any necessary revisions to be undertaken. In most situations this will result in an area of good practice being identified and comment being made.

Recommendations based on best practice, relevant research or recognised sources may be made by the inspector. They promote current good practice and when adopted by the registered person will serve to enhance quality and service delivery.

Substantially compliant
Arrangements for compliance were demonstrated during the inspection yet some criteria were not yet in place. In most situations this will result in a requirement being made.

Partially compliant
Compliance could not be demonstrated by the date of the inspection. Appropriate systems for regular monitoring, review and revision were not yet in place. However, the service could demonstrate acknowledgement of this and a convincing plan for full compliance. In most situations this will result in requirements being made.

Non-compliant
Compliance could not be demonstrated by the date of the inspection. This will result in a requirement being made.

Not assessed
Assessment could not be carried out during the inspection due to certain factors not being available.
<table>
<thead>
<tr>
<th>No</th>
<th>Standard</th>
<th>Requirements/recommendations from previous inspection</th>
<th>Met/not met</th>
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<tr>
<td></td>
<td></td>
<td>First inspection</td>
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## Part 4 - Inspection Outcomes and Evidence and Requirements

### Regulation of Care Act 2013, Part 2 (37) and Care Services Regulations Part 3 (9)

#### Standard 1 - Premises and Equipment

**OUTCOME**
The service is carried out in suitable premises that are safe; using appropriate equipment that accords with legislative and best practice guidelines.

**Our decision:**
Compliant

**Reasons for our decision**
Patients could be provided with privacy in the office if required.

The premises were fully wheelchair accessible, including into the building and into the main hyperbaric chamber itself.

Hand hygiene measures were provided and a hand hygiene poster was displayed in the toilet.

A fire risk assessment had been completed and reviewed in January 2017.

Environmental risk assessments on areas such as control of infection, general office and staff work access, manual handling and slips, trips and falls were in place and reviewed.

A first aid box was available and a Health and Safety Law poster was displayed.

Accidents were recorded.

Liability insurance was displayed and valid until 1/8/17.

An electrical installation condition report from 7/3/16 confirmed the conformity / safety of the premises wiring.

Portable Electrical Appliance Testing (PAT) had taken place on 18/10/16.

All equipment was calibrated, serviced and maintained. This was done on a yearly basis and records dating back to 1999 were available for scrutiny.

**Requirements and recommendations**
None

**Provider’s action plan**
Not applicable
Regulation of Care Act 2013, Part 2 (37) and Care Services Regulations Part 3 (9)
Standard 2 - Introduction & Assessment

OUTCOME
Service recipients receive clear and accurate information about the service, and its likely costs.

Our decision: Compliant

Reasons for our decision
A statement of purpose / service recipient guide contained the information set out in Schedule 3 of the Care Service Registration Regulations. This also contained information on:
- The costs of treatment
- A list of the regulations that the agency adhered to
- The training and qualifications of staff
This document had recently been reviewed to ensure that the information was up to date.

The agency also produced a guide to their service covering:
- Objectives of the guide
- History of hyperbaric oxygen therapy
- Effectiveness of hyperbaric oxygen
- The mechanisms associated with the action of hyperbaric oxygen
- Answers to frequently asked questions related to hyperbaric oxygen therapy
- Details of a hyperbaric treatment session
- Complaints / feedback procedure
- Charity and donation information
- Health and safety policy statement

Requirements and recommendations
None

Provider’s action plan
Not applicable

Regulation of Care Act 2013, Part 2 (37) and Care Services Regulations Part 3 (9)
Standard 3 – Quality of Treatment and Care

OUTCOME
The treatment and care provided are person-centred. Treatment provided is in line with the relevant legislation and clinical guidelines and is properly supervised.

Our decision: Compliant

Reasons for our decision
The agency had a client service charter which provided a statement of what clients could expect by way of services. These included:
- Assessment of patients’ health / medical needs is timely and accurate
- Taking into account patients’ wishes and preferences
- Informing patients of the findings and recommendations
- Patients giving verbal consent for all examinations and the offer of a chaperone
- The respecting of patients’ privacy, dignity and confidentiality at all times
- Providing services in a way that facilitates access by people of different cultural and ethnic backgrounds and those with a physical, sensory or learning disability
Written procedures that detail the treatment protocols and normal operation of equipment was in place. These included:

- In the event of a reported diving casualty protocol
- Treatment protocols for high dosage treatment
- Standard operating and emergency policies and procedures
- Oxygen treatment training and reference manual
- Code of construction and working practice for low pressure barochambers

All treatment was carried out under the supervision of the manager.

