Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Regulation of Health and Social Care Services

Enhanced Authority Monitoring Approach - Guidance

Effective February 2018

Safer Better Care

Introduction

This guidance provides a summary of the Health Information and Quality Authority's (HIQA's) approach to the regulation of designated centres. It outlines the key enhancements to its approach arising from its review of the Authority's Monitoring Approach (AMA). These enhancements apply from 1 January 2018.

The purpose of regulation

The purpose of regulation is to safeguard vulnerable people of any age who are receiving residential care services. Regulation provides assurance to the public that people living in designated centres are receiving a safe, high-quality service that meets the requirements of the regulations. In addition, providers should constantly strive for ongoing improvements in the quality of the service by applying National Standards.

Regulation has three aspects:

- Registration. Under Section 46(1) of the Health Act 2007 (the Act) — any person carrying on the business of a designated centre can only do so if the centre is registered under this Act and the person is its registered provider
- Monitoring compliance. The purpose of monitoring is to assess compliance with the Act, regulations and Standards by gathering information and evidence, reviewing and risk-rating this information to inform regulatory judgments
- Enforcement. In taking enforcement action, the primary concern is to protect the safety and wellbeing of residents. When other means of seeking compliance and improvements have failed, enforcement action may be taken. It may be either:
  - civil action (that is, a refusal of registration, imposition of conditions, cancelation of registration) or
  - criminal prosecution.

1. Registration

The purpose of registration is to protect people using services by determining which designated centres can be registered and who can be its registered providers. Registration provides for scrutiny of the information available about the centre and:

- provider and person or persons participating in managing the point of entry into the regulated area, and

- ongoing monitoring throughout the cycle or cycles of registration.

In other words, the process of registration controls entry into the sector for the provision of care to vulnerable people in designated centres. The process of registration confirms publicly that as the registered provider, you are fit and legally permitted to provide that service. The following sections explain changes to the process of registration.

(a) When does registration begin?

1. New designated centre (the intended provider is seeking to register a designated centre for the first time) — ***minor amendments to application forms***.
2. New intended provider who is seeking to take over the running of an existing registered designated centre only where written consent has been given by the current registered provider — ***minor amendments to application forms***.
3. New commencements where centres are 'as if' registered under the provision of Section 69 of the Health Act 2007 as amended — ***minor amendments to application forms***.
4. Where a provider is seeking to register a new extension or new building that increases the footprint of an already registered designated centre — ***change to current process; such applications will no longer be accepted as applications to vary the current registration, they are instead an application to register.***
5. Registered providers who apply to renew their registration six months in advance of the expiry of their current registration — ***minor amendments to application forms***.

An application for registration* will only be accepted where it meets the requirements of the Act: the provider submits a completed application form and the prescribed fee. A ***key change*** from 1 January 2018 will be the return to the applicants by HIQA of applications and fees that do not meet these requirements.

In addition, providers must submit prescribed† information and this information will be assessed in terms of compliance with the relevant registration regulations.

* Includes renewal of registration.
† As prescribed by regulations.

Another ***key change*** is that when you apply to register a new designated centre or to increase the footprint of a current designated centre, then the premises must be ready for assessment at the time of application. Updated guidance on the process of applying for registration is available on our website.

(b) The role of registered provider

You as registered provider are legally responsible for the designated centre and through a process of regulation and monitoring will be held to account for the quality of the service provided. Your role is to ensure that the centre is suitable for its stated purpose and function and complies with the regulations and National Standards. Key to this is the Statement of Purpose.

The statement of purpose

The statement of purpose is a fundamentally important document. In it, you are required to set out the purpose and function of the designated centre, the specific services you intend to deliver and the specific care needs that you and your staff can support and manage. A ***key enhancement*** is that the Office of the Chief Inspector has set out clearly the expectations of this document and how it should be used to define the service for residents.

Registered provider's representative

Another ***key enhancement*** of the approach is the introduction of the registered provider's representative. This is the person or persons put forward by the registered provider[‡] to present, answer questions on and provide clarification regarding its executive governance arrangements.

This person or persons will be asked to explain how the provider assures itself that the service is being operated in compliance with the Health Act 2007 as amended, the regulations and nationally mandated standards in relation to safely carrying on the business of the designated centre.

The registered provider's representative does not replace the responsibilities of the provider but is a person with whom the Office of

[‡] Where the registered provider is a partnership, company, unincorporated body or statutory body.

the Chief Inspector can speak with whenever the provider is an entity made up of a group of people.

(c) The role of the person in charge

The person in charge (PIC) is responsible for the day-to-day operation of the designated centre, which includes the quality of care being delivered either social or clinical. The person in charge must be suitably qualified and experienced with authority, accountability and responsibility for providing the service.

