

Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Regulation Handbook

A guide for providers and staff of designated centres Version 4.1 — May 2025 Regulation handbook: A guide for providers and staff of designated centres

Regulation handbook: A guide for providers and staff of designated centres

About the Chief Inspector of Social Services

The Chief Inspector of Social Services within the Health Information and Quality Authority (HIQA) (referred to in this handbook as the Chief Inspector) is responsible for registering and inspecting designated centres in Ireland.

The functions and powers of the Chief Inspector are set out in Parts 7, 8 and 9 of the Health Act 2007 (as amended) (from now on referred to in this handbook as the Act).

The Chief Inspector currently regulates designated centres for:

- older people
- people with disabilities
- young people in special care units.







The role of the Chief Inspector includes inspecting and registering designated centres through assessing compliance with the regulations[‡] and nationally mandated standards.[◊] This is achieved through desktop inspection of information received from the provider about the designated centre, on-site inspection in designated centres and ongoing assessment of compliance by centres with the regulations and national standards.

⁺ The regulations are as follows:

Health Act 2007 (Care and Support of Residents in Designated Centres for Persons (Children and Adults) with Disabilities) Regulations 2013

Health Act 2007 (Registration of Designated Centres for Persons (Children and Adults) with disabilities) Regulations 2013 (as amended)

Health Act 2007 (Care and Welfare of Residents in Designated Centres for Older People) Regulations 2013 (as amended)

Health Act 2007 (Registration of Designated Centres for Older People) Regulations 2015 (as amended)

Health Act 2007 (Care and Welfare of Children in Special Care Units) Regulations 2017 (as amended)

Health Act 2007 (Registration of Designated Centres) (Special Care Units) Regulations 2017.
 * These are:

⁻ National Standards for Residential Services for Children and Adults with Disabilities (2013)

[—] National Standards for Residential Care Settings for Older People in Ireland (2016)

⁻ National Standards for Special Care Units: November 2014 (published 2015)

⁻ National Standards for infection prevention and control in community services (2018)

⁻ National Standards for Adult Safeguarding (2019).

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Introduction to this handbook

Introduction to the Regulation handbook

Welcome to this updated edition of the *Regulation handbook*. Since the previous edition, there have been significant developments in the regulation of designated centres in Ireland, including 'compliance notices' for designated centres for older people and people with disabilities, and significantly amended care and welfare regulations for nursing homes.

A compliance notice is a new escalation and enforcement tool under section 78A of the Health Act 2007 (as amended), commenced on 14 February 2025. Its purpose is to require the person to whom it is addressed to either take an action or actions or refrain from an activity in order to ensure compliance by the registered provider with the relevant statutory or regulatory obligations.

Section 78B of the Health Act 2007 (as amended) also commenced on 14 February 2025. It provides that the Chief Inspector shall maintain a list of all registered providers on whom a fine or other penalty is imposed by a court under Section 78A (referred to as a 'non-compliance list'). Section 78B also states that the Chief Inspector may publish the non-compliance list.

While there have been no other changes to the regulation of special care units, the commencement of compliance notices for providers of residential services for older people and people with disabilities, and other regulatory changes for nursing home providers are significant. This handbook reflects these changes, but providers should aways consult the original regulatory instruments for legal certainty.

The updated care and welfare regulations for nursing homes are in effect from 31 March 2025. The regulation on the person in charge has been changed significantly to include the requirement to have a person to deputise when the person in charge is absent and to provide clarity on the experience and qualifications required to be a person in charge both now and in the future.

Other changes to the regulation of nursing homes include changes to the regulations on residents' rights, communication difficulties, visits, governance and management, risk management, infection control, notification of incidents, notification of absence, and notification of procedures and arrangements for the periods when the person in charge is absent from the designated centre, among other changes.

Does this handbook apply to you?

This handbook applies to those designated centres currently regulated by the Chief Inspector of Social Services within the Health Information and Quality Authority (HIQA).

The Act defines what a designated centre is and who its provider can be. Those services are:

- residential centres for people with disabilities, both adults and children
- residential centres for older people, such as nursing homes
- special care units for young people currently provided by the Child and Family Agency (Tusla).

Should any additional services fall within the remit of the Chief Inspector in the future, we will update this handbook to reflect these changes at that point.

There are many regulatory activities that are undertaken when registering or renewing the registration of a designated centre or in assessing compliance with the regulations and standards. These are done through our desktop inspections of information or on-site inspections in these centres. This handbook aims to capture the key moments in the lifecycle of a registered centre.

Providers themselves should actively identify non-compliance with

regulations made by the Minister for Health or made by the Minister in consultation with the Minister for Children, Disability and Equality as may be appropriate.

Providers should also identify noncompliance with national standards approved by the Minister for Health and take any corrective action necessary to maintain high standards of care rather than awaiting an intervention by the Chief Inspector.

Providers should use all available resources — such as guidance on our website and published inspection reports — to achieve this objective.



Is it a designated centre which is, therefore, eligible for registration?

There are two components in our assessment of what constitutes a designated centre. These are the:

- service provided
- care and support requirements of people using the service.

Each provider must determine if the service being provided is a designated centre. If in doubt, please contact our registration team to inform them of the existence of the service, and we can assess if the service should be registered or not.

Under the Act, a designated centre means:

- an institution where residential services are provided by:
 - the Health Service Executive (HSE)
 - Child and Family Agency (Tusla)
 - a service provider under the Act
 - someone who is not a service provider but receives help under section 39 of the Health Act 2004:
- ♦ in line with the Child Care Act, 1991
- to people with disabilities in relation to their disabilities
- to other dependent persons in relation to their dependencies
- a special care unit
- a nursing home as defined in section 2 of the Health (Nursing Homes) Act, 1990.

The following are not designated centres:

- a centre registered by the Mental Health Commission
- an institution managed by or on behalf of a government minister
- a place where most people are being treated for:
 - acute illness or
 - receiving palliative care
- an institution primarily used for providing educational, cultural, recreational, leisure, social or physical activities
- school arrangements or day care services for children or adults with disabilities
- a children detention school under the Children Act, 2001.

If a district hospital, convalescence care, respite centre or supportive care home meets the definition of a designated centre and is registered, it must comply with the Act, regulations and national standards.

The Health Act 2007 (as amended) provides for children's residential centres to become designated centres; however, this part of the Act has not yet been commenced and is not in operation.

The Chief Inspector has produced <u>What is a designated centre? A guide</u> <u>to understanding the definition of</u> <u>designated centres</u> to help service providers decide whether their services needs to be registered with the Chief Inspector. This guidance is available on <u>www.hiqa.ie</u>.

Communicating with the Chief Inspector

The Chief Inspector has a number of avenues for you to make contact. You should consider the nature of your query or correspondence and direct it to the appropriate section as outlined below.

All communication related to your registration should be directed to <u>registration@hiqa.ie</u>.

Any queries related to notifiable events should be directed to <u>notify@hiqa.ie</u>.

For day-to-day management of the centre, such as inspections, queries for your case-holding inspector or general queries, you should contact the relevant regulatory support team for your area:

- Disability services <u>dcd@hiqa.ie</u> for receipt and delivery of correspondence to and from registered providers of designated centres for people with disabilities
- Older persons' services <u>dcop@hiqa.ie</u> for receipt and delivery of correspondence to and from registered providers of designated centres for older people
- Special care units <u>children@hiqa.ie</u> for receipt and delivery of correspondence to and from registered providers of special care units.

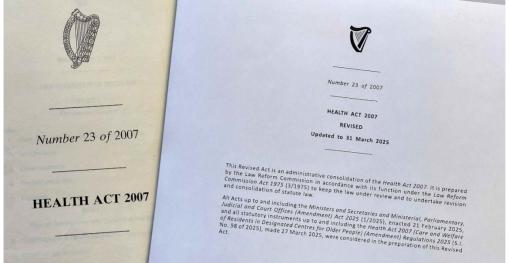
Complaints

We welcome comments, suggestions and complaints about our performance and conduct in the discharge of our statutory duties and responsibilities. Should you wish to make a complaint, please email: <u>complaints@hiqa.ie</u>. However, HIQA's complaints procedure is separate to providing feedback to the Chief Inspector on regulatory judgments.

Complaints included with feedback on regulatory judgments will not be considered by the Chief Inspector. You should instead make a complaint. See our complaints policy on <u>www.hiqa.ie</u> or go to <u>https://www.hiqa.ie/reports-and-publications/corporate-publication/complaints-policy</u>. See Chapter 5 for more on providing feedback on a draft inspection report to the Chief Inspector.

Regulation handbook: A guide for providers and staff of designated centres

Chapter 1. The regulatory framework in which designated centres operate



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Legal basis for regulation⁺

The Chief Inspector of Social Services (referred to in this handbook as the Chief Inspector) within the Health Information and Quality Authority (HIQA) was established under the Health Act 2007 (as amended) ('the Act').

The functions of the Chief Inspector include:

- establish and maintain registers of designated centres
- register and inspect designated centres to assess whether the provider is in compliance with the regulations and standards.

The regulatory framework through which the Chief Inspector discharges these duties comprises:

- Health Act 2007 (as amended) ('the Act'). This is the primary legislation under which the Chief Inspector and providers operate.
- **Regulations** made under the Act. These are the minimum legal requirements that providers must meet.
- National standards developed by HIQA under the Act to promote safety and quality in services.

The regulations are made by the Minister for Health (having consulted with the Minister for Children, Disability and Equality as may be appropriate), and the national standards are

[†] This document should not be relied upon for legal purposes — in such cases, please refer to the original legislation, the Health Act 2007 as amended.

mandated by the Minister for Health. The regulations set the minimum standard of safe, quality care to be provided to residents or children by registered providers. The standards are intended to support providers to achieve a high standard of care.

Providers of designated centres should thoroughly familiarise themselves with — and continually self-assess themselves against — the Act, regulations and standards that apply to them. The most up-to-date and correct versions of these are listed in Table 1 on pages 4 and 5 of this chapter.

The purpose of regulation

Regulation aims 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, highquality service that meets the requirements of the regulations. Regulation has three aspects:

- 1. Registration.
- 2. Assessing compliance.
- 3. Escalation and enforcement.

Registration. Under section 46(1) of the Act, any person carrying on the business of a designated centre can only do so if the centre is registered under the Act and the person is its registered provider.

Assessing compliance. The purpose of monitoring is to assess compliance with the Act, regulations and national standards by gathering information and evidence and reviewing and risk rating this information to inform regulatory judgments. Where the Chief Inspector refers to 'monitoring' in this handbook, it includes inspection, review of information submitted by the designated centre, information held about the centre and ongoing review of information, which is all taken into account when assessing compliance.

Escalation and enforcement. The aim of the Chief Inspector is to regulate for improvement. But where a registered provider fails to comply with a requirement of the Act, the regulations or standards and does not demonstrate sustained improvements, we will take action based on the seriousness of the breach and the risk posed to the residents or children.

A proportionate approach is taken when providers do not comply with their regulatory requirements. When other means of ensuring sustained compliance with the regulations and standards have failed, such as a cautionary or warning meeting with providers or a warning letter, enforcement action may be taken.

Legal ready reckoner

electronic Irish Statute Book (eISB)

This website features all Irish legislation and changes to primary legislation (acts) and secondary legislation (regulations). Visit <u>www.irishstatutebook.ie</u>.

Revised acts

At the time of writing, over 500 revised acts (administrative consolidations of acts) are available on this Law Reform Commission website. Search online for 'Revised Acts' or go to: <u>http://revisedacts.lawreform.ie/revacts/intro</u>.

Classified list of acts in force in Ireland

This list, published by the Law Reform Commission, is a complete register of acts that remain in force in Ireland. Search online for 'classified list of legislation' or go to:

https://www.lawreform.ie/classification-list-of-legislation-in-ireland.361.html.

designated centres in Ireland [*]			
People with disabilities	Older people	Young people in special care	
Legislation			
Health Act 2007 (as amended)^	Health Act 2007 (as amended) [^]	Health Act 2007 (as amended) [^]	
Regulations	1		
Health Act 2007 (Care and Support of Residents in Designated Centres for Persons (Children and Adults) with Disabilities) Regulations 2013.	Health Act 2007 (Care and Welfare of Residents in Designated Centres for Older People) Regulations 2013 (as amended).	Health Act 2007 (Care and Welfare of Children in Special Care Units) Regulations 2017 (as amended).	
Health Act 2007 (Registration of Designated Centres for Persons (Children and Adults) with disabilities) Regulations 2013 (as amended)	Health Act 2007 (Registration of Designated Centres for Older People) Regulations 2015 (as amended).	Health Act 2007 (Registration of Designated Centres) (Special Care Units) Regulations 2017.	
National Standards			
National Standards for Residential Services for Children and Adults with Disabilities (2013). https://www.hiqa.ie/reports-and- publications/standard/national- standards-residential-services- children-and-adults	National Standards for Residential Care Settings for Older People in Ireland (2016). https://www.hiqa.ie/reports-and- publications/standard/national- standards-residential-care- settings-older-people-ireland	National Standards for Special Care Units: November 2014 (published 2015). https://www.hiqa.ie/reports- and- publications/standard/national- standards-special-care-units	
Applicable to all providers of designated centres			
National Standards for infection prevention and control in community services (2018) https://www.hiqa.ie/sites/default/files/2018-09/National-Standards-for-IPC-in-Community-			

Table 1. Online sources for the regulatory framework for regulatingdesignated centres in Ireland*

services.pdf. National Standards for Adult Safeguarding (2019)

https://www.hiqa.ie/reports-and-publications/standard/national-standards-adult-safeguarding

 ⁺ Please note that online addresses may change over time. Legislation, regulations and national standards may also change. Providers are also obliged to comply with other legislation relevant to them.
 ^ Number 23 of 2007: Health Act 2007 Revised: Updated to 31 March 2025. Available online from: https://revisedacts.lawreform.ie/eli/2007/act/23/revised/en/pdf?annotations=true.

What does the regulatory framework mean for you?

We undertake all our work, including regulatory activities, in a fair, efficient, transparent, proportionate and consistent manner. We aim to achieve this by ensuring all monitoring and assessment activities are developed and implemented in a clear and consistent way.

The Chief Inspector's statutory mandate, as outlined in this handbook, is underpinned by use of a standardised and consistent approach to our inspection and monitoring activities. We call this the Authority Monitoring Approach (AMA). Consistency means applying this approach and using the regulations, standards and guidance when carrying out the monitoring or inspection of a centre. It does not mean that the judgment made on regulations will be the same in every centre. Every centre is different, residents' needs may change over time and staffing changes. Judgments are made based on the observation, communication and review of documentation.

This approach includes:

(1) Receipt of information

As part of our regulatory activities, we continually receive information. We classify the information we receive in two ways:

a. solicited information, which is information we formally request such as:

- statutory notifications
- registration applications
- self-assessment questionnaires
- data sets
- b. unsolicited information, which is information we receive but have not asked for, such as information that may be of concern from people who use services.

(2) Information review

We review all information we receive and consider its impact on people who use the service.

(3) Take regulatory action

Decisions are made based on all information received as to what regulatory action (if any) is required in response to that information. There are a range of regulatory actions we can take to assure ourselves that people are receiving a service that meets regulatory requirements and is safe. Regulatory actions can include:

- a request for further information to provide assurance
- inspection
- recommendations or decisions regarding the registration of a designated centre
- increased monitoring and regulatory activities up to and including escalation and, when applicable, enforcement.

(4) Reporting

All regulatory activities are reported on. This can include internal or external reports which may or may not be published.

Legislation

Providers must be thoroughly familiar with the Health Act 2007 (as amended) — the primary legislation governing the regulation of designated centres. Please note that the Law Reform Commission has published a revised Act, which is an administrative consolidation of the Act. See: https://revisedacts.lawreform.ie/eli/2007/a ct/23/revised/en/pdf?annotations=true.

The regulations

The Act allows for relevant regulations to be made governing the (a) registration and (b) monitoring of residential designated centres. Providers — and for some duties, persons in charge — have to comply with the regulations by law.

Every designated centre must have a person in charge, in line with the regulations, who is a person participating in management under the Act. Registered providers and managers[≠] must be aware of their responsibilities under the regulations as they may be prosecuted for failing to comply with these obligations.

We publish inspection reports on our website. In our inspection reports and in our approach to monitoring, we have aligned the regulations against the most relevant national standard to support compliance by providers.

National standards

Routinely checking designated centres against the regulations helps to assure the public and the Chief Inspector that people living in these centres are receiving a safe service.

Yet, meeting your legal requirements is only one aspect of providing highquality care. Providers should constantly strive for ongoing improvements in the quality of their services by using the relevant national standards to promote ongoing improvements which enhance the quality of life of the people living in these services.

Within each national standards document, the 'standard statements' are the outcomes expected for residents, and the listed 'features' beneath these statements give

and other persons participating in the management of the designated centre.

^{*} Managers include persons in charge (and deputy persons in charge in nursing homes)

examples of how the standard may be met. However, providers are free to achieve the national standards in other ways.

You should always ensure you are consulting the most up-to-date versions of the standards. The current standards and associated online links are illustrated on the following page.

Registration under the Act

The registration process regulates who can operate a designated centre in Ireland. You apply for registration under section 48 of the Act. Under section 46(1) of the Act, you cannot operate a designated centre unless the centre is registered under the Act and you are its registered provider.

Compliance under the Act

We assess registered providers to check their performance against the Act and to assess compliance with regulations and national standards. We gather information and evidence and review and risk-rate this information in order to inform our regulatory judgments. While our approach will be consistent, judgments may vary as they are informed by the information and evidence collected.

Enforcement under the Act

Our primary concern is to protect the safety and wellbeing of residents living in designated centres or children temporarily living in special care. We only take enforcement action whenever other means of bringing about the desired improvements in a designated centre have failed or where there is a serious risk to the health and welfare of residents or children.

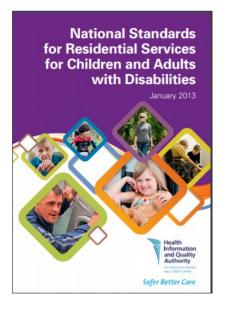
Under the Act, enforcement action may be taken through a:

- civil action (refusing registration, imposing new conditions, varying or removing conditions, or cancelling registration)
- criminal prosecution.

Guidance for providers

We have published a large number of guidance documents to assist providers to comply with the Act, regulations and national standards. A summary of these documents is set out in Appendix 1. Please note that such guidance does not alter the meaning of the Act or the regulations and is intended to be of assistance only.

Are you using the most up-to-date national standards?



National Standards for Residential Services for Children and Adults with Disabilities (published in 2013) https://www.hiqa.ie/reports-and-

publications/standard/nationalstandards-residential-serviceschildren-and-adults

National Standards for Residential Care Settings for Older People in Ireland (published in 2016) https://www.hiqa.ie/reports-andpublications/standard/nationalstandards-residential-care-settingsolder-people-ireland





National Standards for Special Care Units: November 2014 (published in 2015) https://www.hiqa.ie/reports-andpublications/standard/nationalstandards-special-care-units

Conclusion

Providers of designated centres, managers and third-party contractors working on behalf of providers should ensure they are thoroughly familiar with the legal framework in which designated centres operate. They must also ensure they are consulting the most up-to-date version of the Act, regulations and national standards.

Chapter 2. The registration cycle



Introduction to registration

If you run a designated centre, such as a nursing home, residential centre for children or adults with disabilities or a special care unit, you must register that centre with the Chief Inspector and be its registered provider to operate it; not to do so is an offence under the Act.

Registration is granted for three years. In essence, the Chief Inspector decides who is fit and legally permitted to provide care to vulnerable people living in designated centres. The Act requires a registered provider to apply to renew the registration of a designated centre six months in advance of it expiring.

The three-year registration cycle safeguards people using services by

determining which centres can be registered and who can run them. Registration is not a separate 'event' in the regulatory cycle, but is an ongoing process that enables us to scrutinise information about:

- the centre itself
- the intended registered provider and person or people involved in managing the centre (or those already involved and who are renewing their registration)
- evidence and knowledge collected through ongoing monitoring throughout the cycle of registration.

