Independent Medical Agency

Minimum Standards

Registration & Inspection Unit

July 2019

Department of Health and Social Care
Rheynn Slaynt as Kiarail y Theay
Introduction

Independent Medical Agencies as defined within the Regulation of Care Act “is a business that consists of, or includes, the provision of services by medical practitioners”. Exemptions within the Act are:

1. An independent Clinic
2. An independent hospital
3. A business to the extent to which its services are provided under the NHS Act

Currently there have been identified two specific types of services operating on the Isle of Man which come under the definition of a medical agency; these being:

- Hyperbaric Therapies
- Occupational Health Services

Hyperbaric Oxygen Therapy

Hyperbaric Oxygen Therapy (HBOT) is the medical use of oxygen at a level higher than atmospheric pressure. Historically associated for use with divers it is increasingly used as treatment for a number of other medical conditions. Current accepted usage is for the following conditions:

- Air/Gas Embolism
- Carbon Monoxide poisoning and Smoke Inhalation
- Decompression Sickness
- Adjunctive Hyperbaric Oxygen in Intracranial Abscess
- Gas Gangrene
- Crush Injuries
- Necrotizing Soft Tissue Infection
- Enhanced Healing of Selected Wounds
- Exceptional Blood Loss
- Osteomyelitis
- Radiation Tissue Damage
- Skin Grafts and Flaps
- Thermal Burns

The equipment required consists of a pressure chamber, which may be of rigid or flexible construction and a means of delivering 100% oxygen. Chambers can vary in size; accommodating one or more patients.

Occupational Health Services

Occupational Health Services that are subject to the Regulation of Care Act are those services that provide for the health care of people of working age. Within the scope of the Act this is limited to those services that operate outside of the NHS. They apply to core clinical services provided by medical practitioners, who may be supported by nurses and occupational health technicians and may include:

- Health checks and screening
• Fitness for work assessments
• Examinations & reports for occupational diseases
• Immunisation
• Substance misuse testing

They may also provide non-clinical services such as ergonomics but these services do not fall within the scope of the Regulation of Care Act and these standards.

Standards 1 – 8 reflect the core requirements for all medical agencies. Standard 9 is specific to hyperbaric therapies.

Any other services which are found to be operating and which meet the definition of an Independent Medical Agency will be required to register and meet the core requirements plus any additional standards that are deemed to apply to that particular service.

Legal status of the Standards

The Standards are issued by the Department of Health & Social Care under section 35 of the Regulation of Care Act 2013. Regulation 9 of the Regulation of Care (Care Services) Regulations 2013 requires registered persons to ensure that the care service meets all minimum Standards applicable to that service. The Standards are issued for use by the Registration & Inspection Unit who is able to take them into account when undertaking inspection of the service.

The service provider can also use them to self-assess their own service and they can provide a basis for staff induction and training; they also provide reassurance for people using the service, and their families.

Structure and approach to inspection

The standards focus on delivering good quality and safe services for people using the service. The expected outcome for each standard is clearly stated in bold text and is supported by criteria, which if met, indicates that this outcome will be achieved. The Department takes a proportionate and flexible approach to the supporting criteria, which do not have to be followed exactly, if the provider can demonstrate to the satisfaction of the inspector that the outcome is being met in a different way. The exception to this is that anything in the criteria that is duplicated in the Act or in Regulations must be met.

Inspectors will use evidence which demonstrates the provider’s compliance with standards, regulations and the primary legislation, as well as information from other sources to make an inspection judgement about the overall effectiveness of the service and the registered persons continued suitability to provide that service. There is a range of ‘steps’ that can be taken by the regulator to ensure that services remain ‘fit for purpose’ and in this respect inspectors have a monitoring role that goes beyond simply carrying out an annual site visit. The Department has published inspection guidelines which can be accessed via the web-site and will show registered persons the approach taken to inspection.

Review of care Standards

These standards will be reviewed every 3 years.
Glossary

Audit: The process of setting or adopting standards and measuring performance against those standards with the aim of identifying both good and bad practice and implementing changes to achieve unmet standards.

Calibrate: To determine, check, or rectify the graduation of (any instrument giving quantitative measurements).

Disability: Any continuing condition that restricts everyday activities.