In line with the regulations, there must be a person in charge of the centre at all times. It is your responsibility to ensure that in the event that the person in charge is absent for more than 28 days, you appoint a person in charge.

(d) The role of the person participating in management of the centre (other than the person in charge)

The person or persons must be actively engaged in and responsible for the operational management of the overall designated centre. A person participating in management (PPIM) is not always required and will depend on the type and size of the provider entity.

When one is required, a PPIM is the person appointed by the intended and or registered provider with delegated authority from the provider to make **senior decisions** about the overall operational management of the entire centre.

He or she must support the person in charge is ensuring that the centre is operationally effective and that a safe, good quality service is being delivered on behalf of the registered entity.

(e) Fitness

Fitness of the provider and persons participating in the management of the centre (including the person in charge) is essential to the proper governance and management of that centre. Fitness is, among other things, the ability of the registered provider, PPIM and person in charge to:

- perform his or her role
- ensure the delivery of a service providing suitable and sufficient care that protects the rights and promotes the wellbeing and welfare of residents

- comprehensively understand and comply with regulations and nationally mandated Standards
- have comprehensive governance arrangements in place which include timely and responsive quality assurance processes to assure themselves of the quality and safety of the service they are registered to provide.

The assessment of fitness is not based on a single source of evidence. It is a dynamic process which is continually informed by solicited and unsolicited information and ongoing regulatory findings. Updated fitness guidance can be found on our website.

(f) Decisions on registration

Following consideration of the application for registration and review of all information in relation to the centre (including any inspections carried out), a decision on registration will be made.

Notice of Proposed Decision

You will first receive a written Notice of Proposed Decision (NOPD), which will set out:

- a Proposed Decision to grant the application for registration outlining any operating conditions attached to the registration, or
- a Proposed Decision to refuse the application for registration outlining the grounds relied on for the decision.

When you receive this proposed decision, you can either (1) accept the proposed decision and inform the Chief Inspector that you do not intend to make representation or (2) make representations in writing (within 28 calendar days [date as specified on the Notice of Proposed Decision]) on the proposed decision.

Written representations on proposed decision

When making any written representation on a Notice of Proposed Decision, it should refer to the matters (grounds) as laid out in the schedule attached to that Notice of Proposed Decision. The representation should specify why you disagree with the proposed decision and outline your reasons for disagreeing.

Notice of Decision

Following consideration of either your acceptance of the Proposed Decision or your representation, a Decision will be made taking into account all the information

available, including any additional information provided.

You will be sent:

- a **Notice of Decision** to grant the application for registration, or
- a **Notice of Decision** to refuse the application for registration, or
- following representation and if the decision is different from what was initially issued to you, a new **Notice of Proposed Decision**, with the same process outlined above applying.

On receipt of the Notice of Decision, you can either accept the decision and the decision will take effect, or appeal this decision to the District Court.

If you do appeal to the District Court, you may continue to operate the designated centre until a determination is made by the court or the appeal is withdrawn. You may also continue to operate the centre until a determination is made should there be a further appeal to the Circuit Court.

(g) Conditions of registration

The purpose of conditions of registration is to set the parameters by which a provider may provide a service, or to restrict what a provider can provide in a designated centre. Conditions may be restrictive or permissive in nature.

Once a centre has been registered with conditions, you will be inspected against them and you cannot operate outside of them. To fail to comply with a condition of registration is an offence under Section 79 of the Act and is likely to result in enforcement activity.

(h) Seeking to change a condition

As a provider, you may wish at times to seek to change or amend the conditions of registration. For example, to increase the number of places you are registered to provide. You may do so by applying to vary your conditions, in line with Section 52 of the Act and accompanied by the prescribed fee. Depending on the type of change applied for, an inspection may be required.

A decision to grant an application for a variation or removal of a condition of registration will only be made where it is: (a) appropriate in the circumstances **and** (b) will not adversely affect the persons who are resident in the designated centre. You will be issued with a Notice of Proposed Decision

following a similar process as outlined above.

2. Monitoring compliance

We continually monitor and assess designated centres to make judgments on compliance with the regulations and Standards. This means we review and analyse all the information we have about a centre.

Monitoring is a dynamic and continual process and through our enhanced monitoring approach we have additional tools which will enable us to use the information available to verify whether providers are providing safe, good quality care.

Monitoring includes:

- inspection
- compliance plans
- compliance with conditions of registration
- receipt of information:
  - solicited information such as notifications from providers, assurance reporting and requests for information
  - unsolicited information such as information received from the public that may be of concern.