To decide on an application to register or renew registration, we will examine the information and, if required,

inspect the designated centre or proposed designated centre. We may conduct formal interviews to assess the fitness of the provider and people managing the centre, depending on the type of application being made.

If a centre becomes registered for the first time or where an application to vary a condition of registration is being granted for an extension (an increase in the size of the footprint of an existing designated centre), we will follow up within six months of registration being granted with a further inspection.

If registration is granted for a new provider of an existing centre, we will inspect the centre after the registration is granted. Centres may be inspected at any time after being registered depending on risk.

If the provider of the centre will comply or is in compliance with the relevant regulations and standards and if the provider and all persons participating in the management of the centre are fit, then the Chief Inspector can register the centre. Registration assures the public that the provider and others involved in the management of the centre are fit to provide the service at that time.

The main provisions in the Act governing applications to register or renew registration are section 48 (applications by providers or intended providers to register or renew registration) and section 50 (our decision to register, refuse to register, or grant with conditions).

We will now look at your route to registration and the key principles underlining your application for renewal of your registration or applying for the first time.

The four key tests

There are four tests that providers or intending providers must satisfy before registration can be granted:

1. Is the centre in compliance with the regulations (or for a first registration, will it comply)?

2. Is the centre in compliance with the national standards (or for a first registration, will it comply)?

3. Are the provider and people participating in management (including the person in charge) fit persons?

4. Is the centre compliant with any other legislation deemed by the Chief Inspector to be relevant?

When does the registration process begin?

The registration process begins when an intending provider makes an application to register or to take over an existing designated centre or where an existing provider applies to renew registration with the Chief Inspector.

Applications can fall into the following categories:

- timely renewals
- new intended provider
- new centre
- late renewals.

Timely renewals

Registered providers who apply to renew their registration at least six months in advance of the expiry of their current registration are regarded as **renewal applications**.

Increased or decreased footprint of existing centre

You should apply to vary a condition of registration under section 52 of the Act whenever any structural development increases or decreases the size and scale of an existing registered centre or the size of the footprint of an already registered designated centre.

This application to vary a condition of registration should be made to the Chief Inspector when structural work has been completed in the designated centre and it is ready for assessment. We have published guidance on designated centres for older people and people with disabilities being ready for the site visit as part of their application to register. Click on the links below or search online:

- <u>Guidance and checklist: Designated</u>
 <u>Centres for people with disabilities</u>
- <u>Guidance and checklist: Designated</u> <u>Centres for Older People</u>.

New provider

A **new provider** is deemed to be a new application where the new provider wishes to take over the running of an existing registered designated centre. Written permission from the current registered provider must be included in the application.

New centre

A **new centre** is deemed to be a new application. This is when an intended provider is seeking to register a designated centre for the first time.

Late renewals

Providers are responsible for applying to renew the registration of a designated centre six months in advance of when the centre's current registration expires. Where providers do so, the Act provides safeguards should the Chief Inspector have not

yet reached a decision on the application before the current registration expires.

This safeguard allows for current registration to remain in effect until the decision is made. However, providers who fail to apply in time do not have this safeguard under the Act and risk being unregistered and committing an offence if the decision cannot be made before the current registration expires.

Any provider not complying with the six-month advance time frame requirement will be subject to escalated regulatory action.

Extensions to existing designated centres

For new extensions that increase the footprint (as submitted as part of the original registration process) of an already registered designated centre, providers can apply to vary the current registration of the centre.

New buildings and extensions should be ready for assessment when you apply to register the centre or vary the registration of the centre. There are two options available in such circumstances:

Option 1. An extension can be registered as its own separate designated centre, where this

building has all the necessary ancillary services and meets the definition of a designated centre. It would have a separate identity number, which is referred to as an OSV number.

Option 2. You can apply to add a new extension to the existing centre's registration through an application to vary. This centre would retain its existing OSV number. The assessment of the application would consider the existing centre's current compliance history and fitness.

Reducing the size of your designated centre

If you wish to reduce the footprint of a designated centre, you can apply to do this by applying to vary the registration of the centre.

New applications to register

Intending providers of new centres or new providers of an existing designated centre can make an application for first-time registration to us at any time — **provided they are ready for assessment** (see also page 15 of this chapter). Not being ready for assessment may lead to refusal of the registration application.

We will consider if the evidence shows that the provider and person in charge 'will comply' with the regulations and standards or any other legislation which appears to the Chief Inspector to be relevant. Once a valid application is received, the registration pathway follows a similar course to applications to renew registration.

Operation of unregistered centres

Providers must not operate a designated centre without the centre being registered. Carrying on the business of a designated centre which is not registered is a criminal offence. If the Chief Inspector has reasonable grounds to believe that a person is carrying on the business of a designated centre that is not registered, inspectors may enter and inspect such premises at any time. The Chief Inspector may also apply to the district court for a warrant authorising such entry.

Renewals of registration

A complete application to renew registration must be made **at least six months before your current registration is due to expire**. A date which is six months before the date of expiry of a designated centre's registration is referred to as the 'application due date'.

Existing providers should pre-plan their applications to renew based on the application due date (rather than the registration expiry date). We will issue the application form and associated information to providers two months in advance of the application due date.

Providers who are renewing registration are advised to have all the required documentation up to date and to hand, while the signatory to the application or authorised signatory should be available to sign the application to the Chief Inspector.

For renewals, we consider if the evidence shows that the provider and each person who will participate in the management of the designated centre are `in compliance'.

Use the correct application form

Please note that different application forms are used for registration and renewal of registration and for different types of provider entities, such as:

Companies

Continued on next page

- partnerships
- individuals (sole traders)
- unincorporated bodies
- statutory bodies.

To access the correct forms, please visit the Registration Information section of our website. Go to:

Disabilities

https://www.hiqa.ie/guidanceproviders/disabilityservices/registration-information

Older people

https://www.hiqa.ie/guidanceproviders/older-peoplesservices/registration-information

Special care

https://www.hiqa.ie/guidanceproviders/childrens-services/specialcare-units/registration-information

There is only one application form for an application to vary or remove a condition of registration.



Key personnel in the designated centre

In your application to register or renew your registration of a centre, you must identify at the time of application the key personnel who will be involved in running and managing the centre. These individuals (or entities in the case of the provider) will play a pivotal role in ensuring the centre complies with regulations and national standards. They are the:

- provider
- persons participating in management, including a person in charge
- registered provider's representative (if nominated).

The provider

If the application is successful, a 'registered provider' is the person whose name is entered onto the official public register of designated centres as the 'person' running the designated centre. The provider is the legal entity which applies to register or to renew registration. A provider can be:

- an individual, such as a sole trader
- a company
- a partnership
- an unincorporated body
- a statutory body.

For definitions of these legal entities, please see our *Guidance on the assessment of fitness for designated centres*.

The registered provider is 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. The provider's role is to ensure that the centre is suitable for its stated purpose (and is operated in line with the statement of purpose) and complies with the regulations and national standards.

Person participating in management (PPIM)

The regulations state that any application for registration of a designated centre must include the name of each person involved in managing the designated centre. The person participating in management (referred to in this handbook as PPIM) must be actively engaged in and responsible for running the centre. For further information, see the section on **Additional persons participating in the management of the centre** on the following pages.

The person in charge

The person in charge is critical to the success of a designated centre. Every designated centre must have a person in charge at all times, in line with the regulations. The person in charge is a person participating in management (PPIM) under the Act.

The person named as the person in charge in section 1.5 of the registration application form will be the person whose name is entered on the register and certificate of registration as being in charge of, or managing, the designated centre.

It is the provider's responsibility to appoint a person in charge that meets the requirements of the regulations. The person in charge should have sufficient training and experience to ensure the delivery of a good quality and consistent service to the residents or children for whom he or she is responsible, and have a good knowledge of the regulations and national standards.

The person in charge is responsible for the day-to-day operation of the designated centre. However, the registered provider is legally responsible for the centre and as such should support the person in charge in carrying out his or her functions.

From 31 March 2025, registered providers of designated centres for older people must also ensure that deputising arrangements are in place for the person in charge and other key management roles. From that date, the person deputising for the person in charge must be suitably qualified and experienced in line with the requirements of the regulations.

The role of the person in charge

The role, duties and requirements for persons in charge are set out in the various regulations. The person in charge is responsible for the quality of care being delivered, either social and or clinical, and must have delegated authority, accountability and responsibility for providing the service.

For nursing homes, registered providers must have a suitably qualified and experienced person who is able to deputise for the person in charge in the event that the current

person in charge is away from the designated centre for more than 42 calendar days. For all other designated centres, registered providers must appoint a person in charge in the event that the current person in charge is away from the designated centre for more than 28 calendar days.

Section 46(2) of the Act prohibits persons in charge from managing a designated centre unless it is registered under the Act. For a full description of the post of person in charge, as outlined in the Act, please see:

- Regulation 14 of the Health Act 2007 (Care and Welfare of Residents in designated centres for older persons) Regulations 2013 (as amended).
- Regulation 14(1) of the Health Act 2007 Care and Support of Residents in Designated Centres for Persons (Children and Adults) with disabilities) Regulations 2013.
- Regulation 13(1) of the Health Act 2007 (Care and Welfare of Children in **Special Care Units**) Regulations 2017 (as amended).

Do persons in charge need a specific management qualification?

Different legal requirements under the regulations apply to the post of person in charge of designated centres for older people (including person deputising for the person in charge in these centres), designated centres for disabilities and special care units. It is the registered provider's responsibility to ensure that these requirements are met.

From 1 November 2016, newly appointed persons in charge of designated centres for **people with disabilities** need a minimum of three years' experience managing or supervising in the area of health or social care; and a related management qualification `at the appropriate level'. (See Appendix 5 of this handbook for further information.)

In most cases, the person in charge of a designated centre **for older people** must be a registered nurse with relevant experience or, in certain circumstances, can be a registered doctor.

Where the person in charge must be a registered nurse, that nurse must have at least three years' experience of nursing older persons within the previous six years. They must also have 3 years experience in a nurse management role in the health and socials care area.

In certain circumstances where no resident in the designated centre has been assessed as requiring full-time nursing care, the requirement for the person in charge to be a registered nurse does not apply.

From 31 March 2025, any registered nurse employed as a person in charge in a designated centre for older people also needs to have, on or before 31 March 2028:

 a post-registration management or leadership certificate in health or a related field at a minimum of Level 8 qualification or a nursing postgraduate Level 9 qualification which includes management or leadership.[¥]

A person in charge of a **special care unit** must have 'the qualifications, skills and experience necessary to manage' the unit. After 1 January 2021, they must also have a minimum of three years' experience managing or supervising in health or social care and a related management qualification.

Providers must ensure these requirements for the person in charge are met, and they are required to demonstrate to us how they satisfy themselves of this.

Additional persons participating in the management of the designated centre

An additional person participating in the management (PPIM) of the designated centre is not always required. The provider should consider the type and size of the centre and whether or not it has other designated centres. If appointed, however, he or she[^] must be in a senior management role and be a senior decision-maker who is authorised for and on behalf of the intended or registered provider to make **senior operational decisions** about the running of the entire centre.

They must be senior to the person in charge and provide leadership and support to persons in charge in order to ensure centres comply with the regulations and national standards. The person or people named in the registration application, or in a later notification to us while registered, as the PPIM[#] must ensure a safe, quality service is delivered on behalf of the registered provider entity.

When we believe the nominated PPIM named in the application form, or in a later notification, does not meet the necessary criteria for this role, we will inform the provider about this decision.

The registered provider's representative

Every provider entity (with the exception of a sole trader) can identify who its registered provider's representative will be. The registered provider's representative is not the registered provider but rather is the

 $^{^{\}rm Y}$ There are some exceptions to this requirement set out in the regulations. Providers should ensure they are familiar with these.

[^] Please refer to the guidance on assessing fitness published on HIQA's website.

[#] Section 50 of the Health Act 2007 (as amended) requires that persons participating in the management of the designated centre must be a 'fit person'.

person or people put forward by the registered provider to represent it where the registered provider is a partnership, company, unincorporated body or statutory body.

Where a provider chooses to nominate a registered provider's representative, they must inform us in writing of the name of their registered provider's representative. Nominating a registered provider's representative helps to ensure that we can effectively communicate with the provider if there are concerns about the governance in place to ensure the sustainable safety and welfare of residents.

Where a registered provider's representative is nominated, this person **does not** replace the legal responsibilities under the Act of the registered provider. However, they will engage with us in response to any **escalated or significant concerns or risks** to residents or children living in the designated centre that we may identify.

This person should have the knowledge, ability, autonomy and authority to answer for and act on behalf of the provider in relation to such matters. The person will be asked to explain how the provider assures itself that the service is complying with the Act, regulations and national standards.

If nominating a registered provider's representative, providers should identify the person in their application form to register or renew registration. Alternatively, when there is no live application, such as when there is a change of registered provider's representative, you can email the person's details to <u>registration@hiqa.ie</u>.

Table 2 outlines examples of who we will accept as a registered provider's representative. Conversely, for dayto-day management and routine monitoring of the centre, we will engage with the person in charge and or other people participating in the management of the centre.

Should you have any queries on the registered provider's representative, please contact the regional manager for your designated centre. People intending to become registered provider's representatives and who have questions can contact registration@hiqa.ie.

Table 2. Examples of who can be a registered provider's representative

Type of provider entity	Registered provider's representative	
Company	A director of the company	
Partnership	A partner of the partnership	
Unincorporated body	A member of the committee of	
	management or other controlling	
	authority of the unincorporated body	
Statutory body	Person with delegated authority as	
	provided for by the relevant act for the	
	statutory body	

Key registration documentation Your statement of purpose

The statement of purpose is an important document which is required in order to register or renew the registration of a designated centre. The regulations require providers to compile a written statement of purpose for designated centres and to submit it as part of the registration process.

A registered provider must at all times operate strictly in line with the statement of purpose.

The Chief Inspector considers the statement of purpose to be one of the most important documents that a registered provider is required to have in relation to its services. The document describes the purpose and function of a designated centre and underpins the delivery of safe, highquality care in the designated centre. When applying to renew registration or register, you must submit a copy of your statement of purpose. This document should clearly state the **name** of the designated centre or proposed centre and the **date** of the document.

We have published guidance on the statement of purpose and supporting templates to assist registered or intending providers in updating or devising their service's statement of purpose.

The following statement of purpose guidance documents are available to providers:

 Guidance on the Statement of Purpose for designated centres for children and adults with disabilities (DCD): <u>https://www.hiqa.ie/reports-and-</u> publications/guide/guidance-statement-purpose-designated-centres-children-andadults



 Guidance on the Statement of Purpose for designated centres for older people (DCOP): <u>https://www.hiqa.ie/reports-and-publications/guide/guidance-statement-purpose-designated-centres-older-people-dcop</u>



 Guidance on the Statement of Purpose for designated centres — Special Care Unit: <u>https://www.hiqa.ie/reports-and-publications/guide/guidance-</u> <u>statement-purpose-special-care-unit-scu</u>



You must make a complete and valid application

An application to register or renew registration is when the intended or registered provider submits a **complete** application[¥] and pays the prescribed application fee. An application is not deemed to have been made unless it is complete.

In addition to the application, the provider must also submit a number of prescribed documents which are required by the registration regulations (see the application checklist on the following pages). The following four items are required for a complete application:

- 1. Completed application form.
- 2. Up-to-date floor plans of the designated centre.
- 3. Statement of purpose.
- Registration or renewal fee (€500).

Applications will be returned to applicants who do not meet these requirements and the application will be deemed not to have been made. In such cases, any application fees paid can be refunded if requested by the provider or applicant.

Only where an application is complete can we begin to deliberate on it.

Please note that each designated centre must have its own registration. Therefore, a separate application must be made for each centre.

Offence

You should be aware that it is a criminal offence for a person making an application for registration or renewal of registration to knowingly make a material statement which is false or misleading.

Your notes

In addition, certain other documents are required, called 'prescribed information'.

⁴ The application contains four parts: the completed application form, the required fee, the floor plans, and the statement of purpose.



Are you ready for assessment?

When providers apply to register a new centre or to take over an existing centre, they must ensure that they and the centre are ready at the time of the application for an assessment by the Chief Inspector. This means the centre is ready for operation and that providers:

- are clear about the purpose of the centre and that this is captured clearly in the statement of purpose
- are familiar with and will comply with the Act, regulations and national standards
- are familiar with this handbook and other relevant guidance
- are ready for an on-site^{*} or desktop inspection, including providers ensuring that:
 - the designated centre site is ready for a site assessment

- key personnel are available for assessment of their fitness
- representatives and or staff speak with inspectors when they are on site or when they contact them by email or telephone
- all the required records are available for the inspection process
- requests for information are responded to in a timely manner and deal with all matters as outlined in the requests
- will be able to comply with any proposed operating conditions of registration
- have completed the selfassessment checklist contained in our site-visit guidance.[«]

^{*} If you intend to take over the running of a currently registered centre, we will not carry out a site visit as part of your application. However, other criteria still apply. Please see our site-visit guidance for further details.

 $^{^{\}rm *}$ Please note that the checklist is for your own use and that you do not have to complete and submit it to the Chief Inspector.

Site-visit guidance and self-assessment

We have published new guidance on being ready for the site visit as part of your application, which is available on the provider guidance pages of www.hiqa.ie, as follows:

- <u>Are you ready for assessment of</u> <u>the application to register:-</u> <u>Guidance and checklist: Designated</u> <u>Centres for people with disabilities</u>
- <u>Are you ready for assessment of</u> <u>the application to register:-</u> <u>Guidance and checklist: Designated</u> <u>Centres for Older People.</u>

Checklist for making valid applications to register or renew

Four key items⁺ must be included in your application to make it a complete and valid application. These are:

- 1. Completed application form.
- 2. Floor plans of the designated centre.
- 3. Statement of purpose.
- Registration or renewal fee (€500).

In addition to these four key items,

certain other information and documents, called 'prescribed information', that are required by the regulations must accompany your application (see the section on the following pages).

Applications will be returned to applicants who do not meet these requirements, while any application fees paid can be refunded if requested by the provider or applicant.

This prescribed information should be submitted at the same time as the application or shortly thereafter (see the section on the following pages). Failure to submit this information or submit it on time will inform our assessment of compliance with regulations.

Only where an application is complete can we begin to deliberate on it.

You must also be clear about who will sign the application to register and other documents relating to the registration of the centre. If you have completed the application form electronically, please print it out and sign the declaration in section 1.8 (renewals) or 1.9 (applications to register) of the form by hand, as we will only accept original signatures. Finally, please send it by post to our Registration Office.

⁺ Section 48, Health Act 2007 (as amended).

The **four key items** are firstly considered here.

1. The completed application form

Please complete all sections of the application form in full in order to make the application form valid. In addition, the application must be signed, and it must be signed by an individual on behalf of the provider entity. Please note, however, that the person who signs the application does not have to be same person who signs other documents. Table 3 indicates who will be acceptable to the Chief Inspector to sign registration applications on behalf of the provider.

Provider applicant	Who will be acceptable to the Chief Inspector to sign the application on behalf of the provider?
Sole trader	The individual person (the sole trader — the person applying to register or renew registration)
Company	A director of the company OR A named individual authorised by the company in line with the constitutional documentation of the company and or the Companies Act 2014 to sign on behalf of the company and notified to the Chief Inspector by the provider
Partnership	A partner of the partnership OR A named individual authorised by the partnership in line with the partnership deed and or the Partnership Act 1890 to sign on behalf of the partnership and notified to the Chief Inspector by the provider
Unincorporated body	A member of the committee of management or other controlling authority of the unincorporated body OR A named individual authorised by the unincorporated body in line with the terms of the rules of establishment or constitution or deed or other documentation or governing principles of the unincorporated body to sign on behalf of the unincorporated body and notified to the Chief Inspector by the provider
Statutory body	Person responsible on behalf of the statutory body for the application [±]

Table 3. Peo	ple who can	sian rea	distration	applications
		- Sig ii i C	gisciación	applications

[±] Health Act 2007 (Registration of designated centres for older people) Regulations 2015 (as amended); Health Act 2007 (Registration of designated centres for persons (children and adults) with disabilities) Regulations 2013 (as amended); Health Act 2007 (Registration of Designated centres) (Special Care Units) Regulations 2017.