Patients were seen by their GP and were then referred to the agency’s Medical Advisor. The Medical Advisor would then come to the agency to discuss the referral form and treatment with the Hyperbaric Chamber staff. On arrival at the agency and prior to treatment, a patient would receive a verbal treatment briefing to help them understand the treatment protocol they were about to receive. The staff member would go through a patient pre-treatment check sheet that covered:

- Introductions of the staff team and their roles.
- Information about the building, such as toilets, fire exits and chamber access and egress.
- Health and safety, covering actions such as treatment card given, equalization techniques, instructions on what a patient must do if any discomfort occurs, temperature increases and decreases, cleaning of the O2 mask and when to put the mask on/off.

Requirements and recommendations
None

Provider’s action plan
Not applicable

Regulation of Care Act 2013, Part 2 (37) and Care Services Regulations Part 3 (9)
Standard 4 – Treatment Records

OUTCOME
There is an accurate and up to date treatment record for every patient/client. Records are maintained of adverse incidents. All records are stored securely.

Our decision:
Compliant

Reasons for our decision
Patient records from the GP included:

- Patient details
- Medical history
- Details of the initial consultation
- Diagnosis – reason for treatment

On arrival at the hyperbaric chamber the patient signed a consent form.

An attendance register completed by the patient recorded the time of their session and their name and signature. The chamber operator completed details of each session, recording the start and finish times, air break times, depth of treatment, number of patients, the operator’s signature and any other comments relating to that particular session.
Excel spreadsheets also recorded patient treatment details, including the condition name, category name and number of treatments required.

Records were stored in locked cabinets and were available for inspection.

**Requirements and recommendations**
None

**Provider’s action plan**
Not applicable

**Regulation of Care Act 2013, Part 2 (37) and Care Services Regulations Part 3 (9)**

**Standard 5 – Staffing & Recruitment**

**OUTCOME**
All staff are appropriately trained and have the knowledge, skills qualifications and experience for the task/s they perform. Their competence is regularly reviewed and refresher training provided.

**Our decision:**
Substantially compliant

**Reasons for our decision**
Staff were registered with the relevant regulatory body and certificates of training attended were kept.

Staff files were examined. Some pre-employment records such as job descriptions and contracts were in place but the inspector was informed that other checks were kept on file at the Snaefell Surgery. The checklist supplied from the surgery confirmed that some pre-employment checks were completed including proof of identity, health check questionnaire and Disclosure and Barring Service (DBS) checks. There was no evidence of completed application forms and interview notes and there was no evidence in one staff members file / checklist of any references being taken up.

All staff were professionally indemnified.

Staff had defined roles and responsibilities.

Staff had received an annual appraisal / Performance Development Review (PDR).

**Requirements**

**Standard 5.2**
Two references should be sought as part of pre-employment checks.

**Timescale:** Immediate when appropriate

**Standard 5.2**
Application forms should be completed as part of the employment process.

**Timescale:** A job application form was developed by the agency post inspection.

**Provider’s action plan**
Click here to enter text.
### OUTCOME
The Agency is managed ethically, effectively and efficiently, delivering a service which meets the needs of its users. Registered persons have the appropriate skills, experience and qualifications to deliver an efficient and effective service.

### Our decision:
Substantially compliant

### Reasons for our decision
The manager was registered with the Department of Health and Social Care under the Regulation of Care Act 2013. He has held the position of manager since 1984 and is well qualified in hyperbaric medicine.

The agency carried out an annual patient questionnaire survey in 2016. The purpose was part of the agency’s continued assessment of the service, facilities and procedures. Seventy two questionnaires were distributed and forty were returned by 1/11/16. A summary of the answers were compiled and broken down under the following headings:

- The referral process
- Waiting list or planned treatment
- The hyperbaric facility
- Chamber Technologist and / or Medical Director
- Chamber Operators
- Your care & treatment
- Treatment & procedures
- Overall experience
- About you

Other comments made by patients were also recorded.

Bar charts / graphs were produced that showed the range of responses to each question asked.

There were clear arrangements for backing up the agency’s electronic data and IT systems were securely managed, including password protection and restricted access.