HIQA's enhanced Authority Monitoring Approach takes a risk-based approach to regulation, which means prioritising regulatory activities and allocation of resources. This means that, based on risk, we will make decisions regarding a range of regulatory matters including:

- the type and intensity of monitoring activity necessary to respond to non-compliance with the regulatory framework
- what monitoring and information gathering methods are needed and when they should be used
- the target and focus of inspection programmes
- the type and intensity of enforcement activity required to respond to non-compliance with a provider's responsibility with the law.

(a) Inspection

Inspection is an important regulatory activity which assists in the making of ongoing regulatory decisions, informs you of our assessment of your compliance with regulations and or Standards at a point in time, gives a voice to the resident about what it is like to live in the centre and informs the public of the quality of services being provided against regulations and or Standards.

Types of inspection

HIQA carries out the following types of inspections:

- monitoring compliance with regulations and standards to inform a decision for registration (Sections 50, 51, 59 or 60), including concerns regarding fitness of provider and or persons participating in the management of the centre
- monitoring compliance with regulations and standards as a result of identified risk, and or enforcement activity
- thematic inspections to drive improvements in the sector.

(a) Difference between announced and unannounced inspections

Announced inspections

Our inspection findings are informed by people using the services; therefore the main purpose of announcing our inspections is to let residents and their relatives and or representatives know the date of our inspection so they can speak with inspectors on the day if they wish to.

A ***key enhancement*** will be that HIQA notifies providers of planned announced inspections four weeks in advance of the date of inspection, an increase from the current two weeks. There will be at least one planned announced inspection in every three-year cycle of registration of a designated centre, which we expect providers to inform residents about.

Another ***key enhancement*** is the introduction of short-notice announced inspections. This will only be in exceptional circumstances, for example, to facilitate meeting with people who participate in management or to meet with the provider. Short notice will be given no more than 48 hours in advance of an inspection.

Unannounced inspections

All other inspections that we carry out are unannounced. This means that the provider, person in charge or any other person in the centre has not been informed either formally or informally of our inspection visit in advance.

What happens during an inspection?

Arrival: we will meet with the provider and or person in charge or

their delegated person on site and explain the purpose of our inspection.

A ***key enhancement*** will be a walk around of the centre with the person in charge of the centre or the person who is in charge on the day of the inspection, which will give them the opportunity to outline to the inspector how the service is being delivered in line with its statement of purpose.

This walk around will respect residents' personal space, privacy and dignity.

Gathering evidence: the focus of inspections will be on consulting with residents, relatives and staff, observing practices, and reviewing documentation to triangulate[§] our findings. Inspectors will use HIQA's assessment judgment framework as a tool to assist in this process. Please note that our revised assessment judgment framework is now a combined document

Review of evidence and preliminary findings: when the inspector believes that they have sufficient evidence by which to make a judgment, the inspector will set out their preliminary findings. Informal feedback will be given throughout the inspection process.

Provider feedback meeting: this is the last phase of the on-site part of the inspection. At a minimum, the provider (or delegate) and person in charge (or delegate) should be in attendance. The inspector will give you feedback on the preliminary findings from the day or days of inspection.

Final judgments will not be given at this meeting as the inspector will need to review all information gathered before final judgments can be made. Any additional information you or your delegate may bring to the attention of the inspector will be reviewed and taken into account. The feedback meeting should take one hour or less.

Responding to risk

Where an immediate risk has been identified, the inspector will outline this to the provider and or person in charge and or person participating in management immediately and the person and or persons will be requested to address this risk before the end of the inspection.

Where urgent risk has been identified, the provider (or delegate) or person in charge or PPIM will be informed of this at the

[§] There may be in a small number of regulations where review of documentation is the only method required for gathering evidence.

time; later again during the feedback meeting; and a compliance plan for that risk will be issued by the inspector to the provider within 24 hours of the completion of the inspection.

(b) Judgments on compliance with regulations

Once inspectors have gathered information, they make a judgment about the level of compliance against each regulation reviewed. While some regulations attribute responsibility to the person in charge to comply, overall responsibility for compliance is with the registered provider. A ***key enhancement*** is our revised judgment descriptors which inspectors use to judge whether the registered provider or person in charge has been found to be: **compliant**, **substantially compliant** or **not compliant** with the regulations associated with them.

(c) Reporting the findings of an inspection

This is where you will notice the ***greatest change*** in the monitoring tools used by HIQA. Following an inspection, you will receive a stage 1 inspection report from HIQA. As part of our enhanced approach, our inspection report template is new and includes the following sections.

About the designated centre

This section will be taken from your statement of purpose.

Views of the people who use the service

This section will be a summary of what residents told us through the residents' questionnaires and our communication with them on inspection.

Capacity and capability of the registered provider to deliver a safe quality service

This section describes the governance, leadership and management arrangements in the centre and how effective they are in assuring that a good quality and safe service is being provided. It outlines how people who work in the centre are recruited and supported through education and training, and whether there are appropriate systems and processes in place to underpin and ensure the safe delivery and oversight of the service.