2. Floor plans of the designated centre or proposed designated centre

You must include accurate and dated floor plans for the designated centre as it exists or proposed designated centre with the application. When registered, the centre is registered in line with the footprint of the building as outlined in the floor plans submitted. Floor plans must meet the following criteria:

- 1. All areas on the floor plan must be clearly labelled (text must be clear).
- 2. All rooms must have dimensions within that room.
- 3. A clear scale; for example: 1:100, 1:250 and so on.
- 4. Have all parts of the designated centre outlined in red.
- 5. Have all overnight accommodation (bedrooms) outlined in blue, as illustrated on the following page.
- 6. PDF format which permits zooming into detail without losing quality (for soft copy).
- 7. Permits printing in larger paper size without losing quality; for example, page size 'A0'.
- 8. Each page of a floor plan needs to state the OSV and building or unit name or floor number (as appropriate).

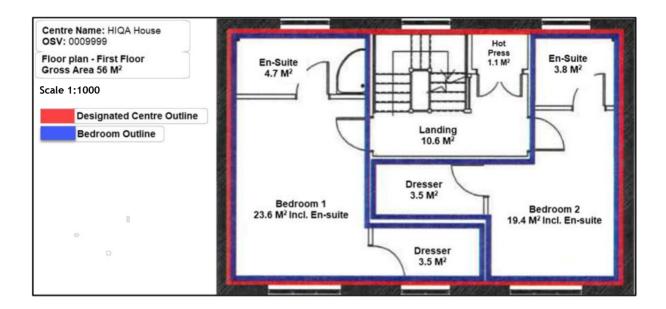
Additional criteria required for designated centres for older people (DCOP) only:

9. All bedrooms must include a room number.

These floor plans do not necessarily have to be drawn up by an architect or other qualified person, but they must be accurate, clear, legible and to scale. All parts of the centre must be outlined in red, and overnight accommodation (bedrooms) must be outlined distinctively using blue lines. Please see example on the following page.[‡]

If submitting floor plans in soft copy, please email them to registration@hiqa.ie or if submitting them in hard copy through the post, please ensure that the centre's name and OSV number (where an OSV has been issued) are on the floor plans. Having them clearly labelled this way will help us to easily identify which centre and provider or intending provider that they relate to. Please note, however, that floor plans which do not state the name of the centre and its OSV (where issued) on either the soft copy or the hard copy will be returned to the applicant and will delay the application.

⁺ *Registration handbook: Guidance on making applications, providing prescribed information and submitting registration notifications,* available on <u>www.hiqa.ie</u>.



3. 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.

It must include all the relevant details as required by the regulations, which are set out in the schedules of the regulations for designated centres.

4. Registration fee

The application must include the registration application fee,[†] which is \in 500,^ as set out in the registration regulations. Payment will only be accepted by EFT (electronic funds transfer) payment; for example, using either online banking or through a bank. Please do not send us a cheque as it will be returned to you. Our Registration Team will accept a copy of the EFT payment confirmation as proof of payment for your application.

Our banking details for EFT are provided below. Guidance on how to pay the application fee is available on HIQA's website^o or by searching online for our <u>*Registration handbook*</u>. After paying your application fee, please forward a copy of your bank remittance (copy of proof of payment) to AR@hiqa.ie. In your email to us, please include the OSV number and centre name so that we can assign your payment on our records.

Centre ID (OSV) [¥]	This unique number has been issued to you by HIQA	
Centre name [#]	Name of the designated centre	
Account name	Health Information and Quality Authority	
Bank name and address	Danske Bank, 3 Harbourmaster Place, IFSC, Dublin 1, D01 K8F1	
Bank sort code	95-15-99	
Account number	80006688	
IBAN	IE94DABA95159980006688	
Swift/BIC	DABAIE2D	

Banking details for payment of the registration fee

⁺ Section 48(2)(c) Health Act 2007 (as amended).

[^] Regulation 4(3) of the registration regulations for older people; Regulation 5(4) of the registration regulations for persons with disabilities; Regulation 4(4) of the special care unit registration regulations.

[•] Health Information and Quality Authority (HIQA). *Registration handbook: Guidance on making applications, providing prescribed information and submitting registration notifications.*

⁴ Centre ID is the designated centre's identification reference number issued to you by the Registration Office. The format of the centre ID is 'OSV-0009999'. Please reference your centre ID on all documentation submitted to us. A new designated centre that is not on the register of designated centres will not yet have a centre ID. In this instance, please leave the field blank on your application form.

[#] This is the name by which your designated centre will be known and registered with the Chief Inspector. Please use the same centre name consistently across all documentation. In the case of a new designated centre that is not on the register of designated centres, please insert the proposed name of the designated centre here.

Contact person

The registered provider or intended registered provider may nominate a 'contact person' during the registration application process. On the application form, you can state the name and valid business contact details of the 'contact person'. We will only use these details to deal with administrative matters relating to your registration pack.

However, if the person named in this section of the application form fits the description of a **person participating in management (PPIM)**, you should also complete the PPIM section of the form for this person.

Prescribed information which you must include in your application

Providers and or applicants must also at the same time submit certain information and documents about themselves, the person in charge, other people involved in managing the centre, and — in the case of residential centres for people with disabilities and special care units for the designated centre itself.[±]

This is called *prescribed information*,[¥] and includes, for example, proof of identity, a Garda Síochána (Ireland's National Police and Security Service) vetting report and details of previous experience operating a designated centre.

Why must I submit prescribed information?

This is a legal requirement which is set out in the following registration regulations:

- ➤ 4(2) older people
- ➤ 5(3) persons with disabilities
- \rightarrow 4(2) special care units.

Is there any other time I should submit prescribed information?

Yes, where there is a change to the person in charge or other person participating in management of a designated centre or where there are changes to the information supplied for registration purposes, such as a change of director. In such circumstances, you must send us full and satisfactory information as outlined in the registration regulations.

[±] For further information, see our *Registration handbook*.

^{*} Section 48(2)(a) Health Act 2007 (as amended).

What happens if information is not submitted?

Failure to submit this information will be reviewed and assessed as part of the assessment of your compliance with regulations. The details of prescribed information are set out in the registration regulations and relate to:

- > the applicant or the provider
- the person in charge
- > each other person participating in

management

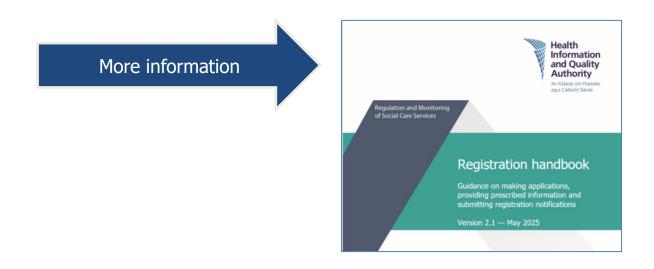
the centre itself in the case of special care units and residential centres for people with disabilities.

This information will be assessed in terms of compliance with the relevant registration regulations. In order to assist providers, detailed guidance on submitting prescribed information is available on HIQA's website and referred to below.

Prescribed information for your application to register

The requirement for prescribed information as part of your application to register is not identical for designated centres for older persons, people with disabilities and special care units. It is your responsibility to ensure you submit the correct documentation.

For more guidance on prescribed information and what you should submit, please read Chapter 2 of our *<u>Registration handbook</u>*. This document is available on our website.



Signing the application to register

Legally, you must apply to the Chief Inspector to register or renew the registration of a designated centre. Any person[≠] seeking to register or renew registration must submit an application in the format set out by the Chief Inspector.

Who is the applicant?

The applicant is the person applying to register or to renew registration whose name, if the application is successful, will be entered onto **the official public register of designated centres** as the person operating the designated centre. This person will be the 'registered provider'.

Who can sign the application form?

If you have filled in the application form electronically, please print it out and sign the declaration in section 1.8 (renewals) or 1.9 (applications to register) of the form by hand as we will only accept original signatures. This should be posted to our Registration Office. The application must be signed by an individual[‡] who is an inherent part of the provider entity, such as:

- the individual person in the case of a sole trader
- a director of the company
- a partner of the partnership
- a member of the committee of management or other controlling authority of an unincorporated body
- the person responsible for the application on behalf of a statutory body'⁴ in the case of a statutory body.

Authorised signatories

Sole traders must sign all relevant documents themselves. If the provider is a company or a partnership, any director or partner may sign the application. These providers, as well as any unincorporated body, may appoint a person or people as an authorised signatory or authorised signatories to sign relevant documents[±] on their behalf.

^{* &#}x27;Person' can mean a legal entity, such as a limited liability company or an unincorporated body of persons, as well as an individual.

⁺ It is the responsibility of such an individual to ensure that they have been duly authorised by the provider to sign an application.

[¥] See the 2015 registration regulations for older people; the 2013 registration regulations for

children and adults with disabilities; and the 2017 registration regulations for children in special care units.

[±] Relevant documents include application forms to register or renew registration, Registration Notification Forms NF30–NF37 and Prescribed Information Forms that require a signature.

Once validly appointed, an authorised signatory or signatories will be authorised to sign all relevant forms on behalf of the provider until the provider revokes the authorisation and such revocation is notified to the Chief Inspector in writing.

Where an authorised signatory has been appointed, an original hard copy authorisation letter signed by the provider must be sent to us by post in advance of the authorised signatory exercising signing authority during the application process. For example, before an application to register or renew registration is made by the provider.

This letter should confirm the person has been validly authorised to sign documents on behalf of the provider. This authorisation must take the form of a resolution passed following proper procedure by one of the following:

- board of directors of the company named as being the provider or
- partners of the partnership named as being the provider or
- members of the committee of management or other controlling authority of the unincorporated body named as being the provider.

Letter of authorisation for authorised signatories

The letter notifying the Chief Inspector of the appointment of an authorised signatory must include the following information:

- **1.** Confirmation that such a resolution has been passed by those persons or directors named as the provider.
- Confirmation that the provider validly authorised the appointment in line with all applicable laws and according to the rules of establishment or any of its other constitutional documents.
- Confirmation that the authorised signatory or signatories has been appointed with the knowledge and consent of all relevant parties, including the authorised signatory or signatories.
- 4. Confirmation that there are no limits or restrictions of any kind on the provider that would prevent the appointment of an authorised signatory or signatories.
- An undertaking by the provider to inform the Chief Inspector immediately and in writing of any change to the authorised signatory or signatories.

Template letter available to notify us about authorised signatories

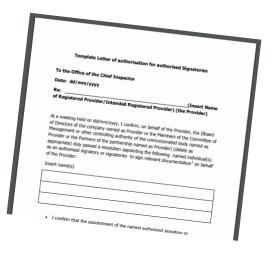
We have created a template letter that providers can use, if they so wish, to notify us about authorisation of authorised signatories. This is available on <u>www.hiqa.ie</u> or can be accessed on the following link:

https://www.hiqa.ie/sites/default/files/201 8-08/Template-Letter-of-authorisation-forauthorised-Signatories.pdf.

Who can sign the letter of authorisation?

The letter notifying the Chief Inspector of the appointment of an authorised signatory may be signed by an individual who is an inherent part of the provider entity, such as:

- a director of the company
- a partner of the partnership
- a member of the committee of management or other controlling authority of an unincorporated body.



Your notes



When we receive your application

When we receive your application, we first carry out an **administrative check** to ensure the four key items have been included in your application (that is to say, the completed application form, accurate floor plans of the centre, its statement of purpose and the application fee).

If any of the four key items for your application have not been received, the application is deemed not to have been made and the provider will be informed in writing. Whenever this happens, all documentation in the provider's application will be returned to it, while any application fees paid can be refunded if requested by the provider or applicant.

Where we deem the application to have been made at this stage, a **qualitative check** can then be carried out. The application form will be scrutinised to ensure that the information in it is of a quality that can be considered for making a registration decision.

If it fails this step of the process, we will inform the provider of this in writing and the registration pack will be returned to the provider, along with the fee if requested. Once an application is deemed to be of an acceptable quality and valid, the Chief Inspector can begin to deliberate on the application. In addition, the prescribed information that has been submitted with the application will also be reviewed.

'Fit person' assessments during applications

As part of the registration application process, and onward regulation, we will assess the fitness of the:

- provider
- person in charge
- other people participating in management.

The provider must satisfy the Chief Inspector that she or he or the legal provider entity is fit to be the registered provider and to participate in the management of the designated centre. Any other person participating in the management of a designated centre will also be assessed for fitness.

Assessment of fitness during the registration process relates to a judgment of fitness at a specific point in time. However, fitness is a continual assessment throughout the registration cycle.

At all times, the Chief Inspector must continue to be satisfied that the provider and all persons involved in the management of the centre are fit and that the centre is operating within the conditions which have been attached at registration.

The 'fit person' requirement is based on section 50 of the Act. As part of the application to register, the Chief Inspector must be satisfied that the registered or intended registered provider and each other person managing the designated centre is a 'fit person'.

However, neither the Health Act 2007 (as amended) nor the regulations expressly define what a 'fit person' is. For the purpose of assessing fitness, therefore, the Chief Inspector has developed and published guidance setting out the fitness assessment process.[¥]

Fitness for the purpose of registration and ongoing regulation is, among other things, our confidence in the ability of the registered provider, person in charge and other managers to:

- perform his or her or its statutory role
- deliver a service that:
 - provides safe, suitable and sufficient care
 - protects the rights and promotes the wellbeing and welfare of residents
- comprehensively understand and comply with regulations and national standards
- have appropriate governance arrangements in place to assure themselves of the quality and safety of the services they are registered to provide.

[¥] See *Guidance on the assessment of fitness for designated centres* on <u>www.higa.ie</u>.

We will assess the fitness of the:

1. Registered or intended registered provider.

2. The person in charge (who is a person participating in management) and (in nursing homes) any person appointed to deputise for the person in charge in the absence of the person in charge.[±]

3. Any other person or people participating in management.

The assessment of fitness is not based on a single source of evidence, and, rather than being a one-off process that happens at registration, it is instead a dynamic process which is continually informed by information we receive about the centre and ongoing regulatory monitoring and findings.

In order to assist providers in this area, HIQA has published *Guidance on the assessment of fitness for designated centres.* You can search for it online or on our website, <u>www.hiqa.ie</u>. It should also be consulted when fitness is being considered in relation to our decisions to cancel registration, vary, remove or add new conditions of registration under section 51 of the Act (see Chapter 7).

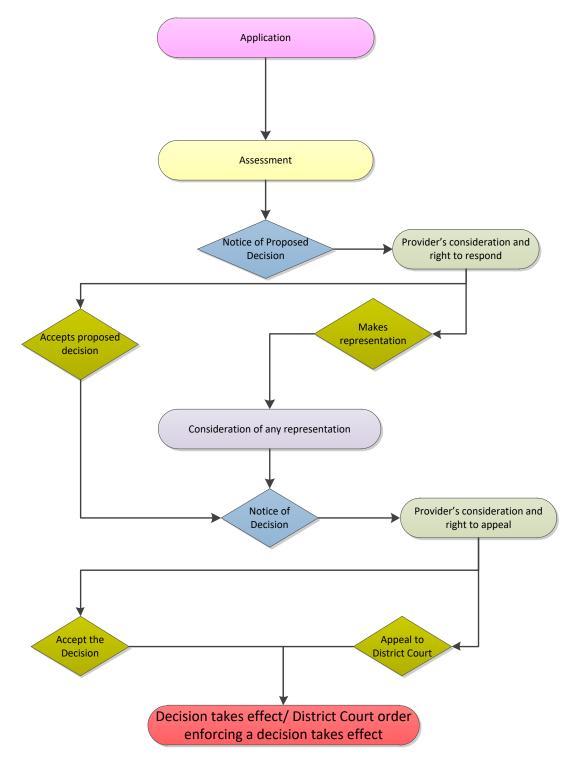


[±] The provider and the person in charge can be the same person, although the roles are distinct.

Registration decision-making process

Chart 1 illustrates the decision-making process for any application to register or renew the registration of a designated centre.

Chart 1. Path to registration



How long does it take on average to register a centre?

The time frame for a registration decision-making process for new designated centres can in some cases be less than 12 weeks from the time the application was made. However, this is only in situations where:

- all the necessary information had been received initially
- where there are no issues with the fitness of the intended provider or persons participating in the management of the centre
- the providers have been assessed as 'will comply' with the regulations and standards.

Section 50 decision on applications

In deciding on an application for the registration or renewal of registration, the Chief Inspector is obliged to satisfy herself that:

- the registered provider and people participating in management are fit persons (as set out earlier)
- ✓ the designated centre complies with national standards, regulations and any other relevant laws (if cited by the Chief Inspector)

- ✓ in the case of the first registration, the designated centre will comply with national standards, regulations and any other laws deemed to be relevant by the Chief Inspector
- ✓ the required prescribed information has been submitted.

The evidence relied on to make the decision on registration will be sufficient and verified. Decision-making will be in line with administrative law and fair procedures. Where an application for registration (or renewal) is made, the Chief Inspector may under section 50:

- grant the application
- grant the application with an operating condition or conditions
- refuse the application.

The assessment of fitness process

As mentioned previously (pages 27 and 28 of this chapter), the assessment of fitness of the provider and any person participating in the management of the centre, and the person in charge is an essential component of the registration or renewal of registration of a designated centre.

A review of all information related to the application to register or renew, along with a structured interview, will be conducted with all new applicants for an existing designated centre and applicants for the first-time

registration. Interviews are held faceto-face, by telephone or using video conferencing. Interviews may also be held with existing providers depending on the circumstances.

The information gathered at the interview will be assessed along with all other relevant evidence in order to make a judgment on fitness. The person whose fitness is being assessed will be informed of any concerns regarding fitness at the time of inspection or interview or shortly afterwards, and the provider will be informed in writing following the assessment.

After the evidence presented is reviewed, the final decision to grant, refuse or renew the application to register the designated centre is made. Where concerns arise regarding fitness, the provider will be given 10 working days to respond to the reasons for the concern as stated in the letter.

Assessment of compliance

For new registrations, we will consider how the intended provider and each other person who will participate in the management of the designated centre 'will comply' with the regulations (including care and welfare or support and registration regulations) and standards.

For renewals, we consider if the provider and each other person who will participate in the management of the designated centre 'is in compliance' with the regulations (including care and welfare or support and registration regulations) and standards.

Assessment of compliance with other enactments

Where relevant and cited to the applicant in writing by the Chief Inspector, we will assess compliance with other laws. For new registrations, we will consider if the intended provider and each other person who will participate in the management of the designated centre 'will comply with' such laws.

For renewals, we consider if the provider and each other person who will participate in the management of the designated centre 'is in compliance with' such laws. In both cases, we will use the test of substantial compliance for 'will comply with' or 'is in compliance with'.

Making an application recommendation

Our review of the application will include the following questions:

1. Has a valid application been made?

2. Are the provider, person in charge and any other people who will be managing the centre fit to do so?

3. Is the provider complying with, or will comply with, the regulations?

4. Have all of the prescribed documents been received and are they acceptable?

5. Is the centre complying with, or will it comply with, the national standards?

6. Is the centre complying with other laws which the Chief Inspector believes to be relevant and which have been cited to the applicant in writing by us?

Where we are unable to answer some or all of these questions or where the evidence is not up to date or is insufficient, we will gather further evidence on which to make the assessment and decision — this will likely include carrying out an inspection of the centre.

Proposed decision on registration

Based on our assessment, we will make an evidence-based proposed decision to:

- register with conditions
- register without conditions or
- refuse to register.

