The Regulation and Quality Improvement Authority

RQIA Provider Guidance 2021-2022

Independent Health Care

Independent Medical Agency

What we do

The Regulation and Quality Improvement Authority (RQIA) is the independent body that regulates and inspects the quality and availability of Northern Ireland's health and social care (HSC) services. We were established in 2005 under The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 to drive improvements for everyone using health and social care services.

Through our programme of work we provide assurance about the quality of care; challenge poor practice; promote improvement; safeguard the rights of service users; and inform the public through the publication of our reports. RQIA has four main areas of work:

- We register and inspect a wide range of independent and statutory health and social care services.
- We work to assure the quality of services provided by the HSC Board, HSC trusts and agencies - through our programme of reviews.
- We undertake a range of responsibilities for people with mental ill health and those with a learning disability.
- We support establishments and service providers to improve the service they deliver.

All work undertaken by RQIA is focused on the following four domains:

- Is care safe?
- Is care effective?
- Is care compassionate?
- Is the service well led?

RQIA registers, and inspects and supports a wide range of health and social care services. These include: nursing, residential care, and children's homes; domiciliary care agencies; day care settings/centres; independent health care; nursing agencies; independent medical agencies; residential family centres; adult placement agencies; voluntary adoption agencies, school boarding departments and young adult supported accommodation (inspected only).

The four domains

How we will inspect

We will inspect every independent medical agency (IMA) at least annually. Our inspectors carry out an announced inspection.

When we inspect an independent medical agency, we aim to provide assurances in respect of the standard, quality and safety of services delivered. We do this by:

- Seeking the views of the people who use the service, or their representatives.
- Talking to the management and other staff on the day of the inspection.
- Examining a range of records including care records, incidents, complaints and policies.
- Providing feedback on the day of the inspection to the registered person/manager on the outcome of the inspection.
- Providing a report of our inspection findings and outline any areas for quality improvement.

Our inspections are underpinned by:

- The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003
- The Independent Health Care Regulations (Northern Ireland) 2005
- The Regulation and Improvement Authority (Independent Health Care) (Fees and Frequency of Inspections) (Amendment) Regulations (Northern Ireland) 2011
- The Department of Health (DoH) Minimum Care Standards for Healthcare Establishments July 2014

Provider guidance in respect of the maintenance and upkeep of the premises and the management of medicines are also available on our website. These documents should be reviewed to ensure compliance with the minimum standards and legislation.

Should you have additional categories of care, please ensure that you review and adhere to the relevant provider guidance document i.e. Private Doctor (PD).

What we look for when we inspect

To help us to report on whether the care is safe, effective and compassionate and whether the service is well led, we will look for evidence against the following indicators.

Is care safe?

Avoiding and preventing harm to service users from the care, treatment and support that is intended to help them.

Indicator S1
There are, at all times, suitably qualified, competent and experienced persons working in the service in such numbers as are appropriate for the health and welfare of service users.

Examples of evidence

Staffing

- There are sufficient numbers of staff in various roles to fulfil the needs of the IMA and patients.
- There is an induction programme in place appropriate to the role.
- A system is in place to ensure staff receive annual appraisals and records are retained.
- A system is in place to ensure all staff receive appropriate training to fulfil the duties of their role in keeping with the RQIA training guidance including professional body Continuing Professional Development (CPD), records are retained.
- There are arrangements for monitoring the professional registration status of clinical staff, records are retained.
- There are arrangements in place for monitoring the professional indemnity of all staff who require individual indemnity cover, records are retained.
- Evidence that each private doctor has confirmation of identity; current General Medical Council (GMC) registration; professional indemnity insurance; qualifications in line with service provided; evidence of ongoing professional development and continued medical education that meets the requirements of the Royal Colleges and GMC.
- Evidence that each private doctor has an appointed responsible officer (RO).
- Arrangements are in place to link into the wider system of RO's for doctors with practising privileges agreements.
- Evidence for arrangements for revalidation.
- Each private doctor is aware of their responsibilities under GMC Good Medical Practice and Good practice in prescribing and managing medicines and devices.

Recruitment and selection

- Staff have been recruited in line with Regulation 19 (2), Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005, as amended.
- There is a written policy and procedure for staff recruitment in keeping with Regulation 19 (2) Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005.
- Staff personnel files are in keeping with 19 (2) Schedule 2, as amended.
- Enhanced AccessNI /Disclosure and Barring Service or equivalent checks are received prior to new staff commencing work.
- Recruitment and selection records should be retained in keeping with Regulation 21 (3) Schedule 3 Part II.
- An up-to-date staff register should be maintained and retained in keeping with Regulation 21 (3) Schedule 3 Part II.