Notifications: Providers must notify Registration and Inspection no later than 24 hours from the occurrence of:

(a) the death of any service recipient at the care service and the circumstances of the death;
(b) the outbreak of any notifiable disease (within the meaning of Part II of the Public Health Act 1990) at the care service;
(c) the serious injury or illness of any service recipient at the care service;
(d) the suffering of serious harm of any service recipient at the care service;
(e) any event at the care service affecting the well-being of any service recipient;
(f) any unexplained absence of a service recipient from a care service;
(g) any serious incident necessitating calling the police to the care service;
(h) the making of any allegation that a service recipient has committed an offence;
(i) any theft, burglary, fire or accident at the care service; and
(j) any serious staffing issues for example conduct of a member of staff at a care service that may be such that they may not be a suitable person to be involved in the care of service recipients;
(k) staffing levels;
(l) a near miss.

Outcome: The end result of care and treatment that is the change in health, functional ability, symptoms or situation of the person, which can be used to measure the effectiveness of care and treatment.

Personal Plan: Also known as: Care Plan; Plan of Care; Support Plan, Person Centred, is the document that contains an individual personal details and instructs the reader of the plan about how to deliver services that are tailored to that individual needs.

Person-Centred: A person centred process involves listening, thinking together, coaching, sharing ideas, and seeking feedback.

Planning: The process by which the service determines how it will achieve its aims and objectives. This includes identifying the resources which will be needed to meet the aims and objectives.

Policy: An operational statement of intent in a given situation.
**Procedure:** The steps taken to fulfil a policy.

**Risk Assessments:** Written documents that form part of the service’s safety strategies. They can be personal, environmental or generic. Risks are identified and plans set in place to minimise those risks.

**Registered Manager:** Is the person in day to day charge of the setting. The manager may be the same person as the responsible person if that provider is an individual and in limited circumstances may also be the same person as the responsible person of a corporate body. If not the same person, the manager will be recruited by the registered provider but will be registered by the Department and must meet the registration criteria set out in the Regulation of Care Act 2013, the Registration of Care (Registration) Regulations 2013 and in these Standards. A manager must have appropriate qualifications and experience.

**Responsible person:** A person deemed suitable to provide a care service. They may be the registered provider or the registered manager. Each registered person has responsibility for ensuring that the requirements of the Act, Regulations and Standards are met. A company, committee or other group may be the registered person and they will be required to nominate a responsible person to speak on their behalf. The responsible person also has to be vetted by the Department and has specific obligations within the Regulation of Care Act 2013 and Regulation of Care (Care Services) Regulations 2013.

**Staff:** Those employed by the regulated establishment/agency.

**Standard:** An overall statement of desired performance.

**Statement of purpose:** A statement of purpose is a document which includes information about a service describing aims and objectives, the kinds of services provided the health or care needs the service sets out to meet.

**Treatment records:** Contains details about the client/patient/ their medical history, records of treatment, adverse incidents.
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

Supporting Criteria

1.1 Premises must be of sufficient size to provide an adequate number of consulting rooms and examination/treatment rooms.

1.2 Consulting, examination & treatment rooms must provide privacy through adequate soundproofing and solid doors.

1.3 Premises must comply with the Health & Safety of Work Act 1974. Risk assessments (including fire risk assessments) must be carried out and risks must be eliminated or managed. Records of these are maintained.

1.4 Electricity at Work Regulations 1989 is complied with. A certificate of conformity/safety is available for the agency’s electrical installations that comply with ‘The 17th Edition, Wiring Regulations’, its successor or equivalent. Portable Electrical Appliance Tests are must be carried out and recorded in compliance with current guidance and instruction.

1.5 Premises must be accessible to people with disabilities.

1.6 Hand hygiene measures must be provided in examination and treatment rooms.

1.7 The registered person must provide medical equipment relevant to the service being provided.

1.8 All equipment must be calibrated, serviced and maintained according to the manufactures’ requirements; records must be maintained of calibration, servicing and repairs.

1.9 Dedicated vaccine refrigerator must be provided and maintained if vaccines are stored. These must be kept locked in a lockable room and have an appropriate temperature thermometer.

1.10 Vaccines must be stored in a manner that prevents overcrowding and promotes a steady flow of air.
Standard 2 - Introduction & Assessment

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

Supporting Criteria

2.1 The agency must be available for prospective service recipients a statement of purpose and a service recipient guide expressed in clear, relevant language and in a format suitable for the profile of the service, with regard to language and translation, and with regard to people with sensory disabilities or people with a learning disability who may wish to use the service. The statement of purpose must contain the information set out in Schedule 3 to the Care Service Registration Regulations.