Our decision will be informed by our policies and processes and our assessment-judgment frameworks (for more on our assessment-judgment frameworks, see Chapter 5 on **inspection of your centre**).

We will issue all notices of proposed decision by registered post. If urgent, it may be hand delivered.

Proposed decision to register with conditions

Once we have made a proposed decision to register a centre, we decide if the registration should be subject to a condition or conditions. Whenever we propose to attach such conditions, we will clearly tell providers why we have set them so that they can consider them.

Providers must carefully read and make themselves aware of the specific conditions that are proposed to be applied to their centres and the significance of these conditions. Conditions of registration must be complied with at all times.

Proposed decision to refuse registration

Whenever we make a proposed decision to refuse registration, we will inform the provider of the grounds for the proposed decision.



The notice of proposed decision

A notice of *proposed* decision to grant or refuse the registration of a designated centre is a statutory notice, which sets out the Chief Inspector's proposed decision on your registration or renewal application.

A notice of *proposed* decision to grant or refuse registration consists of the notice and, if subject to conditions, a schedule attached to it outlining the particulars of the conditions or the grounds for refusal.

The notice of *proposed* decision will give you sufficient information in order to consider the proposed decision. This information is referred to in section 53 of the Act as 'the particulars' which the Act obliges us to outline.

These notices will be issued by registered post or in some cases may be hand delivered. In our notice of *proposed* decision, we will advise you of your right to make representations in writing to us within 14 calendar days after the notice is given. This representation window had previously been 28 calendar days but changed under the Health (Miscellaneous Provisions) (No. 2) Act 2024.

Notice of *proposed* decision to grant

In a proposed decision to register a centre without conditions, the notice of *proposed* decision to grant registration will be issued to the registered provider or intended provider without conditions attached.

Whenever the proposed decision is to register the centre subject to conditions, the notice of *proposed* decision to grant will have a schedule attached which will list the proposed conditions and the rationale for these conditions. Please carefully read these conditions as they are specific to your designated centre. We will clearly explain the reasons for the conditions to ensure that providers can fully consider what is being proposed.

Notice of *proposed* decision to refuse

Where the notice of *proposed* decision is to refuse the registration of the centre, we will explain why and outline the evidence to support the grounds we relied upon. We consider all evidence, either in favour of or against the proposed decision; for example, new information given to us by the provider. In our notice, we will advise you of your right to make representations.

What happens after you receive a notice of *proposed* decision?

Providers have three options after they receive a notice of *proposed* decision from the Chief Inspector.

The provider can:

- 1. Inform the Chief Inspector in writing that the provider accepts the proposed decision.
- 2. Not take any action and wait 14 calendar days for the next part of the process to start.
- Make a representation on the proposed decision to the Chief Inspector within 14 calendar days after the notice is given.

If you are informing the Chief Inspector in writing that you accept the notice of proposed decision, you can use and sign the hard copy document issued with the notice, and send it by post to our Cork office. We will also accept a scanned copy of this

Your right to make representations

Whenever we issue a notice of *proposed* decision, you have by law the right to respond to it. Providers can make written representations to the Chief Inspector within **14 calendar days** after the notice is given.

Your written representation should refer to the grounds relied on for the proposed decision, as laid out in the document by email to registration@hiqa.ie, once it is signed by the appropriate person as detailed in the form. Only submit one copy of this document by either email or post.

schedule attached to the notice of *proposed* decision. The representation should specify why you disagree with the proposed decision and outline your reasons or evidence for disagreeing. Once your representation is received, we will decide — based on a full review, including a decision on whether or not an inspection is needed to verify information submitted — to:

- proceed to notice of decision or
- where the decision following review of the representation differs from that contained in the earlier notice of proposed decision, we will issue a new notice of *proposed* decision for the provider or intended provider to consider.

If we issue a new notice of *proposed* decision, you have a further 14 calendar days after the notice is given in which to make further representations in writing to the Chief Inspector.

A further inspection is only required to verify measures which the applicant says, in representations, have been taken to comply with regulations and national standards or to verify mitigating actions which the provider says have been taken in response to a proposed condition.

If required, this inspection will take place within 15 working days of receipt of the representation.

The findings of this inspection, which will be communicated to the provider at a close-out meeting at the end of the inspection, will be used to verify or assess the representation or representations made by the provider in order to inform the decision on registration.

Separate to this decision on registration, you will receive an inspection report of this inspection. Any decision of registration is separate and distinct to the process for and the right of reply to inspection reports (see Chapter 5). The provider is afforded a right of reply on the decision of the Chief Inspector through the statutory provisions of the Act.

The notice of decision

The notice of decision to grant with or without conditions or to refuse registration follows the notice of *proposed* decision. This is a statutory notice telling the provider or intended registered provider of the decision and giving sufficient information to allow either to consider the decision.

These notices will be issued by registered post or, in some cases, they may be hand delivered.

Notice of decision to grant, with or without conditions

Whenever our decision is to register the centre without conditions, the notice will be issued without conditions attached. Whenever the decision is to register the centre subject to conditions, we will issue the notice with a schedule listing the conditions and the rationale for these conditions. The notice and schedule will have sufficient detail to ensure that the registered or intended provider can fully consider them. The notice will include the date by which you must lodge an appeal to the district court.

Notice of decision to refuse

Whenever the notice of decision is to refuse registration, we will include the relevant grounds for refusal and outline the evidence to support those grounds. The notice will include the date by which you must lodge an appeal to the district court.

What happens after you receive a notice of decision?

After you receive a notice of decision from the Chief Inspector, the provider can:

- 1. Inform the Chief Inspector in writing that the provider accepts the decision.
- Do nothing and wait for the registration to take effect after 14 calendar days have passed.
- 3. Appeal the decision to the district court.

If you are informing the Chief Inspector in writing that you accept the notice of decision, you can use and sign the hard copy document issued with the notice and send it by post to our Cork office. We will also accept a scanned copy of this document by email to <u>registration@hiqa.ie</u>, once it is signed by the appropriate person as detailed in the form. Only submit one copy of this document by either email or post.

Your right to appeal a decision

You have the right to appeal a decision contained in the notice of decision under section 57 of the Act and the right to be given written notice of your right to appeal. This appeal can be made to the district court in the relevant district⁺ where the designated centre is located or will be located.

Section 57 of the Health Act 2007 has been amended by the Health (Miscellaneous Provisions) (No. 2) Act 2024. The relevant section commenced on 23 September 2024. From this date, where a registered provider or the person applying to be the registered provider brings an appeal to the district court, they must:

- appeal within 14 calendar days (previously this had been 28 days) after receiving written notice of the decision, and
- at the same time that the appeal is brought, notify the Chief Inspector in writing of the appeal.

Where renewal of registration of an existing registered centre has been refused, you can continue to operate the centre until the appeal has been determined in the district court or until the appeal has been withdrawn or a further appeal to the circuit court has been decided on.

The intending provider may not operate the designated centre until the matter is decided on by the court or courts. If no appeal is lodged against the Chief Inspector's notice of decision, the decision takes effect 14 calendar days (previously 28 days) after receipt

⁺ For further information, see:

https://www.courts.ie/court-offices-jurisdiction.

by the applicant or the registered provider of the notice.

Conditions of registration

The purpose of conditions of registration is to set the parameters by which a provider must operate, or to restrict what services a provider can provide in a designated centre.

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

Penalties for this offence are listed in section 79 of the Act.

Under section 51A of the Health Act 2007 (a new section of the Act which came into effect in autumn 2024), the Chief Inspector may now remove a condition of registration where the Chief Inspector is satisfied that:

- it is appropriate in the circumstances and
- will not adversely affect people who are resident in the designated centre.

Certificate of registration and opening of new centres

If registration is granted, we will issue a certificate of registration to you, which will note any condition or conditions attached to the registration. Once received, you must display the certificate in a conspicuous place at the designated centre.

While failure to prominently display the certificate in the centre is an offence under the Act, providers should note that once registration is granted, they can begin admitting residents and do not have to wait until they receive their registration certificate from us.

Once a centre has been registered, the opening date for new centres is a decision that rests with the registered provider.

Your name and the public register under the Act

The registered provider and the person in charge of each designated centre are named on the public registers, which are available on <u>www.hiqa.ie</u>.



Examples of incomplete applications to renew registration or seek registration

In order to assist providers or intended providers with their applications, we have included below some common errors or omissions in applications that we have received from providers:

- The application form is incomplete or has been signed by a person who is not authorised to do so.
- The registration fee has not been paid.
- The floor plans are not legible and do not accurately reflect the footprint of the designated centre.
- The period of any lease agreement on the premises housing the centre is not listed.

Further examples of delays with the registration of new-build centres are provided in our guidance and self-assessment checklists for applications for designated centres for both older people and people with disabilities, published on www.hiqa.ie.

Incomplete applications

Please be advised that if you fail to submit one or more of the above items of information and or the fee, or where any of these items are deemed invalid, this will automatically result in your application being deemed invalid and being returned to you to fully complete and resubmit. In these circumstances, the application will be deemed not to have been made.

Should the provider fail to submit a valid and complete application six months before the current registration expires, then they are in danger of operating an unregistered centre if a decision on registration has not been made before the current registration expires.⁺

If providers need assistance or have any queries on the application process, you should contact our Registration Team at <u>registration@hiqa.ie</u>.

Common errors with prescribed information

In addition to the application form, providers are also required to submit information prescribed by the relevant registration regulations. Below are some of the common errors and omissions providers have made with regard to this information. These include:

- all the required prescribed information not being fully submitted
- Garda vetting disclosures not being submitted

⁺ Section 48(3) Health Act 2007 (as amended).

 Garda vetting disclosures do not comply with the guidance for prescribed information.

As previously mentioned, a complete and valid application comprises:

- the completed application form
- floor plans
- statement of purpose
- and the application fee.

Following submission of a complete and valid application, if some or all of the prescribed information has still to be submitted, we will contact the provider identifying the remaining items that should be provided to us.

An individual authorised on behalf of a provider to sign an application to renew registration of a designated centre or to register will also be accepted as a signatory for those statutory registration notifications[±] and prescribed information forms that require a signature.

Afterwards, any prescribed information not provided to us may result in non-compliance with the relevant registration regulations and will be assessed in terms of compliance with the regulations. Regulatory actions resulting from these non-compliances may include escalation such as a warning letter and warning meeting up to and including a proposed decision to refuse the application to register or renew. For related queries, please contact our Registration Office at registration@hiqa.ie.

Your notes

 $^{^{\}pm}$ Those related to notifications captured in notification forms NF30–NF37.

Applications to vary or remove conditions of registration



The Act allows for a provider to apply to vary or remove a condition of registration. Section 52 of the Health Act 2007 (as amended) allows registered providers of designated centres to apply to do so.

You can use the same form for applying to vary or remove conditions across older people, disabilities and special care units. The form (shown across) should be completed in full. Click here to download the <u>Application</u> for the Variation or Removal of a <u>Condition of Registration Form.</u>

In the case of an extension, it is advisable that providers contact their case-holding inspector so that the inspector is made aware of the date when the proposed application to vary a condition of registration will be submitted to the Chief Inspector.

Please note that if you submit an application to vary or remove a

condition of registration without providing the prescribed information and the application fee, your application will be deemed to have not been made and will be returned to you unprocessed.

An application to vary or remove a condition of registration can be granted where:

- a. it is appropriate in the circumstances and
- b. it will not adversely affect people who are living in the designated centre.

If not satisfied in this way, the Chief Inspector must refuse the application.



Checklist for applications to vary or remove conditions

A registered provider operating a designated centre may apply under the Health Act 2007 (as amended) to the Chief Inspector for the variation or removal of any condition applied to the registration of the designated centre. There are four essential criteria used to determine if you have made a complete application:

Application form (The same form for applying to vary or remove conditions can be used across older people, disabilities and special care units)	All sections complete.
Application fee	Paid electronically (see Table 4 on the next page for a list of fees).
Statement of purpose	An updated statement of purpose to reflect any changes arising from the application to vary or remove the condition(s) of registration.
Floor plans (if required)	Floor plans are required if there will be structural changes to the premises that are used as the designated centre. For example, changing the footprint of the designated centre as detailed in the floor plan (either to increase or decrease it).

The form should be completed in full. Only where an application is complete (including receipt by the Chief Inspector of the relevant application fee when required) can we decide on the application. If one or more of the four criteria fail to meet the requirements, your application will not be processed and we will:

- return, via post, all documentation received as part of your registration pack
- refund any application fee that you have paid.

You must apply according to the terms set out in the registration regulations,⁴ including submitting the prescribed information and paying the relevant application fee, as outlined under section 52(3) of the Act.

^{*} Health Act 2007 (Registration of Designated Centres) (Special Care Units) Regulations 2017; Health Act 2007 (Registration of Designated Centres for Older People) Regulations 2015 (as amended); Health Act 2007 (Registration of Designated Centres for Persons (Children and Adults) with Disabilities) Regulations 2013 (as amended).

Table 4. Application fees for varying or removing a condition ofregistration

The fee required is not identical for all services.

Disability

When applying to vary a condition or conditions of registration, the registration regulations specify a fee of ≤ 100 per condition for minor variations. So if you apply to amend two conditions, the fee is ≤ 200 . The fee for major variations is specified as ≤ 500 per variation in the registration regulations. We reserve the right to apply a major variation fee if appropriate, in line with the regulations. The fee for applications to remove a condition is ≤ 100 for each condition.

Older persons

The fee for applying to *vary* a condition of registration is \in 200 per application, regardless of the number of conditions you are applying to vary. The fee for applying to *remove* a condition of registration is \in 100 per application, regardless of the number of conditions you are applying to remove. If you use one application form to apply for both variation and removal of conditions, the fee is \in 300.

Special care units

In special care units, the fee to accompany an application for the variation of a condition or conditions of registration is \in 200. The fee to accompany an application for the removal of a condition or conditions of registration is \in 100. These are set out in the 2017 special care unit registration regulations.

A	pplication type	Disability	Older persons	Special care unit
V	ary a condition	€100 per condition [^]	€200 per application	€200 per application
	lemove a ondition	€100 per condition	€100 per application	€100 per application

An application **is deemed to be invalid if the prescribed fee has not been paid** by the registered provider.

 $^{^{^{}}}$ A major variation fee of €500, if appropriate, may also be applied, in line with the regulations.

In addition to the completed application form, prescribed information and the fee, the provider must supply the following information in the application:

(a) identify which condition or conditions that the application refers to and whether the application is to vary or remove the condition or conditions

(b) if applying to vary a condition or conditions, outline the change or changes sought and why you are applying

(c) if applying to remove a condition or conditions, you must outline the reason or reasons for the proposed removal

(d) changes proposed in the designated centre due to the variation or removal of a condition or conditions, including:

(i) structural changes to the designated centre^{\pm}

(ii) additional staff, facilities or equipment

(iii) changes to the management of the centre that the registered provider believes are required to introduce the proposed changes

(e) any other additional information that we reasonably need in order to consider your application. Quantitative and qualitative check of application to vary or remove a condition

We will complete a **quantitative check** to see if all the required items of information and fee have been submitted. If this is not the case, then the application is deemed not to have been made. We will inform the provider of this in writing and the application form and fee (if applicable) will be returned to the provider.

Conversely, when the application has been deemed to have been made at this stage, we will carry out a **qualitative check** on it. The application form and any additional information will be scrutinised to ensure they can be considered for an application to vary or remove a condition of registration.

When an application has been deemed to have been made after the qualitative check, we can begin deliberating on it. We will review all information available and make an evidence-based recommendation to:

- (i) grant or refuse the application to vary a condition or
- (ii) grant or refuse the application to remove a condition of registration.

[±] Structural changes should fall within the floor plan of the registered designated centre. If the structural change is greater than the registered floor plan, or reduces it, you must complete an application to vary a condition of registration.

Assessment of information for varying or removing a condition

In order to decide on an application, we will assess the information available and determine whether this evidence is:

- sufficient
- verified
- up to date.

Whenever a provider has applied to vary or remove more than one condition, we will treat each application separately. An inspection may be carried out to inform the decision we make.

When we make a proposed decision to grant an application, we must be satisfied that it is:

- appropriate in the circumstances <u>and</u>
- will not adversely affect people living in the designated centre.

Where we are refusing the application, we will clearly outline to you the grounds and evidence for the decision. Beforehand, we will first consider whether or not there is additional evidence that should be considered; for example, has the provider submitted new or additional information? The application will only be refused where we believe there is evidence that it is inappropriate in the circumstances and would adversely affect people living in the designated centre.

Removal of a condition of registration by the Chief Inspector

Section 51A of the Act allows the Chief Inspector to remove a condition where certain circumstances exist. In these instances, an application does not need to be made by the registered provider.

Similarly to section 52, before the Chief Inspector removes a condition of registration using section 51A of the Act, she must be satisfied that

- it is appropriate in the circumstances and
- will not adversely affect people who are resident in the designated centre.

Your notes

Notice of *proposed* decision to vary or remove a registration condition

Similar to the notices issued by the Chief Inspector during the process to register or renew registration, when an application is made to vary or remove a condition of registration or where the Chief Inspector proposes to remove a condition of registration, she will issue a statutory notice of proposed decision.

While providers can apply in the same application to vary or remove more than one condition of registration, sometimes the Chief Inspector may issue individual notices of *proposed* decision and notices of decision for each condition applied for.

Notices will be issued by registered post or, if urgent, we may hand deliver them.

Notice of *proposed* decision to grant the application to vary or remove a condition

Where the proposed decision is to grant the application to remove a condition, the notice will be issued to the registered provider without a schedule. When the proposed decision is to grant a variation to the condition, the notice will have a schedule attached which clearly outlines the proposed varied wording of the condition and the reason for the variation.

Notice of *proposed* decision to refuse the application to vary or remove a condition

Where the proposed decision is **to refuse to vary or remove a condition**, we will ensure that the relevant grounds are included and will clearly state the evidence to support the grounds — for example, the Chief Inspector believes it is inappropriate in the circumstances and would adversely affect people living in the designated centre.

Notice of *proposed* decision to remove a condition

Where the Chief Inspector proposes to remove a condition of registration, a notice of proposed decision will be issued to the registered provider without an explanatory schedule (as would be included in a notice of proposed decision to grant a variation of a condition).

Written representations on a proposed decision to vary or remove a condition

Similar to notices of decisions by the Chief Inspector on applications to register or renew registration, the registered provider has by law the right to respond to notices of proposed decision to grant or refuse an application to remove or vary a condition of registration. The provider also has the right to respond to proposed decisions by the Chief Inspector to remove a condition.

This is covered in section 54 of the Act which has been amended under the Health (Miscellaneous Provisions) (No. 2) Act 2024 and which now states that a registered provider may make written representations to the Chief Inspector within 14 calendar days (previously, this time frame was 28 such days) after the written notice of *proposed* decision to grant or refuse applications to remove or change (vary) a condition is given. The provider also has the right to respond to proposed decisions by the Chief Inspector to remove a condition of registration where a provider has not made an application to remove a condition. The Chief Inspector shall not make a final decision until:

- the 14 calendar days have elapsed or
- a written representation is received from the registered provider or
- the registered provider tells us in writing that it does not intend to make a representation.

If a representation is received, we will decide — based on a full review, including a decision on whether or not an inspection is needed to verify information submitted — to:

- proceed to a notice of decision or
- where the decision following review of your representation differs from that contained in the earlier notice of *proposed* decision, we will issue a new notice of *proposed* decision for the provider to consider.

If we issue a new notice of *proposed* decision, you have 14 calendar days after the date on which the new notice is given to make further representations in writing to the Chief Inspector.

We will decide if an on-site inspection is required to verify the information submitted. If so, we will inspect within **15 working days** of receipt of the representation.

The findings of this inspection, which will be communicated to the provider at a close-out meeting at the end of the inspection, will be used to verify or assess the representation or representations made by the provider in order to inform the decision to grant or refuse an application to remove or vary a condition of registration.