Indicator S2
The service promotes and makes proper provision for the welfare, care and protection of service users.

Examples of evidence

Safeguarding

Adult

- Policies and procedures are in line with the regional Adult Safeguarding Prevention and Protection in Partnership policy (July 2015) and Northern Ireland Adult Safeguarding Partnership Operational Handbook June 2017.
- The IMA has identified an adult safeguarding champion (if required).
- There is an identified safeguarding lead and staff are aware of who the safeguarding lead is.
- All staff receive the relevant level of training as outlined in RQIA training guidance.
- Staff training should be in keeping with the Northern Ireland Adult Safeguarding Partnership (NIASP) Training Framework (revised June 2016).
- Staff are knowledgeable about adult safeguarding and are aware of their obligations in relation to raising concerns.
- All suspected, alleged or actual incidents of abuse are fully and promptly referred to the relevant persons and agencies for investigation in accordance with procedures and legislation; written records must be retained.
- Where shortcomings are highlighted as a result of an investigation, learning arising should be assessed, implemented and quality assured.
- Staff are familiar with their responsibilities and know how to appropriately recognise poor practice and raise concerns.
- The IMA ensures arrangements are in place that pharmacists who are providing patient group directions (PGDs) have awareness of actions to be taken should a safeguarding issue arise.

Children

- Policies and procedures are in line with the regional Co-operating to Safeguard Children and Young People in Northern Ireland, (August 2017) and Safeguarding Board for Northern Ireland (SBNI) Procedures Manual (November 2017).
- There is an identified safeguarding lead and staff are aware of who the safeguarding lead is.
- All staff receive the relevant level of training as outlined in RQIA training guidance.
- Staff training should be in keeping with SBNI Child Safeguarding Learning and Development Strategy and Framework 2020 – 2023.
- Staff are knowledgeable about safeguarding children and are aware of their obligations in relation to raising concerns.
- All suspected, alleged or actual incidents of abuse are fully and promptly referred to the relevant persons and agencies for investigation in accordance with procedures and legislation; written records must be retained.
- Where shortcomings are highlighted as a result of an investigation, learning arising should be assessed, implemented and quality assured.
- Staff are familiar with their responsibilities and know how to appropriately recognise poor practice and raise concerns.
- The IMA ensures arrangements are in place that pharmacists who are providing PGDs have awareness of actions to be taken should a safeguarding issue arise.

Patient identity

- There are protocols to identify and verify the patient at the start of the first consultation and subsequent consultations.
- The registered persons protects against patients using multiple identities.

Indicator S3
There are systems in place to ensure that unnecessary risks to the health, welfare or safety of service users are identified, managed and where possible eliminated.

Examples of evidence

Management of medical emergencies

- The IMA has arrangements in place to ensure that pharmacists who are providing PGDs have awareness of actions to be taken in the event of a medical emergency.

Infection prevention control and decontamination procedures

- The IMA ensures that pharmacists who are providing PGDs have infection prevention and control policies and procedures in keeping with The Northern Ireland Regional Infection Prevention and Control Manual.

Management of patient group directions (PGD)

- For each PGD there should be governance arrangements with clear lines of responsibility and accountability.
- PGDs should be developed in accordance with The Human Medicines Regulations 2012.
- All PGD's should be authorised by a pharmacist registered with the Pharmaceutical Society of Northern Ireland (PSNI).
- The IMA ensures arrangements are in place to review PGDs to ensure that they are kept up to date and reflect more frequent changes eg: Seasonal Influenza Vaccine.

Risk management

- There are risk management procedures in place.
- All risks in connection with the IMA, treatment and services are identified, assessed and managed.
- Arrangements are in place to provide evidence of appropriate review of risk assessments. Any findings/learning arising from risk assessments should be implemented and assured.
- An overarching corporate risk register is in place which details the measures in place to mitigate and control identified risks.

Indicator S4
The premises and grounds are safe, well maintained and suitable for their stated purpose.

Examples of evidence

- Not applicable.

Is care effective?

The right care, at the right time in the right place with the best outcome.

Indicator E1
The service responds appropriately to and meets the assessed needs of the people who use the service.