2.2 The service recipient guide must be reviewed annually to ensure the information in it remains up to date. It includes information about:

- The services philosophy and ethos.
- The terms and conditions of treatment.
- The range of costs associated with the service.
- A copy of the services complaints procedure.
- A statement of service recipients’ rights.
- An outline of the policies and procedures that affect the people having examinations and/or receiving treatment. For example confidentiality, risk assessments, accident reporting etc.
- The training and qualifications of staff.
- The registered person ensures that information on treatment provided by the service is not misleading, that information provided to people is accurate and that any claims made in respect of treatment are justified.

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.

Supporting Criteria

3.1 The registered person must have policies and procedures in place to ensure that the care and treatment provided is person-centred, as follows:

- assessment of service recipients health/medical needs must be timely, appropriate and accurate;
- service recipients must be informed of the recommended interventions for treatment and/or care;
• service recipients must give verbal consent to all intimate examinations, and must be offered a chaperone if undergoing such an examination, or are able to bring a relative or friend with them if they wish;  
• service recipients, and their relatives if appropriate must be consulted about the planning and delivery of services provided to them, which includes taking into account their preferences and requests;  
• service recipients must have access to their health records in line with the:
  - Data Protection Act 2018 and GDPR  
  - Recommendations of the Caldicott Committee report  
  - and guidelines from professional bodies  

• Services must be provided in such a way that facilitates access by people of different cultural and ethnic backgrounds and those with physical disabilities, sensory disabilities and learning disabilities.  
• privacy, dignity and confidentiality must be respected at all times  
• service recipients must be addressed by their preferred name and title; and are treated with courtesy, consideration and respect.  

3.2 The registered person must have written procedures that detail the examination/treatment protocol and normal operation of any equipment used (including when it is being used on a trial or demonstration basis) and these procedures cover:

• Contra-indications  
• Technique  
• Pre-treatment tests  
• Pre-treatment checks  
• Post-treatment care  
• Recognition of examination/treatment-related problems  
• Procedure if anything goes wrong with the examination/test/treatment  
• Permitted variation on machine variables  
• Procedure in the event of equipment failure  
• The potential hazards associated with examination/tests and or treatment including a robust risk assessment  
• Controlled and safe access  
• Operators’ responsibilities  
• Methods of safe working  
• Safety checks  
• Personal protective equipment  
• Prevention of use by unauthorised persons  
• Adverse incident procedures  

3.3 All treatment must be carried out under the supervision of a medical practitioner (except hyperbaric therapies who must meet standard 9).  

3.4 All patients/clients must have an appointment/consultation for assessment with the medical practitioner who will be carrying out supervising or arranging the procedure/treatment.
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

Supporting Criteria

4.1 The treatment record must include the following information:

- Patient/client details
- Medical History
- Signed consent form
- Record of treatment delivered and by whom
- Details of the initial consultation with the medical practitioner

4.2 Adverse incidents must be fully recorded and clearly identify the action taken as a result of the incident, including the notification to Registration & Inspections under Regulation 10 of the Regulation of Care (Care Services) regulations 2013.

4.3 Records must be stored in locked cabinets and are available for inspection at any time.

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.

Supporting Criteria

5.1 All clinical staff employed must be registered with the relevant regulatory body on the appropriate part of the register and the registered person keeps an updated list detailing pre-employment and annual verification checks of the register together with documentary evidence of certificates and relevant training attended.

5.2 The employer must be fair and competent, and operate sound employment practices and good support for its staff; the employer must comply with current employment legislation and requirements of the Isle of Man. Where vulnerable adults are being provided with a service all staff and volunteers must be checked in accordance with the appropriate level of disclosure by the Disclosure and Barring Service.

5.3 At least one member of staff employed must have a qualification in occupational medicine or nursing. (Occupational Health Services only).

5.4 All clinical/professional staff must be professionally indemnified.
5.5 All staff, including the registered manager and the responsible person (if appropriate) must have defined roles and responsibilities must be properly managed, supported and understand to whom they are accountable.

5.6 Suitable arrangements must exist for professional/clinical supervision of staff where applicable and support provided for continuous professional development and re-validation.

5.7 All staff must have access to support and advice, and be provided with regular supervision by appropriately qualified and experienced staff; this to include formal supervision sessions which should take place at not more than 3 monthly intervals.

5.8 A written or electronic record must be kept by the service detailing the time and date and length of each formal supervision held for each member of staff, including the registered person. The record must be signed by the supervisor and the member of staff at the end of the supervision and must be available for inspection when required by the registration & inspection unit.