At the time of the inspection the agency did not have any policy for managing the risks associated with clinical records. Subsequent to the inspection a records retention policy was written. This policy detailed the type of records kept, the retention period, where these records were kept and how the records were disposed of. An access to medical records (data protection) policy was also written post inspection, as well as a patient records policy regarding confidentiality.

### Requirements
**Standard 6.6**
A procedure for managing the risks associated with clinical records should be written.

**Timescale:** Policies were written subsequent to the inspection and copies sent to the inspector for scrutiny.

### Provider’s action plan
Not applicable
### Regulation of Care Act 2013, Part 2 (37) and Care Services Regulations Part 3 (9)
#### Standard 7 – Financial Viability & Business Continuity

<table>
<thead>
<tr>
<th>OUTCOME</th>
<th>The Agency is financially sound. Where there are plans to close or substantially change, there is proper planning to make the transition for patients/clients and staff as smooth as possible and to ensure the necessary continuity of treatment.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Our decision:</td>
<td>Compliant</td>
</tr>
</tbody>
</table>
| Reasons for our decision | Chartered accountants completed annual accounts for the agency and these demonstrated that the agency was financially viable.  
A business case for relocation to a new purpose built premises had been written in May 2016. |
| Requirements and recommendations | None |
| Provider’s action plan | Not applicable |

### Regulation of Care Act 2013, Part 2 (37) and Care Services Regulations Part 3 (9)
#### Standard 8 – Medicine Management

<table>
<thead>
<tr>
<th>OUTCOME</th>
<th>Medicines are handled appropriately and where immunisation services are provided this is done in accordance with recognised minimum standards for immunisation.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Our decision:</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Reasons for our decision</td>
<td>This standard is not applicable as no medicines are handled or stored at this service.</td>
</tr>
<tr>
<td>Requirements and recommendations</td>
<td>None</td>
</tr>
<tr>
<td>Provider’s action plan</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

### Regulation of Care Act 2013, Part 2 (37) and Care Services Regulations Part 3 (9)
#### Standard 9 – Hyperbaric Therapies

<table>
<thead>
<tr>
<th>OUTCOME</th>
<th>Equipment used meets required specifications &amp; operators are competent.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Our decision:</td>
<td>Compliant</td>
</tr>
</tbody>
</table>
| Reasons for our decision | The hyperbaric chambers conformed fully to the appropriate quality standards as well as:  
  - Built in accordance with the European Pressure Directive |
Certified by Lloyds Register as Pressure Vessels Safe for Human Occupancy (PVHO)
Lloyds Register design appraised

Operators of hyperbaric treatment chambers received up to date training in hyperbaric oxygen chamber safety and received up to date awareness training. This was evidenced through the agency’s qualification and training matrix.

### Requirements and recommendations
None

### Provider’s action plan
Not applicable

Please complete the provider action plan sections beneath each requirements and recommendations providing details of action taken (or to be taken) with timescale for each.

The inspector would like to thank the management, staff and service users for their co-operation with this inspection.

If you would like to discuss any of the issues mentioned in this report please do not hesitate to contact the Registration and Inspection Unit.

**Inspector:** Kevin West  
**Date:** 10/7/17
Part 5 - Provider’s comments/response

To: The Registration and Inspection Unit, 3rd Floor, Murray House, Mount Havelock, Douglas IM1 2SF

From: The Hyperbaric Chamber

I / we have read the inspection report for the unannounced inspection carried out on 14/6/17 at the establishment known as The Hyperbaric Chamber, and confirm that the contents of this report are a fair and accurate representation of the facts relating to the inspection conducted on the above date(s).

☐

I/we agree to comply with the requirements/recommendations within the timescales as stated in this report.

☐

Please return the whole report which includes the completed action sections to the Registration and Inspection Unit within 4 weeks from receiving the report. Failure to do so will result in your report going on line without your comments.

Or

I/we am/are unable to confirm that the contents of this report are a fair and accurate representation of the facts relating to the inspection conducted on the above date(s)

☐

Signed
Responsible Person
Date

Signed
Registered Manager
Date

Due to a change of Responsible Person/Registered Manager the provider did not return their response within the specified timescale and consequently it has been placed on the website without their comments.

Action plan/provider’s response noted and approved by Inspector:
Date: Signature/initials