Examples of evidence

Clinical records

- Arrangements are in place for maintaining and updating clinical records.
- The treatment plan is developed in consultation with the patient and includes information about the costs of treatment, options and choices.
- Record keeping is in accordance with legislation, standards and best practice guidance GMGR records management.
- A policy and procedure is available which includes the arrangements in relation to the creation; storage; recording; retention and disposal of records and data protection.
- Records are securely stored (electronic and hard copy).
- A freedom of information publication scheme is in place.
- The IMA is registered with the Information Commissioners Office (ICO).
- There are systems in place to audit the completion of clinical records and an action plan is developed to address any identified issues.
- The private doctor/staff have a good knowledge of effective records management.
- The establishment has arrangements in place to comply with the General Data Protection Regulation (GDPR) legislation.

Indicator E2
There are arrangements in place to monitor, audit and review the effectiveness and quality of care delivered to service users at appropriate intervals.

Examples of evidence

- A range of audits, including clinical audits are undertaken routinely and actions identified for improvement are implemented into practice.

Indicator E3
There are robust systems in place to promote effective communication between service users, staff and other key stakeholders.

Examples of evidence

Communication

- There is an open and transparent culture that facilitates the sharing of information.
- Patients are aware of who to contact if they want advice or if they have any issues/concerns.
- Staff meetings are held with doctors involved in the IMA service.
- Staff can communicate effectively.
- Learning from complaints/incidents/near misses is effectively disseminated to staff, implemented and assured.
- The IMA has a website which contains comprehensive information regarding the types of treatment provided.

- The IMA also provide specific information to patients to explain the treatment provided and associated risks and complication.

Communication with registered general practitioners

- There are systems in place to contact the patient's registered general practitioner (GP), with their consent, for further information if necessary.
- The IMA must support private doctors to practise in line with the GMC guidance on remote prescribing as outlined in Good practice in prescribing and managing medicines and devices and open a dialogue with patients to explore when consent to share information with registered GPs is declined.

Is care compassionate?

Service users are treated with dignity and respect and should be fully involved in decisions affecting their treatment, care and support.

Indicator C1
There is a culture/ethos that supports the values of dignity and respect, independence, rights, equality and diversity, choice and consent of service users.

Examples of evidence

- Staff can demonstrate how confidentiality is maintained.
- Discussion with staff demonstrated that patients are treated with dignity and respect.
- There is a policy and procedure on maintaining confidentiality which is regularly assured.

Consent

- Staff can demonstrate how consent is obtained.
- Consent is obtained in line with GMC guidance on consent.
- There are systems in place to ensure patients are effectively involved in making decisions about their treatment and are provided with clear and accessible information about the implications of the treatment and the options available to them.
- Informed consent or refusal is documented in the patient's record and completed consent forms are kept in with patient records.

Dignity, respect and rights

- Patients' privacy and dignity is respected at all times.
- Patients' rights to make decisions about care and treatment are acknowledged and respected.
- Patients are treated and cared for in accordance with legislative requirements for equality and rights.

Informed decision making

- Information regarding services provided by the IMA accurately reflects the types of service provided and is prepared in line with GMC Good Medical Practice.
- Information provided includes the costs of treatments.
- Information is written in plain English.

Mental capacity

- There are systems and processes in place to identify where there may be evidence of lack of mental capacity.
- There is a model of consultation, which facilitates an assessment of capacity in line with legal expectations.

Indicator C2
Service users are listened to, valued and communicated with, in an appropriate manner.

Examples of evidence

- There are arrangements in place to support patients to make informed decisions.

Indicator C3
There are systems in place to ensure that the views and opinions of service users, and or their representatives, are sought and taken into account in all matters affecting them.

Examples of evidence

Patient consultation

- Patient consultation (patient satisfaction survey) about the standard and quality of care is carried out at least on an annual basis.
- The results of the consultation relevant to Northern Ireland (NI) are collated to provide a summary report.
- The summary report is made available to patients and a subsequent action plan is developed to inform and improve services.
- RQIA staff/patient questionnaire responses are reviewed and used to improve services.
- Reports summarising patient comments and action taken by the IMA are presented regularly to the various governance committees (where appropriate) and are made available to patients and interested parties.

Is the service well led?

Effective leadership, management and governance which creates a culture, focused on the needs and the experiences of service users in order to deliver safe, effective and compassionate care.

Indicator L1
There are management and governance systems in place to ensure the overall quality and safety of services provided.

Examples of evidence

Governance arrangements

- Where the entity operating the agency is a corporate body or partnership or an individual owner who is not in day to day management of the agency, in accordance with Regulation 26 of The Independent Health Care Regulations (Northern Ireland) 2005, arrangements are in place to ensure the registered person/nominated representative monitors the quality of services and undertakes an unannounced visit to the premises at least six monthly and produces a report of their findings (where appropriate).
- There are arrangements in place for policies and procedures to be reviewed at least every three years.