Separate to this decision, you will receive an inspection report of this inspection. Any decision on removal or variation of a condition of registration is separate and distinct to the process for inspection reports (see Chapter 5). The provider is afforded a right of reply on the decision of the Chief Inspector through the statutory provisions of the Act.

Notice of decision to vary or remove a registration condition

Statutory notice of decision

The statutory notice of decision to grant the application to vary or remove a condition of registration — or the notice of decision that the Chief Inspector will remove a condition of registration where an application has not been received from a provider will give the registered provider sufficient information so that it can consider the decision.

In the case of applications from providers, sometimes, more than one notice of decision may be issued if the application related to more than one condition. For example, a notice to grant and a notice to refuse may be issued in respect of different conditions. Where the decision is to **grant an application to remove** a condition or where the Chief Inspector decides to remove a condition of registration, the notice of decision will be issued to the registered provider without an explanatory schedule. However, where the decision is to **grant the application to vary**, the notice of decision will include a schedule and rationale with the proposed varied wording of the condition so that the provider can fully consider what is being proposed.

The notice of decision will advise providers of their right to appeal our decision to the district court and will include the date by which such an appeal must be lodged.

Notice of decision to refuse applications to vary or remove a condition

Where the decision is to **refuse the application** to vary or remove a condition, we will clearly state the relevant grounds for the decision and the supporting evidence. The decision will advise providers of their right to appeal the decision to the district court and will include the date by which such an appeal must be lodged with the district court.

Notices of decision will be issued by registered post or, if urgent, they may be delivered by hand.

Your right to appeal a decision on varying or removing a condition

Similar to decisions made following an application to register or renew registration, registered providers can

appeal our notice of decisions about their applications to vary or remove a condition of registration. The provider also has the right to appeal notices of decision by the Chief Inspector to remove a condition when there has been no application from a provider. This is again covered by section 57 of the Act.

A registered provider must be given written notice of their right to appeal to the local district court; therefore, this will be included in our notices to providers. The same time frames and conditions of appeal apply to decisions on varying or removing conditions as to those appeals involving other registration decisions:

- appeal within 14 calendar days after receiving written notice of the decision, and
- at the same time that the appeal is brought, notify the Chief Inspector in writing of the appeal.

Annual fee

Registered providers of designated centres for older people, people with disabilities and special care units for children must pay an annual fee to HIQA. The registration regulations set out the fee to be paid by designated centres and how it is calculated.

How much is the annual fee?

The annual fee is €183 for each resident or child.

Complying with the regulations on the payment of annual fees is essential for the ongoing registration of your centre.

When should I pay my annual fee?

The annual fee is payable in three equal instalments every four months.

The fee due for each resident or child for each of the three billing periods is €61 and becomes due on 1 January, 1 May and 1 September each year for each period of four months immediately following those dates.

Each instalment is payable not later than the last day of the calendar month in which the instalment fee falls due. So, for instance, annual fees that fall due on 1 January must be paid by 31 January and so on.

Registered providers of designated centres for older people and designated special care units can submit a declaration of the occupancy in their centre to the Chief Inspector on the first day of the billing period, if occupancy is below the level of registered residential places on 1 January, 1 May or 1 September.

An NF60 notification form can used for this. Providers can submit the NF60 between the 1st and 15th of the month in January, May and September. If providers are at a full occupancy on the first day of the billing period in question, there is no need to submit an NF60.

How do I pay my annual fee?

You will receive an invoice by email for each of the three annual billing periods. The payment requested will be based on the number of registered residential places or the occupancy on the first day of the billing period (registered providers of designated centres for older people and designated special care units only).

We can only accept electronic funds transfer (EFT) payments for the annual fee. Therefore, please do not send us a cheque, postal order or bank draft, as it will be returned to you. Our banking details for electronic funds transfer for paying the annual fee are provided on the following page.

Please include your account number that is issued to you on your invoice or in the subject line of your billing email, which will have the invoice attached.

We recommend that providers of centres for older people make their annual occupancy declarations using our Provider Portal website. This is the most efficient and secure method of submitting your NF60 or Annual Return Notification. Once you have clicked 'submit', you will receive a real-time confirmation on screen from us that your notification has been received. Special care units can email their NF60 to us at notify@hiqa.ie.

Providers should consult our <u>*Registration handbook*</u> for further information on paying the annual fee.

Banking details for payment of the annual fee

HIQA only accepts electronic fund transfer (EFT) payments. **Please do not send us a cheque, postal order or bank draft as it will be returned to you**. Please quote the following information when making your EFT payment using either online banking or through a bank:

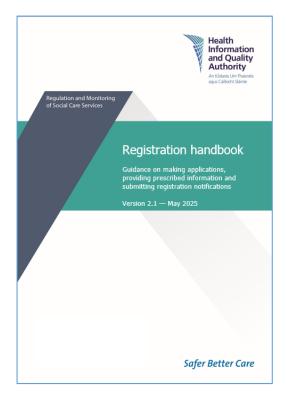
Your account number	Your account number is issued to you on your invoice or in the subject line of your billing email which has the invoice attached. This number is:	
	 12 characters long 	
	 starts with the letter `D' 	
	 combines your centre ID (OSV) 	
	 ends with the numbers 001 or 002 and so on. 	
Centre name	Name of the designated centre	
Account name	Health Information and Quality Authority	
Bank name and address	Danske Bank, 3 Harbourmaster Place, IFSC, Dublin 1, D01 K8F1	
Bank sort code	95-15-99	
HIQA account number	80006688	
IBAN	IE94DABA95159980006688	
Swift/BIC	DABAIE2D	

After completing payment of your annual fee, please forward a copy of your bank remittance (copy of proof of payment) to <u>AR@hiqa.ie</u>. In your email to us, please include the OSV number and centre name so that we can assign your payment on our records.

Further reading on registration

For further information on the annual fee, please consult the relevant registration regulations for your centre.

More information on the registration process is available in our new *Registration handbook*.



In addition, further information is available in the following publications, which are available on the provider guidance pages of <u>www.hiqa.ie</u>:

 <u>Are you ready for assessment of</u> <u>the application to register:-</u> <u>Guidance and checklist: Designated</u> <u>Centres for people with disabilities</u> <u>Are you ready for assessment of</u> <u>the application to register:-</u> <u>Guidance and checklist: Designated</u> <u>Centres for Older People</u>

See also the following document:

 Guidance on the assessment of fitness for designated centres: Effective January 2018: V2: Revised June 2022. Available online from: https://www.hiqa.ie/sites/default/fil es/2022-06/Assesing-fitness-fordesignated-centres Guidance.pdf.

Conclusion

Providers must be thoroughly prepared for the registration process and all its associated checks. This includes having the statement of purpose and the designated centre site ready for assessment. Providers are, therefore, encouraged to consult our published guidance on our website and to contact their case-holding inspector if they have queries in advance.

The provider should be clear about the key personnel involved in the running of the centre and must ensure that authorised people are available to sign the relevant documents and or application. All information required must be included in the application as otherwise the application pack will be returned unprocessed.

Your notes

Chapter 3. Governance and a risk-based approach to regulation



Introduction to governance

Governance is the organisational framework that incorporates systems, processes and behaviours that support an organisation to do the right thing or make the right decision at the right time.

The regulations and standards that we assess place people using services at the centre of care delivery. That means a service which is well governed does the right thing by the person receiving care. This is the essence of personcentred care.

Governance is not just about having the correct policies in place or measuring progress against targets. It is also about leadership. A service that is well led sets the tone for the whole organisation. Our compliance data shows that services which are well run tend to deliver better outcomes for service users.

The importance of good governance

Regulation of designated centres takes place against a framework of the primary legislation; regulations; and national standards. The quality and safety of your service is assured by complying with and exceeding these requirements and standards.

In this context, the registered provider plays a critical role in leading, building and maintaining a culture that places the resident or child and the quality and safety of services at the centre of

the delivery of care. To achieve this, the registered provider must be clear about the scope of its service (as outlined in its statement of purpose) and how it provides and measures the efficiency of the service.

The registered provider must provide a service compliant with the required regulations, nationally mandated standards, legislative frameworks, national guidelines and best practice.

To succeed, the registered provider will have communicated to all relevant and interested parties a clearly defined and formalised governance arrangement that identifies clear lines of accountability at individual, team and service levels. The registered provider will have arrangements in place to ensure responsibilities are appropriately delegated.

For that reason, the PPIM, the person in charge, all health and social care professionals, care staff, managerial staff and everyone working in the service are acutely aware of their individual operational and professional responsibilities and accountabilities.

Where there is more than one identified person participating in the management of the centre, the operational governance arrangements are clearly defined. Decisions are communicated, implemented and evaluated.

Voice of residents and children

Residents living in a well-governed designated centre for older people, people with disabilities and their families, and children in special care units and their families will be confident that the registered provider has effective governance arrangements in place to ensure their voice is heard and listened to.

The registered provider makes certain that the organisational culture protects the rights of residents and it has arrangements in place to monitor this on an ongoing basis. These arrangements include the:

- timely and effective identification and management of risk
- continual evaluation of the quality, safety and outcomes of service provision
- enhancing a culture of continual improvement through staff learning and development.

To accomplish the goals and objectives of the service, the registered provider must be assured that the operational management processes are effectively carried out by the PPIM and or person in charge. In designated centres for older people, the registered provider must also have made deputising arrangements for the person in charge and other key management roles.

Governance is, therefore, central in our risk-based approach to regulation. Our enhanced monitoring approach reflects this principle. To this end, services must focus on governance in order to be able to deliver safe and sustainable services into the future.

It is impossible for us to be 100% assured that residents or children are always safe and are being provided with a good-quality service regardless of how many inspections we carry out. That is why the governance and management practices of the services we regulate are critical in ensuring that people are safe and have a good quality of life.

People providing services have to be empowered to do the right thing or make the right decision at the right time. Trust and confidence in service providers, along with proportionate public interest safeguards, are often the best assurance of regulatory compliance across the whole service. We measure this trust and confidence through our risk framework.

Introduction to risk-based regulation

A risk-based approach to regulation means that we make decisions based on the information we have. We prioritise our regulatory activities and organise our resources for monitoring, inspection and enforcement, based on the assessment of the risk that the regulated services pose.[¥]

This means, based on the risk assessment, we make decisions regarding a range of regulatory matters including:

- whether or not to register a designated centre
- the type and intensity of monitoring activity necessary to respond to non-compliance with the regulatory framework
- what assessment, 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 escalation and enforcement activity required to respond to non-compliance by providers[‡] with the regulations.

Using this approach means that we, as a regulator, can tailor our regulatory responses so that they are proportionate to the relevant risks.

This approach informs how frequently we inspect any individual designated centre and the nature, intensity and type of any inspection carried out. It also means proportionate and meaningful sanctions.

[¥] Better Regulation Commission, 2006.

⁺ Provider means intended or registered provider or service provider.

What is regulatory risk?

Regulatory risk is about identifying and evaluating risk caused by noncompliance with legislation, regulations and national standards by the provider and PPIM (including the person in charge), and the impact that this regulatory risk has on residents and people using services.

We carry out risk assessment in order to direct our regulatory response where it can have the maximum impact. A risk-based approach to regulation means that we will make good decisions based on the information we have.

What is risk assessment?

Risk assessment identifies a potential risk and estimates the level of that risk in a situation, thereby focusing our response where it is needed most. The level of risk will be compared to the accepted standards and or regulations to determine an acceptable level of risk.

Risk-approach principles

Our approach to risk is based on the following principles:

- we will be proactive to promote and encourage compliance and thereby reduce risk
- we will focus on those designated centres and services posing the most serious risk

- our regulatory responses will be proportionate to the risks identified
- we will be consistent in our responses
- the evidence we gather will inform our response to regulatory risk.

Risk assessment and response

Risk assessment is made up of three processes:

- 1. Risk identification.
- 2. Risk analysis.
- 3. Review.

The risk assessment process (see Chart 2) can be triggered by any of the following circumstances:

- receipt of information:
 - applications for initial registration or renewal of registration
 - applications to vary or remove conditions of registration
 - unsolicited receipt of information
 - solicited receipt of information[¥]
- fieldwork events, such as inspections
- enforcement action
- evaluation of information, including trending (for more on trending, see Chapter 4).

[¥] This includes all information requested from the provider to inform regulatory monitoring activity.



Chart 2. Risk assessment and response



1. Risk identification

This is the process that involves identifying, recognising and describing the regulatory risk arising from a non-compliance with regulations and national standards. All information that informs our monitoring approach and regulatory decisions will be risk-rated.

2. Risk analysis

Risk analysis is about considering the likelihood and impact to inform an overall risk rating of a centre or service. This will give a risk score ranging from very low risk to high risk. The action taken will be proportionate to the risk.

3. Review

We will continually monitor and review the actions taken against the risk and review the risk assessment and score.

Responding to regulatory risk

An assessed risk rating of a designated centre gives us an indicator for regulatory actions. Centres can be rated very low risk, low risk, moderate risk or high risk. We will review the risk rating of a centre at certain times, such as when we receive information of concern about it.

All regulatory responses will be proportionate to the risk identified. For example, we would not consider it proportionate to recommend refusal of a centre's registration based on the emergence of a low risk in the centre. In response to regulatory risk, we can consider:

- What type of monitoring or information gathering is required?
- 2. Plan and schedule fieldwork activity, such as an inspection.
- 3. Determine if the risk is acceptable or tolerable or if escalation is required.

4. Where escalation is required, how this will be managed.

Review of regulatory actions

We review all regulatory actions taken to see if they have had the desired impact on non-compliances. Where there has been no improvement, or where a provider's non-compliance is deteriorating further, we will decide on the most appropriate escalation and or enforcement action to take.

Use of business intelligence to inform our decisions

As previously stated, we review all information we have about a provider and the centre to inform our judgments and decisions. We use this business intelligence, such as regulatory reports, history of noncompliance, history of our regulatory interventions and their outcomes, to assist the decision-making process.



Examples of high-level risk areas in designated centres

Fire safety in designated centres

Fire safety in designated centres must be structured and focused on the needs of residents and children and should consider the following:

- the overall suitability of the premises for the specific needs of the residents or children
- adequate staffing to assist in an evacuation, especially at night
- location of bedrooms, taking into account residents' and children's specific needs
- ease of evacuation of the centre in the event of a fire.

The focus on fire safety should be informed by a comprehensive fire safety risk assessment which is specific to the premises and prepared by a competent fire safety expert. This focus is supported by planning and policy (such as carrying out regular simulated fire drills), having adequate staff who are appropriately trained, and providing adequate equipment resources.

All providers and persons in charge (in all types of designated centres) should be aware of their legal obligations under the following legislation:

- Fire Services Acts, 1981 and 2003 amendment
- Safety, Health and Welfare at Work Act 2005
- Building Control Acts 1990 and 2007
- 2013 care and welfare regulations for designated centres for older people
- 2013 care and support regulations for disability centres
- 2017 care and welfare regulations for special care units.

You should seek guidance on meeting your legal obligations from competent fire safety experts and your local authority fire officers and building control authority.

You have a responsibility to have clear and unambiguous fire safety procedures in place, including fire safety risk assessments for the premises, residents and children, residents who smoke, residents with dementia, residents who may have responsive behaviours⁴ or residents whose mobility is restricted.

You must ensure that all your staff are trained in fire safety and know what to do in the event of a fire or a fire alarm going off. The risk posed by fire should be subject to ongoing risk assessment, particularly whenever new staff are recruited or if new residents or children come to live in the centre.

Fire safety concerns in centres

If our inspectors have concerns about fire safety in designated centres, they can consult our fire safety inspectors for advice, or our fire safety inspectors may inspect these centres themselves.

Further reading on fire safety

We have produced new guidance for providers and persons in charge about their responsibilities in relation to fire safety. <u>Click here to view the Fire</u> <u>Safety Handbook: A guide for</u> <u>providers and staff of designated</u> <u>centres</u> on our website, or search online.

An <u>e-learning course to assist providers</u> when reviewing fire precautions in their designated centre and introduce them to the Fire Safety Handbook can be viewed by clicking here. Please note that as these are not a definitive interpretation of the law on fire safety, you should always seek expert opinion.

Staffing levels in designated centres

Each provider and person in charge is responsible for assessing the needs of the residents or children and must employ appropriately qualified staff to cater to those needs.

The person in charge is responsible for developing staff rosters which provide for appropriate staff skill-mix and staff numbers to ensure a safe service is delivered for residents or children. How this is managed over the 24-hour period is the responsibility of the provider and person in charge.

 $^{^{\}diamond}$ Responsive behaviour: how people with dementia or other conditions communicate or

express their physical discomfort or discomfort with their social or physical environment.

Regulations and national standards for centres for older people, residential centres for people with disabilities or special care units in Ireland do not set out any required minimum number of staff that must be on duty, as this will largely depend on the profile of the people living in these designated centres and their assessed needs.

Each centre is different: some centres may be nurse-led and others are supported by social care staff. Providers and persons in charge should know the children's and residents' needs and provide staff accordingly. We are not prescriptive about qualifications for staff working in a designated centre, as this is solely the responsibility of the provider.

Each resident in a designated centre for older people or people with disabilities is required to have a care plan in place which outlines their needs and how they are being met. Special care units are required to have programmes of care in place for children detailing all their required interventions.

What our inspectors look for in terms of staffing is whether there are sufficient staff with the required knowledge, skills and experience to be able to meet those assessed needs of the residents or children in their care.

We check if the provider and person in charge have assessed the minimum staffing levels required to enable the safe evacuation of residents or children in the event of a fire or other emergency. Following review of this information, we will then make a judgment as to whether the service is being run in line with the regulations and national standards and if residents are receiving the appropriate care.

Vetting of staff working in designated centres

Providers must ensure that all their staff and volunteers have undergone vetting by An Garda Síochána (police) and that staff have received training in the protection of vulnerable people from abuse.

The enactment of the National Vetting Bureau (Children and Vulnerable Persons) Act 2012 in April 2016 provided additional legislation which strengthened the provisions around vetting.

In essence, anyone working with children or vulnerable people in any area of Irish society, whether directly employed or self-employed or working with an agency which supplies health and social care staff, requires Garda vetting.

Since 29 April 2016, it has been an offence to employ somebody to care for vulnerable people, or to start such a job after the Vetting Act was enacted, without a vetting disclosure from the National Vetting Bureau of An Garda Síochána.

Garda vetting is an important aspect of safeguarding people who use services.

If an issue arises through the Garda vetting process, it is the responsibility of the provider to risk-assess the information and to decide whether the items in the vetting disclosure constitute a risk to residents or children.

Under the Criminal Justice (Spent Convictions and Certain Disclosures) Act 2016, providers and managers of designated centres — as well as all other staff working in or seeking a job in a designated centre — must disclosure all convictions on the Garda National Vetting Form.

Many people have items recorded on their Garda vetting form, often of a minor nature and historical. The provider must use the information in the vetting process to inform their own safeguarding arrangements. The provider must be able to demonstrate to inspectors that they have undertaken a risk assessment.

If providers have satisfied themselves that the information does not constitute a risk to residents or children and can demonstrate this to inspectors and can show us that they have given the information proper consideration, this will demonstrate compliance with these requirements.

Safe management of medicines in designated centres

Providers and the person in charge of designated centres for older people, people with disabilities and designated special care units for children must ensure there are appropriate policies and or practices in place for ordering, receipt, prescribing, storage, disposal and administration of medicines.

We require providers to put in place policies or practices for managing medicines in order to ensure the safety of residents and or children. Staff must administer medicines as prescribed by a doctor, appropriately qualified nurse or dentist in line with the safety practices set out in the provider's medicine management policy.