5.9 All staff must have their performance individually and formally appraised at least annually and this appraisal takes into account continuous professional development requirements. Personal development plans are in place that takes account of the needs of the individual, the needs of the service and the needs of the people it serves.

**Standard 6 – Management & Administration**

**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.

**Supporting Criteria**

6.1 The Agency must employ a manager who is registered with the DHSC. The manager must hold a qualification in management & leadership that is relevant to the service being provided and is equivalent to QCF Diploma Level 5; and has at least 2 year’s experience of working in the service being provided.

6.2 There is an effective system for quality assurance. This must include:

- Number and types of complaints and any learning resulting from these
- Accidents
- Feedback from those using the service

6.3 There must be clear arrangements for backing up electronic data.

6.4 IT systems must be securely managed and include:

- Password protection
- Restricted access
• System access monitoring

6.5 There must be a system of annual internal or external clinical audit which confirms that a representative sample of clinical records have been audited to ensure compliance with legal requirements and professional practice recommendations. This includes:

• Legible entries which are documented in such a way that they cannot be erased or altered.
• Entries must be signed and dated in such a way that the author can be clearly identified.

6.6 There must be a procedure for managing the risks associated with clinical records which includes:

• A description of the duties and legal obligations that apply to records
• The process for creating, tracking, retrieving and backing up records
• The process for retaining and disposing of records
• The monitoring arrangements in place to ensure compliance.
Standard 7 – Financial Viability & Business Continuity

**OUTCOME**
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

**Supporting Criteria**

7.1 A qualified accountant must certify the annual accounts and these demonstrate that the agency is financially viable and likely to have sufficient funding to continue to fulfil its Statement of Purpose for at least the next 12 months.

7.2 The registered person must have a written development plan, reviewed annually, for the future of the service, either identifying any planned changes in the operation or resources of the service, or confirming the continuation of the services current operation and resource.

7.3 Where the agency, for financial, staffing or other reasons, cannot adequately and consistently maintain provision which complies with Regulations or Minimum Standards, an effective plan must be established and implemented either to rectify the situation or to close down the service. Where there is ongoing treatment suitable arrangements are in place for the continuation of that treatment from another practitioner who is either registered under the Regulation of Care Act or provides the service as part of NHS treatment.

Standard 8 – Medicine Management

**OUTCOME**
Medicines are handled appropriately and where immunisation services are provided this is done in accordance with recognised minimum standards for immunisation.

**Supporting Criteria**

8.1 The service must develop and maintain a procedure for medicines management which is signed by a doctor and addresses:

- ordering
- safe custody
- administration
- disposal and for immunisation - consent and evidence of checks of adherence.

8.2 There must be a comprehensive paper or electronic audit trail of the above.

8.3 A list must be maintained of all staff administering medication/performing immunisation and there are training records from an external provider. Competency must be assessed
at regular intervals as part of the person’s ongoing learning & development plan. Refresher training must be provided at least every 3 years.

8.4 There must be a suitable procedure for the storage, handling and administration of vaccines and a protocol for vaccine management which addresses:

- Receiving vaccines
- Maintaining correct temperature of stored vaccines
- Handling vaccines during immunization sessions
- Disposal of vaccines
- Actions in the event of interruption of the cold chain
- Treatment of anaphylaxis.

8.5 There must be a list of equipment and the presence of in-date drugs that are available to deal with anaphylaxis.

8.6 Staff must be able to demonstrate an understanding of the procedures and protocols in place.

**Standard 9 – Hyperbaric Therapies**

**OUTCOME**

*Equipment used meets required specifications & operators are competent*

**Supporting Criteria**

9.1 The Decompression/Hyperbaric Chambers must be manufactured in Carbon steel; conform to PD5500 and Quality Standard ISO 9001: 2008.

9.2 Decompression/Hyperbaric Chambers must be:

- Built in accordance with the European Pressure Directive (PED)
- Certified by Lloyds Register as “Pressure Vessels Safe for Human Occupancy” (PVHO)
- Lloyds Register “design appraised
- CE marked

9.3 Operators of hyperbaric treatment chambers must have up to date training in hyperbaric oxygen chamber safety, and their use, that complies with current legislative requirements and professional guidelines.

9.4 All support staff must have up to date awareness training in hyperbaric oxygen chamber safety.
This document can be provided in other formats

Review date July 2021

Registration and Inspection Unit
Department of Health and Social Care
Ground Floor, St George’s Court
Hill Street
Douglas
Isle of Man
IM1 1EF
Telephone (01624) 642422
Email: Randi@gov.im