Quality and safety of the service

This section describes the care and support people receive and

whether it was of a good quality and ensured people were safe. It includes information about the care and supports available for people, the environment in which they live and what residents and their families say about the service they are receiving.

Another ***enhancement*** includes the risk-rating of not-compliant regulations.

(d) Compliance Plan

Another ***key change*** for you will be the replacement of the Action Plan with a Compliance Plan. Where non-compliance is identified in the inspection reports, a compliance plan.

This plan will detail the specific regulations that you have not complied with, and you will be required to respond to HIQA on how you intend to comply.

A ***key change*** to this process will be that you will only get **one** attempt to return a satisfactory compliance plan. We have also increased the time frame for you to do this, from 10 working days to 15 working days.

(e) Feedback

Following receipt of the inspection report, you may choose to submit feedback where you reasonably believe the judgments are incorrect or there are factual inaccuracies contained within the report. To this end, we have ***enhanced*** our feedback process.

The feedback process has two distinct levels, as follows:

1. Feedback from a provider.
2. Appeal of a submission decision.

In the first instance, you will be given an opportunity to reply to the lead inspector and author of the report. Following consideration of your feedback, the report may be amended if deemed appropriate by HIQA.

Where a person in charge and or a provider receiving the report is not satisfied with the response from HIQA's lead inspector and report author to the feedback provided, they have an opportunity to send further feedback in the form of a submission appeal. The findings of the appeal are the final step of our internal feedback processes.

Having a comprehensive feedback mechanism ensures you are afforded ample opportunity to be heard.

(f) Publication of inspection reports

Once HIQA has considered the feedback (including any submissions), it will finalise the inspection report to ready it for publication. You will be notified by email when the report will be published.

(g) Complaints

HIQA has in place a clear policy regarding the making of complaints. This process is separate and distinct to the making of a submission on regulatory judgments. Should you wish to make a complaint, please do so via this e-mail address: complaints@hiqa.ie.

Please be advised that any complaint included as part of a submission falls outside the remit of the submission process.

2.2 Notifications

We have introduced new notification forms and updated guidance. A ***key enhancement*** is the separation of the guidance on registration-related notifications from monitoring-related notifications. This guidance can be found on our website.

3. Are you prepared for regulation?

- ✓ Make sure your service is delivered in line with your Statement of Purpose.
- ✓ Check that you and your staff are familiar with the Act, associated regulations and National Standards.
- ✓ Ensure you and your staff are familiar with this guidance and other relevant guidance.
- ✓ Speak with inspectors whenever they are on site; tell them about the improvements or changes you have made.
- ✓ Make sure you have complied with the regulations and meet or exceed National Standards.
- ✓ Make sure you have complied with any conditions of registration.
- ✓ Respond to requests for information in a timely manner dealing with all matters as outlined in the requests.
- ✓ Make sure you have all the required records available for inspection.

4. Enforcement

The Office of the Chief Inspector will take a firm but fair approach in carrying out our enforcement activities. When all other means of bringing about improvements have failed, or there is a serious risk to the health and welfare of residents, we will enforce in a way that is:

- fair and non-discriminatory
- efficient and effective
- transparent
- proportionate
- consistent.

The regulatory activities we will employ to bring about improvements include:

- increased monitoring and focused inspections
- seeking assurance reports
- warning meetings and issue of a warning letter
- requests for information (Section 65).

However, should these fail or if there is a serious risk to the health and welfare of residents, we are likely to take enforcement action if:

- the failure of the provider is having a serious impact on the health, safety or quality of life of residents
- the failure of the provider poses an unacceptable risk to residents
- the provider has persistently failed to meet legislative requirements
- the provider has repeatedly failed over time to meet legislative requirements
- the provider acts outside of the conditions of registration.

Statutory enforcement action taken by HIQA may include:

- prosecutions (Section 79)
- cancelation of registration (Section 51)
- attaching, varying or removing conditions of registration (Section 51)
- urgent application to the district court to cancel or vary, remove or attach conditions of registration (Section 59)
- ex parte emergency application to the district court to cancel or vary, remove or attach conditions of registration (Section 60)
- court order to enforce decisions of the Chief Inspector (Section 58).

Following the decision of the court, HIQA will monitor closely the standards of care in the centre.

5. Data protection and information governance

At times, we may request information from you or you will be required by the regulations to submit information. It is important that you adhere to good information governance and data protection legislation.

We request therefore that you do not use residents' personal identifiable information and instead use the residents' unique identifier in all correspondence with us.

Issued by the Office of the Chief Inspector
Regulation Directorate
Health Information and Quality Authority (HIQA)
Unit 1301, City Gate,
Mahon,
Cork,
T12 Y2XT