- Policies are centrally indexed, a date of implementation and planned review is recorded and they are retained in a manner which is easily accessible by staff.
- Arrangements are in place in relation to medical governance in accordance with the GMC guidance document 'Effective clinical governance for the medical profession: A handbook for organisations employing, contracting or overseeing the practice of doctors'.
- Arrangements are in place to provide evidence of an appropriate review of risk assessments e.g. legionella, fire, Control of Substances Hazardous to Health (COSHH).
- The registered person/manager ensures the agency delivers a safe and effective service in line with the legislation, other professional guidance and minimum standards.

Complaints

- The agency operates a complaints procedure in accordance with the relevant legislation and DoH guidance on complaints handling Health and Social Care Complaints Procedure (Revised April 2019).
- Records are kept of all complaints and these include details of all communications with complainants; investigation records; the result of any investigation; the outcome and the action taken.
- Staff know how to receive and deal with complaints.
- Arrangements are in place to audit complaints to identify trends and improve services provided.
- Themes emerging from complaints are analysed with input from relevant governance committees and any themes identified are disseminated to all staff.
- Complaints are triaged to identify if there are any clinical issues which need to be further reviewed in line with risk management procedures.

Statutory notification of incidents and deaths to RQIA

- The agency has an incident policy and procedure in place which includes reporting arrangements to RQIA.
- Incidents are effectively documented and investigated in line with legislation.
- All relevant incidents are reported to RQIA and other relevant organisations in accordance with legislation and procedures, RQIA Statutory Notification of Incidents and Deaths.
- Arrangements are in place to audit adverse incidents to identify trends and improve services provided.

Equality

- The management have systems in place to consider equality for patients.

Indicator L2
There are management and governance systems in place that drive quality improvement.

Examples of evidence

Quality improvement

- There is evidence of a systematic approach to the review of available data and information, in order to make changes that improve quality, and add benefit to the organisation and patients.

Quality assurance

- Arrangements are in place for managing relevant alerts.
- Arrangements are in place for staff supervision and appraisal.
- There is collaborative working with external stakeholders e.g. community pharmacists.
- There are procedures to facilitate audit, including clinical audit (e.g. records; incidents; accidents and complaints).
- Results of audits are analysed and actions identified for improvement are embedded into practice.

Indicator L3
There is a clear organisational structure and all staff are aware of their roles, responsibility and accountability within the overall structure.

Examples of evidence

- There is a defined organisational and management structure that identifies the lines of accountability, specific roles and details responsibilities of all areas of the agency.
- Staff are aware of their roles and responsibilities and actions to be taken should they have a concern.
- The registered person/s have an understanding of their role and responsibilities as outlined in legislation.
- Patients are aware of the roles of staff and who to speak to if they need advice or have an issue or concern.
- The registered person is kept informed regarding the day to day running of the agency.
- There are opportunities to raise staff awareness through training and education regarding equality legislation to recognise and respond to patients' diverse needs.

Practising privileges

- There is a written agreement between the medical practitioner and the agency that sets out the terms and conditions of granting practising privileges.
- Practicing privileges agreements are reviewed at least every two years.
- There is a written procedure that defines the process for application; granting; maintenance and withdrawal of practising privileges.

Indicator L4
The registered person/s operates the service in accordance with the regulatory framework.

Examples of evidence

- The Statement of Purpose and Patient Guide are kept under review, revised when necessary and updated.
- Insurance arrangements are in place for public and employers liability.
- Registered person/s responds to regulatory matters (e.g. notifications; reports/QIPs; enforcement).
- Any changes in the registration status of the service are notified to RQIA.
- The RQIA certificate of registration is on display and reflective of services provided.

Indicator L5 There are effective working relationships with internal and external stakeholders.
Examples of evidence • Arrangements are in place for staff to access their line manager. • There are arrangements in place to support staff (e.g. staff meetings; appraisal and supervision). • Discussion with staff confirmed that there are good working relationships and that management are responsive to suggestions/concerns. • There are arrangements for management to effectively address staff suggestions/concerns. • There is a raising concerns/whistleblowing policy and procedural guidance for staff.

Inspection reports

Our inspection reports will reflect the findings from the inspection. Where it is appropriate, a Quality Improvement Plan (QIP) will detail those areas requiring improvement to ensure the service is compliant with the relevant regulations and standards as a minimum. Where no areas for improvement result from the inspection this will be reflected in the report.

Once the inspection report is finalised and agreed as factually accurate, it will be made public on RQIA's website.

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