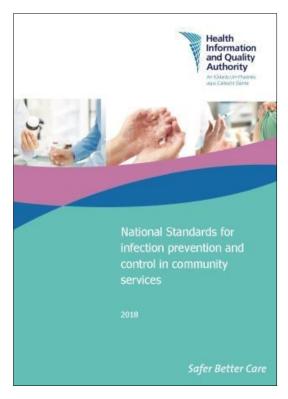
On inspection, we require staff to demonstrate their knowledge of their organisation's protocol and to demonstrate that they are implementing it. Providers generally implement standardised approaches to medicine management to ensure consistency and safety.

We are not prescriptive about who administers medicine in a designated centre but rather how the provider and or person in charge assure themselves that staff are competent to do so.

Infection control in designated centres

We expect to see good systems in place to militate against any risk of infection to residents or children living in designated centres. We also expect to see policies and related training that reflects the requirements of relevant regulations and national standards.

HIQA has developed *National Standards for infection prevention and control in community services*. Standard 2.2 says care is provided in a clean and safe environment that minimises the risk of transmitting a healthcare-associated infection.



We expect to see all providers meet such standards. To read the *National Standards for infection prevention and control in community services*, go to: <u>https://www.hiqa.ie/sites/default/files/</u> <u>2018-09/National-Standards-for-IPC-in-</u> <u>Community-services.pdf</u>.

The Health Protection Surveillance Centre (HPSC) has also produced guidance on the prevention and management of cases and outbreaks of COVID-19, influenza and other respiratory viral infections in residential care facilities. See <u>http://www.hpsc.ie/a-</u> z/respiratory/influenza/seasonalinfluenza/g uidance/residentialcarefacilitiesguidance/.

In designated centres for older people, registered providers are also required to ensure that guidance published by appropriate national authorities in relation to infection prevention and control and outbreak management is implemented in the designated centre.

Restrictive practices for older people and people with disabilities

We have published updated guidance for designated centres for older persons and for people with disabilities on promoting a care environment that is free from restrictive practices and to assess and review the use of such practices in centres with a view to reducing or eliminating them.

While restrictive practices may be sometimes necessary to ensure a person's safety or the safety of others, they are an infringement of a person's fundamental rights to personal liberty and bodily integrity. In recognising this, providers should explore all measures to reduce or end their use.

Although the guidance is aimed at supporting themed inspections to improve this specific area of care in older persons and disability centres, the themed inspection may change to a risk-based inspection where it becomes evident that the findings on inspection are poorer than expected.

A literature review conducted to support this thematic programme found that the importance of goodquality training and education was a recurring theme in the literature. Studies show that targeted education and training effectively reduces the use of restrictive practices in care settings. Effective governance and management is also critical in monitoring the use of restrictive practices and promoting a restraint-free culture.

Our thematic inspection programme in older persons and disability centres focuses on assessing physical and environmental restraint as well as other forms of restrictive practices and does not include chemical restraint. The guidance urges providers not to be overly risk-averse and to support residents to live meaningful lives. See:

- Guidance on promoting a care environment that is free from restrictive practice: Older People's Services: Effective June 2023
- <u>https://www.hiqa.ie/reports-and-publications/guide/guidance-restrictive-practice-dcop</u>
- Guidance on promoting a care environment that is free from restrictive practice: Disability Services: Effective June 2023
- <u>https://www.hiqa.ie/reports-and-publications/guide/guidance-restrictive-practice-dcd.</u>

Safeguarding practices

Providers of designated centres must adhere to modern safeguarding practices to protect vulnerable adults and children from the risk of harm or abuse. HIQA and the Mental Health Commission (MHC) have jointly developed national standards for adult safeguarding.

The *National Standards for Adult Safeguarding* was published in 2019. National and international evidence consulted as part of the development of these standards was published by HIQA and the MHC in 2018. Both documents are available on the HIQA website.* focus on those risks which pose the greatest risk to residents.

Effective governance is central to our risk-based approach to regulation. In our experience, good governance is clearly associated with good regulatory compliance. Our compliance data also indicates that most providers are doing a good job at managing risks in their designated centres.

Your notes

Conclusion

The role of the provider is to own and safely manage its own day-to-day operational and service risks. Our role is to manage regulatory risk, that is to say non-compliances with regulations and national standards and how these impact on people using services.

We risk-assess in order to direct our regulatory response where it can have the maximum impact. The regulatory action we take will be proportionate to the identified regulatory risk and will

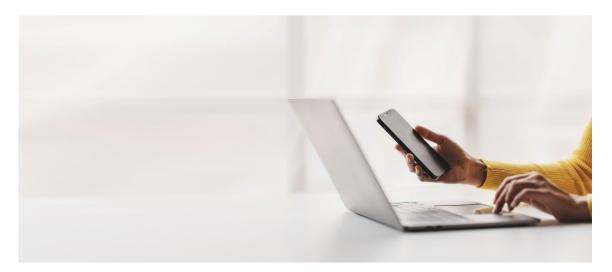
 $^{^{\}ast}$ Health Information and Quality Authority (HIQA) and the Mental Health Commission (MHC):

National Standards for Adult Safeguarding: 2019, https://www.higa.ie/reports-andpublications/standard/national-standards-adultsafeguarding

Background document to support the development of national standards for adult safeguarding, https://www.higa.ie/sites/default/files/2018-05/HIQA%20MHC%20Adult%20safeguarding%20bac kground%20document.pdf.

Your notes

Chapter 4. Information about your designated centre



Introduction to information about your designated centre

Each year, the Chief Inspector receives a significant amount of information about designated centres: from centres themselves and other sources. We categorise this information as receipt of:

- 1. Solicited information.
- 2. Unsolicited information.

Solicited information is information that the registered provider and or the person in charge is required to submit as part of their statutory obligations, such as specified information,^{\$} notifications or application forms or information that inspectors request from a provider. It also means information requested by us from providers to submit as part of monitoring or thematic reviews.

Unsolicited information is

information which is not requested but which is received by the Chief Inspector from people who use services or any member of the public. This could include information that indicates that a designated centre is not meeting regulations or standards.

It can also be compliments or general comments about a centre, service or a provider. It can be received through a number of routes; for example, email, letter, phone call, in person, or media reports.

The management of all information is a dynamic process. In line with the

Specified information is information required by the regulations for registration-related applications and for registration notifications.

relevant legislation, standards and regulations, a regulatory judgment on the quality and safety of a service can only be reached when all information received and gathered is fully validated and assessed in its totality.

We believe good and responsive services encourage a culture of openness and transparency about reporting incidents and accidents to us. This in turn enables effective learning locally from these events and more positive outcomes for people using the service.

Sometimes, HIQA or the Chief Inspector is not the correct entity to respond to the information submitted by the public, or the issue is outside their legal remit. In such cases, HIQA or the Chief Inspector will try to direct the person, if this is appropriate, to the most appropriate organisation which may be able to assist them.

How we use solicited and unsolicited information

All information received is reviewed in the context of the designated centre that it applies to. We use information to:

- check whether the provider and person in charge are meeting the requirements of the regulations and standards
- assess if people using services are receiving safe, high-quality care.

Five-step approach to analysing and using information we receive

After the Chief Inspector receives information (both solicited and unsolicited), we take a five-step approach to analysing and using the information received as follows:

- 1. Review the information.
- 2. Assess risk on people using services.
- 3. Apply a risk rating very low, low, moderate or high.
- Decide the regulatory action, taking into account all we know about the centre.
- 5. Review the risk rating.

Inspectors will critically appraise the information received and try to determine what it is really telling them. Each piece of information helps inspectors to form an overall understanding of how the centre or service is being run. The steps are explained in more detail below.

Step 1. Reviewing the information

In the first instance, the inspection support teams will ensure the information relates to a designated centre. If it does, most information will be risk-rated (applications and certain registration notifications are not riskrated) to help prioritise our work.

This step in the process involves reviewing:

- what has happened
- who the parties involved are
- which regulation and or standard the information is associated with
- what action has been taken to safeguard people using services
- whether there is a possible or probable breach of regulations or deviation from the standards.

Our inspectors consider the information received in the context of what else they know about the centre. The information is also linked to a regulation and or standard, and this ensures that it is within their remit to make a regulatory judgment on it.

Step 2. Assessing risk

Inspectors risk-assess solicited or unsolicited information to identify if there is a possible or probable noncompliance with the regulations and or national standards. They also assess what, if any, impact it may have on the people using the service.

They again consider what else they know about the service and what level of confidence they have in the provider to take the necessary steps to address the concerns. Where this information does not fall within our legal remit, we will try to refer the information to the most appropriate authority or agency.

Step 3. Apply a risk rating

This involves the inspector considering:

- what is the probability of the non-compliance with the regulations and or standards happening again?
- what would the impact on residents or children be if this happened again?

The information is not viewed or riskrated separately to other information we have about a designated centre. It takes into account:

- fitness of the provider and person in charge (such as the provider's proven track record to appropriately manage situations related to the information received)
- history or trends of similar information in relation to the centre and if there were poor outcomes for residents
- active non-compliances with regulations and or standards
- overall profile of the centre.

A single piece of information received, when reviewed in the context of all other sources of information about a centre, may assure inspectors that the service is being managed effectively. However, in some cases, because of its nature, it may increase the overall risk rating of that service and require a proactive response to the risk rating.

Step 4. Decide on a regulatory action

As outlined in the previous chapter, the regulatory action we take will be in proportion to the regulatory risk and what we know of the provider and the service. This step focuses on whether the information requires regulatory activity over and above routine monitoring of compliance with the regulations and standards.

The Chief Inspector's remit is to regulate services rather than manage them. In response to information received about a designated centre, inspectors can choose from the following regulatory activities:

- close and retain for information
- request further information from the provider
- request a provider compliance plan update
- request a provider assurance report
- start escalated regulatory activity such as an inspection.

The inspector's decisions will be proportionate to the assessed risk. Some information received may require no action, while in other cases, inspectors will need assurance that the risk is being appropriately managed by the provider.

Data protection and information governance

Providers should not submit any unnecessary personal data about residents unless expressly asked to do so.

People's personal data[‡] will only be sought from providers where it is necessary to assess compliance with regulations or standards or to allow inspectors to carry out their legal duties. In such cases, providers should only ever use a unique identifier code to identify people in their correspondence with us.

Step 5. Reviewing and or updating the risk rating

Following any regulatory activity, the inspector will review and risk-rate the information again. This assessment takes into account whether we received the necessary assurances from the provider in relation to the issue.

The inspector will determine if the follow-up information received from the provider (if requested) reduced or increased our concern about this centre and its overall risk rating. It will be decided at this stage whether or not we need to take further action.

data or from the data in conjunction with other information that is in, or is likely to come into, the possession of the data controller'.

⁺ Personal data is defined in section 1 of the Data Protection Act 1988 as 'data relating to a living individual who is or can be identified either from the

Overview of solicited information

Solicited information is defined as information that the registered provider and person in charge must submit to the Chief Inspector in order to fulfil their statutory obligations, or information requested from the provider or person in charge. Examples of solicited information that we receive include:

- specified information

 (information required by the regulations for applications and for registration notifications)
- monitoring and registration notifications
- application forms to register or renew registration, including:
 - centre floor plans
 - statements of purpose
- information that inspectors have requested from a provider
- information sought from providers as part of monitoring or thematic reviews.

Notifications about your centre

The most frequent type of solicited information we receive is monitoring and registration notifications, which providers or persons in charge must by law submit to us. These are mandatory and keep us informed about certain incidents and events in the designated centre. Monitoring notifications must be submitted by a provider and or person in charge in order to comply with the care and support and welfare regulations, while they must submit registration notifications to comply with the registration regulations.

Different time frames apply for different types of monitoring and registration notifications. We believe a high level of notifications is indicative of a proactive and responsive provider and is not necessarily an indicator of poor care.

Numbered notification forms

In an effort to help providers and persons in charge to meet their statutory obligations and submit notifications within the correct time frames, we have developed various notification forms, with a number assigned to them.

The preferred method of submission, and most secure, is electronically to the Chief Inspector using HIQA's Provider Portal website, and we encourage all providers to use the HIQA portal, which is accessed through the HIQA website:

https://portal.hiqa.ie/User/Login?Retur nUrl=/.

If for any reason the portal is unavailable, two-day and three-day monitoring notifications can be submitted by email to <u>notify@hiqa.ie</u> or by post, while quarterly monitoring notifications can be emailed to the relevant team.⁺ Most forms are located on the <u>provider resource section of</u> <u>www.hiqa.ie</u> and some are on the portal. As they are in editable PDF format, PDF reading software is required to access them.

While providers and persons in charge are not required by law to use these numbered notification forms, we would encourage them to always do so wherever possible — and to submit them using the Provider Portal — in order to reduce the administrative burden on providers.

Duty to notify the Chief Inspector

Notifications to us should clearly set out the nature of the incident or event and the provider's response to it. It should assure us that the provider has reviewed the circumstances and implemented any changes necessary to ensure the safety and welfare of residents.

When a provider or person in charge notifies the Chief Inspector about a prescribed incident within the required time frames, they have met their legal obligation to notify. However, they should also seek to understand why the incident occurred and put in place corrective or preventative actions where necessary.

Some notification forms request additional information and we encourage providers and persons in charge to submit this information where requested. However, the Chief Inspector may need to request further information where:

- key pieces of information are missing
- it is unclear what has happened
- it is not clear what steps the provider has taken to ensure the safety of residents and or to comply with the regulations
- the person in charge has failed to clarify that set procedures are being followed.

If you are requested by an inspector to demonstrate you have made such notifications, sight of the notification in the 'notifications history' menu on the portal is sufficient evidence of the notification being retained for inspection by the Chief Inspector.

- People with disabilities <u>dcd@hiqa.ie</u>
- Special care units <u>children@hiqa.ie</u>.

⁺ The team email addresses are:

Older people — <u>dcop@hiqa.ie</u>

Monitoring notifications

Introduction

Different timelines apply for various monitoring notifications: some events or incidents have to be notified to the Chief Inspector within three working days (two working days for designated centres for older people) of happening. Others have to be notified within three months or six months. Yet still, other notifications must be made weeks in advance of a planned event.

Notifiable events or incidents

The person in charge must ensure that the Chief Inspector is notified in writing about all incidents listed in:

- Regulation 31 of the 2013 care and support regulations for people with disabilities
- Regulation 31 and Schedule 4 of the 2013 care and welfare regulations for older persons, as amended from 31 March 2025
- Regulation 27 of the 2017 care and welfare of children in special care regulations.

We refer to these as **monitoring notifications**.

Three-day and two-day monitoring notifications

Providers must tell the Chief Inspector about certain events in the designated centre. There are different time frame requirements for different types of designated centre. In disability centres and designated special care units, monitoring notifications must be made within three working days. In designated centres for older people, they must be made within two working days of them happening.

These three-day notifications (two-day notifications for nursing homes) include, for example, unexpected deaths in older person centres and disability centres and deaths of children in special care. They also include the outbreak of any notifiable infectious disease. For nursing homes, any incident of alleged or confirmed abuse of any resident must be reported within two working days. For other designated centres, any allegation, suspected or confirmed, of abuse of any resident or child must be reported within three working days.

Appendix 2 lists of all these two-day and three-day statutory monitoring notifications and the associated regulation(s). The person in charge is not required to personally make the notification, but is responsible for ensuring it is made. When reviewing the notification, the inspector will also review any regulation relevant to the incident.

Quarterly monitoring notifications

By law, certain events or incidents that happen in the designated centre have to be formally reported to us every three months. There are separate notifications forms for each category of these quarterly notifications called NF39s. These forms are NF39A, NF39B, NF39C, NF39D and NF39E.

Those events must be submitted to us by the following dates:

- 30 April
- 31 July
- 31 October
- 31 January.

You only need to submit the relevant NF39 notification form to us if you have had one or more instances of a notifiable event during the relevant quarter. NF39 forms stating nothing notifiable happened in those three months are not required and will not be processed if submitted.

Providers of older persons and disability centres should submit a single nil return (using the NF40 nil return form) every six months for any quarterly notification events that did not happen. This is not required in special care. For example, if there were no thefts or burglaries in older person centres or designated centres for people with disabilities (to be captured in the NF39C form[±]), this should be included on the NF40.

Appendix 2 includes all statutory quarterly monitoring notifications and the associated regulation(s).

When and how to submit follow-up information

If a resident of a designated centre for older people or a designated centre for people with disabilities had died unexpectedly or if a child who has been living in special care has died, you must tell us of this event and can do so by using the NF01 form.

Later, the circumstances and cause of death have to be submitted in writing to the Chief Inspector whenever they are established. In all other monitoring notifications, follow-up information is normally only required if an inspector seeks it.

A notification submitted using the Provider Portal is assigned a notification reference number in the format NOT-XXXXX. You should quote this reference if you need to supply follow-up or additional information. The reference number of past notifications can be found in the

[±] Special care units do not have to report on thefts or burglaries. Please note that in designated centres for older people and people with disabilities, quarterly NF39C forms relate to any recurring

pattern of theft or burglary; while in special care units, NF39C is used to notify any loss of power, heating or water.

section of the Provider Portal called 'notification history'.

If a notification is submitted by email or through the post, a notification reference number may not be issued to you; however, one is generated internally. If the number is unknown, then the following information should be included to enable us to locate the original notification that the follow-up information relates to:

- centre ID (also called ORG SERVICE ID)
- centre name
- notification form number of the original notification (for example, NF01, NF02, NF09, NF39A)
- the date you first submitted your notification of the event.

Impact of notifications on other bodies

Notifications to the Chief Inspector have no impact on any obligation the registered provider or person in charge may have (under statute or otherwise) to report an incident to other bodies such as the Coroner, the Child and Family Agency (Tusla), the HSE, An Garda Síochána or professional bodies such as CORU, Ireland's multiprofession health regulator.

What are the consequences of failure to notify?

Failure to comply with the regulations will be reported on in the compliance plan following an inspection. It may also constitute an offence under the Health Act 2007 (as amended).

Cause of death notifications

The Chief Inspector acknowledges that obtaining the cause of death of a resident or child is often outside the control of the person in charge of the designated centre or special care unit. The regulations require that the Chief Inspector is provided with the cause of death in writing when it has been established; therefore, every effort should be made to seek confirmation of cause of death.

Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023

This Act introduces a new requirement for providers of designated centres to notify the Chief Inspector of particular notifiable incidents within seven days from the time that the provider is satisfied that the incident occurred. These incidents are listed in Part 1 of Schedule 1 of this Act. This notification requirement is in addition to the requirements under the various regulations for two- and three-day monitoring notifications.

In addition, once the relevant section of the Patient Safety Act is commenced, this Act will also

introduce a new discretionary function for the Chief Inspector to undertake a review of a specified incident in a designated nursing home when the Chief Inspector becomes aware of that incident:

- through a complaint about the incident
- through the receipt of a notification of the incident or
- where the Chief Inspector becomes aware by other means.

Registration notifications

In order for the Chief Inspector to carry out its functions effectively, it requires accurate information regarding the registered provider, the designated centre details and certain personnel in the centre. During a cycle of registration, changes can occur which change the information supplied for registration purposes.

The registered provider has regulatory obligations to ensure that this information is submitted to the Chief Inspector within the time frame(s) required by the relevant regulations. They can meet these obligations by submitting registration notifications (see Appendices 3 and 4 for more guidance on registration notification and associated time frames).

Common registration notifications include notifications of changes to the person in charge or when the person in charge will be away from the centre for periods of time set out in the regulations, as follows:

- disability centres and designated special care units — 28 calendar days or more
- designated centres for older people, including nursing homes
 — 42 calendar days or more.

Other requirements in designated centres for older people include notifications of a person appointed to deputise for the person in charge during that period of absence. Some of these notifications will lead to an assessment of the fitness of the person in charge or PPIM. Others will be used later to inform renewal of registration.

When we receive registration notifications, our Registration Team and or inspectors will review the information, take the appropriate decisions and make the required regulatory judgments. Where these changes affect the online public registers of designated centres, such as a change to the person in charge, these registers will be updated.

Prescribed information required for registration notifications

Similar to the registration process, the registration regulations require certain information called 'prescribed information' to be submitted along with the notification where there is a change in the person in charge of the centre or change to any person participating in its management.

The prescribed information requirements (see Chart 3) are contained in Schedule 3 of the registration regulations for children and adults with disabilities; Schedule 2 of the registration regulations for older persons; and Schedule 2 and Schedule 3 of the special care unit regulations.

Chart 3. Prescribed information which must be submitted with registration	
notifications	

Prescribed information —	Type of residential service		
person in charge and each person participating in management	People with disabilities	Older people [¥]	Special care unit
Completed HIQA personal information form	√	√	✓
Copy of current photographic identification	*	√	✓
Copy of current Garda Síochána (police) vetting report	✓	✓	✓
Copy of the person's birth certificate	√ ≠	Not required	Not required
Copy of the person's relevant qualifications	√	1	√
Two references in a format specified by the Chief Inspector (with original signatures)	√	Not required	✓
Medical declaration form	√	Not required	✓

[¥] In the case of nuring homes, provider must submit the name, contact details and qualifications of the person who will be or was deputising for the person in charge.

[#] Note: where the birth certificate is not available, a certificate of adoption is acceptable.

Some key timelines for changes to those running the centre

For changes to the person in charge, the provider must submit the notification and the prescribed information within 10 calendar days of the appointment of the new person in charge.

For changes to other people participating in the management of the designated centre, the provider must notify the Chief Inspector within 28 calendar days of the change along with supplying the prescribed information. If a provider fails to submit the required information or fails to submit it in time, inspectors will assess this as being a possible non-compliance with the regulations, which in turn could lead to escalated regulatory activity. Changes to key personnel involved in the provider entity must also be notified to us eight weeks in **advance**. These changes include changes to company directors or officers; change of partner; and change of manager, chairperson or membership of an unincorporated body. The same eight-week advance notification timeline applies to changes of name or contact information for companies, partnerships or unincorporated bodies. Providers should consult our Registration

<u>handbook</u> for further information about such notifications.

Processing registration notifications

When registration notifications are received, we will process the information, including:

- checking that specified information (required by the regulations) has been submitted and is acceptable
- assess and risk-rate the information (for most notifications)[¥]
- decide what needs to be done, including seeking further information
- update the public register, if required
- issue an updated certificate of registration, if required.

Other solicited information

As part of the Chief Inspector's monitoring role, inspectors or support teams request other information from providers such as:

- non-statutory notifications (made by children's services to HIQA's Children's Team)[‡]
- requests for information or additional information
- completed self-assessment questionnaires as part of thematic monitoring programmes[≠]
- assurance requests.

⁴ Some registration notifications are not risk-rated. We will risk-rate notifications contained in NF30, NF31 and NF35 forms.

^{*} The Children's Team specifically request two nonstatutory notifications from the Child and Family Agency (Tusla): death of a child known to Tusla's child protection services; and a copy of monitoring

reports completed by Tusla for its children's residential centres.

[#] Thematic monitoring programmes focus on a particular aspect of care provided, with a focus on improving the quality of that care.



Using our Provider Portal

Introduction

The HIQA Provider Portal is accessed via <u>www.hiqa.ie</u>. This website is a more secure and better way to submit statutory notifications rather than submitting them by email or hard copy. All portal accounts are password protected. In future, it is expected that the Provider Portal will be the primary communications tool used for sharing information between the Chief Inspector and providers.

Benefits of using the Provider Portal

Reduced administrative burden:

there are fewer fields to fill out. Portal users do not need to complete the provider's or centre's details on each online form — the portal site will autofill these fields. **Reliability:** once you submit a notification or required prescribed information, you can be assured we have received it. A notification reference number will be displayed in real time on screen, in the format NOT-XXXXX. There is no need to submit the notification or information to us again in other formats.

Up-to-date forms: the information is directly inputted into the relevant online forms on the Provider Portal, and these will always be the most upto-date versions. This reduces the chance of you using an out-of-date form and the notification having to be resubmitted.

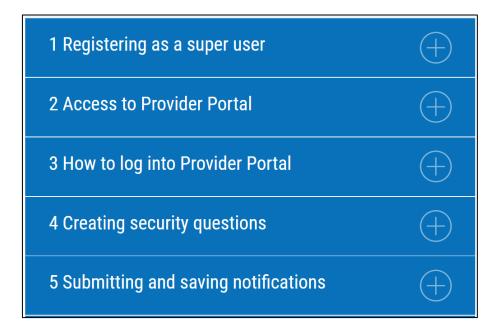
Greater efficiency: all mandatory fields on notification forms on the portal site must be completed. The portal site will not allow you to submit

partially filled-out or incomplete forms, which — if submitted by email or hard copy — would usually have to be resubmitted.

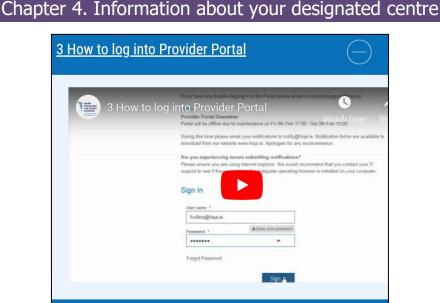
Prescribed information: to support the submission of registration notifications using the portal, we have introduced an upload facility for prescribed information relating to NF30A, NF30B and NF31 notification forms. You can scan the required information and upload it to our secure portal site without having to send us the original documents.

Evidence of submission: inspectors will accept portal notifications as evidence of a notification having been made. All notifications made using the portal can be viewed in your centre's `notification history' in your portal account.

Video support to get you started on the portal



We have published a series of how-to videos covering all steps involved in using the site. If you are having difficulty accessing these videos, you will need to enable marketing cookies on <u>www.hiqa.ie</u>. To view the videos for each step, just click on the plus symbols on the Provider Portal guidance page of our website (illustrated here and online at <u>https://www.hiqa.ie/guidance-providers/provider-portal</u>). You can also search online for our *Provider Portal — user guide for Providers*. This can be viewed online at <u>https://www.hiqa.ie/reports-and-publications/guide/hiqa-provider-portal-user-guide-providers</u>.



Who can use the Provider Portal?

A designated centre can have:

- an unlimited number of 'providerlevel' access users
- one `super user' and
- five `sub-account users'.

To use the portal, you will first need to register as a user. You will only need to register once and will then be able to log in to the portal using your username and password (once received from HIQA's Portal Support Team).

Provider-level access users

Provider-level access can be granted to any individual carrying out a provider role (such as a company director) that has been identified to us through an application form or a notification form. Provider-level access allows the person to:

- submit:
 - all portal registration notifications for the provider and designated centre (however, NF35 notifications must still be submitted in hard copy)
 - all centre-level two-day and three-day monitoring notifications (NF01–NF09)
 - all centre-level quarterly monitoring notifications (NF39s A–E)
 - monitoring notification nil returns when there were no incidents which needed to be notified (NF40 for older persons and disability centres only)
 - prescribed information (relating to NF30 and NF31 notifications)
 - declarations of occupancy in the case of older people (NF60)[‡]

[¥] NF60 notifications for special care units should be submitted to <u>notify@higa.ie</u>.

- view previously portal-submitted registration notifications
- view a history of portal-submitted monitoring notifications.

Only users with a provider-level log-in will be able to submit NF32, NF33 and NF36–37 registration notification forms.[^]

If you would like to register for a provider-level account, please register

by clicking on the Provider Portal log-in option on the HIQA homepage and then clicking on the 'Register Account' button.

In addition, setting up portal access for provider-level roles will depend on the provider entity type. Please use Table 5 as a guide to the provider roles that can be enabled for portal access.

Provider entity	Provider-level role type
Company	Company director, chief executive, company secretary and or chairperson
Partnership	Partners in the partnership
Unincorporated body	Committee member, trustees, chairperson or manager of the body
Individual (sole trader)	Individual person carrying on the business of the designated centre
Health Service Executive (HSE)	Delegated person

Table 5. Provider roles that can be enabled for portal access.

and NF36–37 relate to changes to information supplied (applicant details) for registration purposes: changes to company, partnership, unincorporated personnel and contact information.

[^] NF32 forms are for changes to the ownership of a body corporate (for designated centres for people with disabilities only at the time of writing). NF33

Role of the super user

There is a limit of one super user for each designated centre; super-user access can be granted to a person with one of the following roles in relation to the designated centre:

- 1. Provider.
- 2. Person in charge.
- 3. Person participating in management.

The super user is responsible for managing 'sub-account users' in the designated centre. The super user can add additional 'sub-account users' (up to a maximum of five per centre), and remove access from existing 'sub account users' — such as where a staff member will no longer be working in that centre.

The super user can submit via the portal:

- two-day and three-day monitoring notifications (NF01– NF09)
- quarterly monitoring notifications (NF39s A–E)
- certain registration notifications as follows:
 - change, absence or return of the person in charge (NF30 forms)
 - change of people participating in management (NF31)
 - declaration of residential place occupancy for designated centres for older people (NF60)

- nil return monitoring notifications (NF40 for older persons and disability centres only)
- prescribed information for notifications involving forms NF30A, NF30B and NF31.

'Sub-account users'

The sub-account user can submit the same monitoring and registration notifications and the same prescribed information as a super user (as listed above).

Submitting prescribed information

As previously mentioned, the Provider Portal has an upload facility for prescribed information. These documents relate to copies of references, Garda Síochána (police) vetting reports, medical declarations, qualifications and personal identification forms, which can now be uploaded directly to the portal site, to accompany NF30A, NF30B and NF31 notification forms.

Within two working days of submitting any of these notifications, the registered provider will receive an email confirming that the prescribed information document upload facility is available to use on the portal site.

These documents must be submitted to the portal within 10 calendar days for a person in charge (the NF30 forms) and 28 calendar days for a person participating in management (NF31).

For more information on prescribed information, please read our *Registration handbook: Guidance on making applications, providing prescribed information and submitting registration notifications,* which is available on the HIQA website.

Draft notifications on Provider Portal

You can save a draft of all notifications on the portal site before submitting them to us. This will allow you to return to a notification that you had been working on without losing the details that you have already entered.

In the case of quarterly monitoring notifications (covered by the NF39 forms), this draft-edit function allows you to enter details of notifiable events as they happen and save the draft until it is ready to be submitted on the last day of each three-month period. Please note the following timelines for draft notifications:

- Draft three working-day monitoring notifications for disability centres and special care units (forms NF01– 09) remain in draft form for up to three working days.
- Draft two-working day monitoring notifications for nursing homes (forms NF01–09) remain in draft form for up to two working days.

- Registration notifications (forms NF30–37) will remain in draft form for up to eight weeks.
- Quarterly notifications (forms NF39 A–E) remain in draft form for up to three months to facilitate providers incrementally adding information to these draft notifications.

Nil returns (NF40s)

If no notifiable incidents occurred in the older person or disability centre over the three-month period that would be captured in the quarterly notifications (or NF39 forms), there is no requirement to submit a relevant NF39 form to us stating that this was the case.

Instead, providers only need to submit a nil return (using the NF40 form for older persons and disability centres) every six months for any quarterly notification events that did not happen. For example, if there were no thefts or burglaries in older person centres or disability centres (NF39C[^]), this should be included on the NF40.

Nil returns using the NF40 do not have to be submitted for special care units.

Notifications which cannot be submitted to the portal

Follow-up reports cannot, at the time of writing, be submitted via the portal and should instead be submitted to

[^] Special care units do not have to report on thefts or burglaries. Please note that in designated centres for older people and people with disabilities, quarterly NF39C forms relate to any recurring

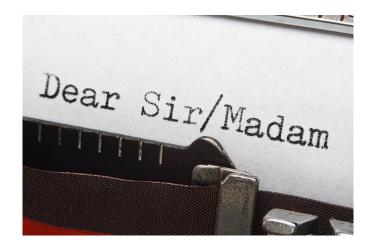
pattern of theft or burglary; while in special care units, NF39C is used to notify any loss of power, heating or water.

<u>notify@hiqa.ie</u>. Follow-up reports are required for notifications of the sudden death of a resident or the death of a child (NF01 forms) and or if requested by an inspector for other notifications.

The notification reference number should be inserted into the subject line of your email. This number is now easy to find on the 'notification history' section of the portal site. If the original notification was submitted in hard copy or email, follow the guidance as outlined earlier in this chapter when submitting a follow-up report. We will also accept a hard copy follow-up report, but email is preferred.

In addition, NF35 forms (for notification of intention to cease carrying on the business of the designated centre and to close the centre) must continue to be submitted to the Chief Inspector by hard copy only.

Overview of unsolicited information



Unsolicited information is received regularly by HIQA and or the Chief Inspector from members of the public, including residents of designated centres, people who use services or their relatives, members of staff,[¥] media and public officials.

This is usually information from people who have a concern or an issue about the care provided in identified centres for older people, people with disabilities, children's services and healthcare services. We risk-rate all items of unsolicited information and take appropriate action in response.

We are unable to investigate or resolve individual disagreements between people and their providers. However, we welcome information and concerns

Reporting a concern to HIQA

If you have a concern in relation to a designated centre, you can contact our Concerns Team. All information it receives is acknowledged, recorded, risk assessed and used to inform further monitoring activity, including inspection, as required. Write to:

Concerns Health Information and Quality Authority George's Court, George's Lane Dublin 7, D07 E98Y.

You can also email your concern to concerns@hiqa.ie or telephone 021 240 9646. For further information, search online for our guidance on 'How to provide feedback or make a complaint about' residential services for older persons and people with disabilities, and children's social services.

[¥] If an employee of a provider contacts us, this can become a protected disclosure.

about the centres we regulate. This may result in an early inspection taking place or may be used to inform the next inspection. When an inspection takes place, the issues raised may inform the questions asked during the inspection.

Categorisation and review of unsolicited information

When the information comes within HIQA's or the Chief Inspector's remit, it is logged, categorised against the relevant regulation and or national standard and assigned to an inspector or authorised person for review and risk rating. The information will be reviewed in terms of the following:

- Does this information give rise to a concern about the overall capacity and capability of the provider to deliver a safe service?
- Does this information give rise to a concern about the quality and safety of the service being delivered?
- What information do we already know about this designated centre and provider?
- Does this information give rise to a concern about the fitness of the provider and person in charge (designated centres)?
- Is there a trend giving rise to concerns as a result of this information?
- What is the overall risk rating of those centres that have a risk profile?

Unsolicited information is managed in the same way as outlined in the fivestep approach to managing solicited registration notifications, and as set out in Chart 4 on the following page.

Trending information to inform monitoring

Inspectors may carry out a trending analysis of all sources of information received about a designated centre. Trending or trend analysis is an additional way to analyse the information that the Chief Inspector receives to help identify a pattern of:

- any safeguarding risks in the centre
- areas where the regulations and standards are not being complied with
- any lack of fitness on the part of the provider or person in charge.

Inspectors are required to monitor services on an ongoing basis, but cannot be in every centre every day, so trending is one way to use the information received by the Chief Inspector to support ongoing monitoring and to inform our riskbased approach to regulation.

For example, for any given centre, inspectors can analyse:

- two-day (older people) or threeday monitoring notifications (SCU and disability) received by month
- high- and moderate-risk-rated unsolicited receipt of information received by month.

Trend analysis can highlight an issue that is not readily apparent and can also provide objective evidence of noncompliance and help support a decision by us on how to act. It can also be used to identify trends in relation to individual residents and the suitability of their placement.

Inspectors mostly trend information:

- before an inspection
- when updating the regulatory risk

- when a two- or three-day monitoring notification is received
- when quarterly monitoring notifications are received
- when making a recommendation on a registration application.

Inspectors may also trend information (solicited and unsolicited) when they update a centre's compliance plan.

Step 1 Review information	 What has occurred? Who are the parties involved? Which regulations and or standards does it apply to? What action has been taken to safeguard people? Is there a possible or probable breach of regulations or deviation from the standard?
Step 2 Assess risk	 What is the impact on outcomes for people using the service? Is there possible or probable non-compliance with the regulations? What else do we know about the service (risk profile, non-compliance, trends in information)? What level of confidence do we have in the provider to take the necessary steps to address the concerns?
Step 3 Apply risk rating	• What is the probability (likelihood) of this occurring again? What would be the impact on residents or children if this were to happen again?
Step 4 Decide on regulatory action	 Is the risk rating low? Case-holder makes decision. Is the risk rating moderate or high? Undertake regulatory activity. Update risk profile.
Step 5 Review risk rating	 Do we have new information that changes our initial rating? Has the information reduced our concern regarding this centre or risk rating? Has the information increased our concern or risk rating? Is further action required?

Chart 4. Processing of solicited and unsolicited information

Conclusion

Providers are obliged by the regulations to submit certain information about their designated centres to us, while we also receive much information about centres from the public. All information received is managed in exactly the same way.

All solicited and unsolicited information received by the Chief Inspector is reviewed and proportionately riskassessed and risk-rated where necessary. It can be used to inform further monitoring activity, including escalation and or inspection, and registration renewal decisions.

The Chief Inspector encourages providers to submit the required notifications via the HIQA Provider Portal and emphasises that a large number of notifications does not necessarily imply there is a risk of noncompliance with the regulations or poor outcomes for residents or children.

For those providers who do not yet have a Provider Portal account, the following notification forms should be sent to the following corresponding email addresses:

- Send all NF01–09s to <u>notify@hiqa.ie</u>
- Send NF39s and NF40s to:
 - Older People: dcop@hiqa.ie
 - Disabilities: dcd@hiqa.ie

- Send NF39s for special care units for children to:
 - children@hiqa.ie.

Unsolicited information received from the public gives a valuable perspective on centres. Along with monitoring and registration notifications from providers, it is carefully considered with all the other information known about the centre when making regulatory decisions.

While we are unable to investigate or resolve individual disagreements between people and their providers, we review all information or concerns we receive about services and we assess this against the regulations and the national standards. We may use this information in future inspections. If there is a serious risk to the health and welfare of service users, we may decide to take immediate action.

Finally, the Chief Inspector regulates rather than manages centres, and, therefore, the onus is always on providers to ensure they are safely managing and learning from challenges in their centres and services after they have submitted their statutory notifications.

Further reading

To assist providers submitting notifications to us, we have developed guidance for them in this area. Please see our <u>Registration handbook:</u> <u>Guidance on making applications,</u> <u>providing prescribed information and</u> <u>submitting registration notifications</u> and the following guidance documents:

- Monitoring notifications handbook for designated centres for older people (DCOP): https://www.hiqa.ie/reports-andpublications/guide/monitoringnotifications-handbook-designatedcentres-older-people.
- Monitoring notifications handbook for disability (DCD): https://www.hiqa.ie/reports-andpublications/guide/monitoringnotifications-handbook-disabilitydcd.
- Monitoring notifications handbook: Guidance for persons in charge of children's special care designated centres): https://www.hiqa.ie/reports-andpublications/guide/monitoringnotifications-handbook-scu.

Chapter 5. Inspection of your centre



Introduction to inspection of your centre

Inspections are not just on-site events that take place in the designated centre. They can also happen through the management and review of all information about the centre held or received by the Chief Inspector of Social Services.

The Health Act 2007 (as amended) requires the Chief Inspector to register and inspect designated centres to check whether or not the registered provider is complying with the regulations and national standards.

We describe activities which inspectors carry out and which are related to an inspection as 'fieldwork events'. A fieldwork event has a series of stages, of which the on-site inspection is but one part.

On-site inspections are categorised as follows:

- Monitoring inspections these are routine inspections that monitor the quality of the service and assess its level of compliance with regulations and national standards. Such inspections can inform a decision on registration (under sections 50 of the Act), including concerns regarding the fitness of the provider and or people who manage the centre.
- Targeted inspections are focused on a specific topic or risk. Targeted inspections may include a focus on a specific area such as Infection Prevention and Control, Fire and Estates or Adult Safeguarding. Targeted inspections can also focus on areas of risk. Risk Inspections are in addition to routine monitoring inspections and may be carried out after we receive information that indicates a potential risk to residents and or as

part of enforcement activity. They may be carried out to inform a decision under the Act, including sections 51, 59 or 79.

 Thematic inspections — these are inspections which aim to improve quality in a specific area of care in the designated centre; for example, dementia care or restrictive practices.

On-site inspection helps the Chief Inspector to:

- assess compliance with regulations and or standards at a point in time
- give a voice to residents or children living in a centre about what it is like to live in the centre
- inform the public of the quality of services being provided
- make ongoing regulatory decisions.

What is a thematic programme?

Thematic programmes aim to promote quality improvement in designated centres and to improve the quality of life of people living in these centres.

Thematic programmes assess compliance against the relevant national standards for the particular thematic programme; for example, restrictive practices in designated centres. The thematic programme consists of an assessment-judgment framework, guidance for providers, self-assessment questionnaire, quality improvement plan and inspection (see Appendix 1 for more information on published guidance).

Providers are expected to use any learning from thematic inspection reports to support continual quality improvement in their designated centres, which will ultimately be of benefit to the people living in these centres.

There may be occasions during the course of a thematic inspection where inspectors form the view that the service is not in compliance with the relevant regulations; for example, those relating to restrictive practices. In such circumstances, the thematic inspection against the national standards will cease and the inspector will proceed to a risk-based inspection against the appropriate regulations.

A thematic inspection follows many of the steps of a fieldwork event. In addition to these steps, the provider will be required to submit a completed self-assessment questionnaire when invited to do so by the inspector. The inspections may be announced or unannounced. A report on the thematic inspection will be produced and published which will follow the stages of preparing an inspection report from a draft report through to the final report.

What is fieldwork?

Fieldwork is the term we use to describe all the activities associated with the pre-, on-site and postinspection activities. We describe activities which inspectors carry out that are related to an inspection as `fieldwork events'.

A fieldwork event has the following 10 steps:

- 1. Scheduling the inspection.
- 2. Planning the inspection.
- 3. On-site inspection in the centre.
- 4. Writing up of findings.
- 5. Generating an inspection report.
- 6. Quality assuring the report.
- 7. Issuing a draft inspection report to providers.
- 8. Managing feedback from providers.
- 9. Approving the inspection report.
- 10. Publishing the report.

Inspection includes a review of all information about the designated centre — both gathered on site in the centre and all information received from and about the centre. For the purpose of clarity, however, we use the term **inspection** from this point on in this chapter for the on-site activity in the designated centre.

How often will you be inspected?

We take a risk-based approach to regulation. Therefore, we will carry out more inspections in those centres which are demonstrating higher levels of repeated non-compliance with regulations and standards.

In general, all designated centres

will have a minimum of two inspections during each three-year registration cycle.[†] These routine inspections may include a planned announced inspection (see Table 6 on the next page for further information on when you can expect to have a planned or additional inspection of your centre). Unannounced inspections can happen at any time of the day or night on any day of the week.

activity being undertaken in relation to each centre. Generally, this are at least two inspections in a three-year registration cycle.

⁺ The frequency of routine inspections may vary depending on which type of service is being inspected and other types of monitoring

Table 6. Frequency of planned and additional inspections

Older people, people with disabilities and special care units for children	Inspection frequency
All designated centres	Generally, centres will have a minimum of two inspections during each three-year registration cycle, one of which may include a planned announced inspection.
New designated centres	 Announced site-visit scheduled one month after the application to register is deemed to have been made. Inspection (generally unannounced) scheduled no later than six months after the registration start date.
New providers of an existing designated centre	Inspection (generally unannounced) scheduled no later than four months after the registration start date.
Additional inspections (usually unannounced)	 Scheduled as required by the regulatory plan* arising from: centres with high or moderate risk profiles representations escalation activity enforcement action receipt of information of concern (solicited or unsolicited).

^{*} See Chapter 6 on escalation for more information about the regulatory plan.

The 10 fieldworkevent steps

The 10 fieldwork-event steps are set out here in more detail. $^{\circ}$

Step 1. Scheduling the inspection

We conduct two types of inspections: announced and unannounced.

Announced inspections

Inspection findings are informed by people using the services. So one of the main purposes of announcing our inspections is to let residents, children, their families,[¥] relatives and or representatives know the time and date of our inspection so that they can meet us if they wish to do so.

Planned announced inspection

We give providers four weeks' advance notice of a planned announced inspection, so that they can let the residents and visitors (when public health restrictions are not in place) to the designated centre know when we will be arriving for the inspection.

As part of your notification, we will send you a poster announcing the inspection. Providers are asked to put up this poster in a prominent place in the centre in order to tell residents, children, relatives, visitors (if permitted where no public health restrictions are in place) and staff about the inspection and to invite them to meet with us during the inspection if they wish to do so.

We will also send you questionnaires to give to residents or children and relatives in advance of the inspection seeking their views on different aspects of day-to-day life in your centre. As part of the announcement of the inspection, providers are also asked to submit certain information, such as their safeguarding policy and risk management policy

Briefing on the questionnaire for residents and children

We will send out copies of the announced inspection questionnaire for residents or children to providers in advance of the inspection. The questionnaire is available to download on <u>www.hiqa.ie</u>.

If staff in the designated centre are assisting residents or children with the questionnaire or are completing it on their behalf, then the Chief Inspector expects that it should be completed from the perspective of the resident or child.

Residents, children in special care, or carers can also complete the form outside of the inspection process and send it to us. The questionnaire is only

^o During public health emergencies, we may change the on-site component of our fieldwork events in order to reflect public health precautions that may be in place. Whenever this happens, these changes will be communicated to providers.

⁴ From 31 March 2025, the definition of 'family' in the older people's regulations means a member of a resident's family, a close friend, a carer of a resident or a person involved in promoting the health, welfare and wellbeing of a resident.

one of the tools for the inspector to review the views and experiences of residents and assess the care being provided.

Resident-questionnaires assist the inspector in reviewing what it is like, from the residents' or children's point of view, to live in the designated centre.

Where to send completed

questionnaires

Older people and adults and children with disabilities

If the older person or disability centre is located in any of the 11 counties listed below, please send your completed questionnaire to: Regulatory Support Team, Health Information and Quality Authority, Unit 1301, City Gate, Mahon, Cork, T12 Y2XT:

- Clare
- Cork
- Donegal
- Galway
- Kerry
- Leitrim
- Limerick
- Longford
- Mayo
- Roscommon
- Sligo.

If the older person or disability centre is located in any of the following 15 counties, please send your completed questionnaire to: Regulatory Support Team, Health Information and Quality Authority, George's Court, George's Lane, Dublin 7, D07 E98Y:

- Carlow
- Cavan
- Dublin
- Kildare
- Kilkenny
- Laois
- Louth
- Meath
- Monaghan
- Offaly
- Tipperary
- Waterford
- Westmeath
- Wexford
- Wicklow.

Designated special care units

Designated special care units or children temporarily living in these centres or their families should send completed children's questionnaires to: Regulatory Support Team, Health Information and Quality Authority, George's Court, George's Lane, Dublin 7, D07 E98Y.

Directly to the inspector

Alternatively, providers, staff, residents, children or family members can give the completed questionnaire to the inspector on the day of inspection.

Short-notice announced inspection

We have also introduced what are called `short-notice announced inspections'. These will only be used in

exceptional circumstances. We will give between 24 and 48 hours' notice of these inspections in order to facilitate meetings with the provider or people managing the centre.

Unannounced inspections

All other inspections we carry out are unannounced. This means that neither the provider, person in charge nor any other person in the designated centre has been informed by us in advance either formally or informally of our inspection. The inspectors simply turn up at the centre to carry out the inspection.

Step 2. Planning the inspection

We plan for all inspections in advance in order to ensure that when our inspectors are on site, they gather relevant information and evidence in sufficient detail to make professional judgments on compliance with regulations and national standards.

The purpose of the planning stage is to plan the regulations and or standards to be inspected.

Lines of enquiry for inspections

The inspector will select lines of enquiry (the questions to be asked) for the inspection and will consider a number of factors including:

- what is already known about this centre
- information submitted by the centre during an application to register or to renew registration
- trending of unsolicited information received
- trending of notifications from the provider
- previous inspection reports
- open non-compliances with regulations and or national standards
- risk rating of those noncompliances
- what information is not answered during this lines-of-enquiry review.

The inspector will also assess the fitness of the provider and person in charge, either formally or informally on the day of the inspection, if relevant to the inspection or regulatory decisionmaking. You will be informed in advance of any formal assessments of fitness.

At this stage, some preliminary judgments can be made in advance of the inspection; for example, about notifications or the provider's statement of purpose.

Step 3. On-site inspection in the centre

We define this inspection as the on-site activity that our inspectors carry out, either in the designated centre or the office of the registered provider (for the purpose of reviewing files). An

inspection should last no more than eight hours a day, but processes are in place to allow for longer inspections.

An inspection has four distinct phases to it, and in some cases a fifth phase, as follows:

- a. Arrival at the centre.
- b. Gather evidence.
- c. Review of evidence and preliminary judgments on compliance with regulations.
- d. Provider feedback meeting.
- e. Responding to risk.

These phases are explained in more detail below.

(a). Arrival at the centre

On arrival, our inspectors introduce themselves and present their official `certificate of appointment / authorisation and personal identification' to the person they meet, the provider (if on site), the person in charge or their delegates or to staff.

Staff should always ask to see this identification document (which is in the style of a passport and is passport sized) before letting them enter the premises. Inspectors will always carry this identification document with them while on inspection.

At the start of the inspection, we will explain the purpose of the inspection.

In most cases, there will be a single inspector but sometimes there are two or more inspectors.

We ask that the person in charge informs both residents or children and staff that we are on site conducting an inspection and to introduce the inspectors to residents or children, where appropriate to do so. While inspectors have powers of entry and inspection, these will be exercised respectfully towards residents and children.

The inspector will walk around the centre with the person in charge to allow the person in charge to outline how the service is being delivered in line with the provider's statement of purpose. We will always respect children's or residents' personal space, privacy and dignity during this initial walk around the centre.

During the inspection, you can tell the inspector about improvements or changes you have made.

(b). Gather evidence

During an inspection, you should ensure you respond to requests for information in a timely manner and deal with all matters as outlined in these requests. You should also ensure all the required records are available for inspection.

During an inspection, we will minimise the time spent in an office reviewing documents and will normally try to

carry out a document review in a communal area, while undertaking indirect observation of the routine of the centre. We may look at any aspect of the service during an inspection.

In order to triangulate our evidence (verify from a number of sources) and make professional judgments, during the course of an inspection we will:

- talk and interact with residents or children, relatives and friends of their choosing, and staff members
- observe practices throughout the day or days of inspection
- observe the condition of the premises or centre
- review documentation
- speak with and obtain information from the person in charge or other manager.

Inspectors will use the **assessmentjudgment frameworks** and guidance on the assessment of designated centres to assist in this process. It is important to note that judgments on compliance are informed by the collective information and evidence gathered before, during and sometimes after the inspection.

Therefore, judgments may vary across centres operated by the same provider or since a previous inspection of the same centre was carried out. This may be due to a number of factors which inspectors consistently and impartially assess using the Authority's Monitoring Approach (AMA).

Assessmentjudgment frameworks

Under the Authority's Monitoring Approach (AMA), we have produced assessment-judgment frameworks for each area of residential care that we regulate: designated centres for people with disabilities; designated centres for older people; and designated special care units for children.

Providers and staff should ensure they are consulting the current versions (listed across). These assessmentjudgment frameworks are guidance documents to assist us with checking compliance and do not replace the professional judgment of the inspector or the requirements of the regulations.

They should also be used by providers to self-assess their own service.

Using the assessmentjudgment frameworks to improve

This handbook should be used by providers in conjunction with our assessment-judgment frameworks for designated centres for older people, people with disabilities, and special care units, and associated guidance for the assessment of these centres (see next entry).

While the assessment-judgment frameworks are used by inspectors in

gathering evidence and to support their decision-making, they should also be used by providers to self-assess their own services. You can search online for them or, at the time of writing, download them from our website at the following locations:

- Assessment-judgment framework for designated centres for people with disabilities: <u>https://www.hiqa.ie/reports-and-</u> <u>publications/guide/assessment-</u> <u>judgment-framework-disability-</u> <u>services-dcd</u>
- Assessment-judgment framework for designated centres for older people: <u>https://www.hiqa.ie/reports-andpublications/guide/assessmentjudgment-framework-designatedcentres-older-people-dcop</u>
- Assessment judgment framework for special care units (SCU): <u>https://www.hiqa.ie/reports-and-publications/guide/assessment-judgment-framework-special-care-units-scu.</u>

Using guidance to improve services

We have also published guidance on the assessment of designated centres for people with disabilities, older people and young people in special care, which can be found at the links below, or you can search online for them or view them on www.hiqa.ie.

- Guidance for the assessment of designated centres for people with disabilities (DCD): <u>https://www.hiqa.ie/reports-andpublications/guide/guidanceassessment-centres-personsdisabilities-dcd</u>
- Guidance for the assessment of designated centres for older people (DCOP): <u>https://www.hiqa.ie/reports-and-</u> <u>publications/guide/guidance-</u> <u>assessment-designated-centres-</u> <u>older-people-dcop</u>
- Guidance for the assessment of special care centres (SCU): <u>https://www.hiqa.ie/reports-andpublications/guide/guidanceassessment-special-care-centresscu</u>.

This guidance should be used in conjunction with the respective assessment-judgment framework. The guidance aims to provide extra supporting information to inspectors and providers on assessing compliance and offers guidance on reviewing each individual regulation and applicable national standard.

Each guidance gives greater detail on how both the Chief Inspector and a provider assess compliance and what an inspector might review during all the activities associated with the inspection, and the making of judgments about compliance.

Each regulation and the associated standard are described in five sections, namely:

- the standards associated with the regulation, where applicable
- what a rights-based quality service looks like (older people and people with disabilities)
- what a service striving for quality improvement looks like (special care units)
- examples of the information and evidence reviewed to assess compliance
- indicators which demonstrate levels of compliance with the regulations and standards sub-divided into compliant, substantially compliant and not compliant
- risk-rating of compliance.

The section on 'what a rights-based quality service looks like' and 'what a service striving for quality improvement looks like' are based on the standards and international research. They are intended to encourage those providers who have met the regulations to constantly strive for ongoing improvements in the quality of their services.

(c). Review of evidence and preliminary judgments on compliance

Once inspectors have gathered information and believe they have sufficient evidence to make a judgment about the level of compliance against each regulation or standard reviewed, they will make a preliminary judgment on compliance. They will also provide preliminary feedback to the provider and or person in charge and or other staff throughout the inspection.

While some regulations attribute responsibility to the person in charge to comply, overall responsibility rests with the registered provider. We make judgments on whether the registered provider or person in charge is: **compliant**, **substantially compliant** or **not compliant** with the regulations associated with the findings.

If for any reason there is insufficient information to make a judgment, the inspectors will revert to the second phase of the on-site inspection in the centre (as part of Step 3); that is to say, they will return to the 'gathering evidence' phase.

Assigning a risk rating

Once we have made a judgment on compliance, we will review the risk to residents or children arising from the non-compliance. Inspectors will report on this risk as being:

- High risk: there is high risk associated with the noncompliance.
- Moderate risk: there is moderate risk associated with the noncompliance.

What the judgment compliance levels mean

Compliant means the provider and or the person in charge is in full compliance with the relevant regulation.

Substantially compliant means that the provider or person in charge has generally met the requirements of the regulation but some action is required to be fully compliant. This finding will have a low risk-rating.

A judgment of **not compliant** means the provider or person in charge has failed to comply with a regulation and that considerable action is required to reach compliance.

Continued non-compliance or where the non-compliance poses a significant risk to the safety, health and welfare △ Lower risk: there is low or very low risk associated with the noncompliance.

Each regulation can be assigned a maximum risk-rating based on the severity of impact on residents or children and the likelihood of occurrence or reoccurrence of the risk.

Continued non-compliance resulting from a failure by a provider to put in place appropriate measures to address the areas of risk may result in escalated regulatory action.

of residents or children will be given a high risk-rating. In such cases, we will set a deadline for the provider to comply with the regulation.

Where the non-compliance does not pose a significant risk to the safety, health and welfare of residents using the service, it is risk-rated moderate and the provider must reach compliance *within a reasonable time frame*.

(d). Provider feedback meeting at the close of each inspection

The provider feedback meeting is the final phase of the on-site inspection. At the close of the inspection, we will give the provider and or person in charge or their delegate feedback on the findings and preliminary judgments. <image>

At a minimum, the provider (or delegate) and person in charge (or delegate) should attend this meeting. This phase is still part of the inspection activity and, therefore, any additional information that a provider or delegate gives to the inspector will be reviewed and taken into account.

Usually, these meetings should take an hour or less. Good practice and areas which require improvement are highlighted. 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.

(e). Responding to risk

Where we have identified an **immediate risk**, we will outline this to the provider and or person in charge and or person participating in management (PPIM) immediately. The person in charge and or other managers 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, both at the time of identification of the risk and again during the inspection feedback meeting. We will issue a compliance plan to the provider for the urgent risk within 24 hours of the completion of the inspection.

A designated centre is a person's home



We are conscious that a designated centre for older people and people with disabilities is a person's home and that, while inspecting, we are visitors in that home. We also take this approach with children and young people temporarily living in special care units. Although an inspection can be disruptive, we will apply the following principles during every inspection.

Every inspector will:

- adhere to HIQA's <u>Code of</u> <u>Conduct</u> when inspecting
- be fair and proportionate in their dealings with registered providers and their staff

- make time to meet and speak with residents, children and their relatives
- apply the regulations and standards in a balanced and even-handed manner
- not impede the ability of staff to care for residents or children
- be courteous and nondiscriminatory
- minimise disruption to the residents or children and staff members' normal routine.

Step 4. Writing up the findings

Inspection reports

We report on our inspection findings and judgments in an inspection report. The inspection report templates feature the following elements:

- about the designated centre
- what the inspector observed, and the views and experiences of residents, or
- the views and experiences of the children and young people in special care service
- capacity and capability of the registered provider to deliver a safe quality service
- quality and safety of the service
- compliance plan, if required, with the risk rating of all noncompliances against regulations, in order to improve outcomes for residents or children.

The inspection report aims to tell the story of what is it like to live in the centre and whether this is a good service or if it needs to improve. It also aims to tell the story of compliance with the national standards and regulations and how this impacts on residents or children. Judgments are described in the inspection report as:

- compliant
- substantially compliant
- not compliant.

The inspection report summarises the impact that our findings about the provider's leadership, governance and management has on the quality of life and safety of residents or children. It also outlines how the provider empowers and enriches residents' or children's lives.

The regulations have been categorised under two aspects which we call 'dimensions' and which are aligned with the relevant national standards. These dimensions are: 1. **Capacity and capability** and 2. **Quality and safety of the service**.

In writing the sections on capacity and capability and quality and safety, inspectors will consider the regulations and also reflect on the relevant national standards. More detail on the various sections of the inspection report is provided here.

Inspection report content overview

About the designated centre

This section will be taken from your statement of purpose.

What residents or children in special care told us and what inspectors observed

This section will be a fair, balanced and proportionate summary of responses to the residents' or children's surveys received before, during or after the inspection, and or our interactions with residents, children or staff, and our observations during the inspection.

It also describes in general terms what we have seen and heard throughout the inspection and how residents or children describe and talk about their daily lives, what it is like to live in the designated centre and how the registered provider and staff support them.

In this section, we are informing residents or potential residents, children living in special care, and their families about what life is like in the centre, through the lens of residents or children.

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

This section focuses on the overall delivery of the service and describes

how effectively it is assuring a good quality and safe service. There are **six critical elements** that determine the capacity and capability of a provider to sustainably deliver a good service. These are:

1. Effective leadership,

governance and management, with clear lines of accountability so that all members of the workforce are aware of their responsibilities and who they are accountable to.

2. Adequate resources are in place to support the effective delivery of quality care and support to people using the service.

3. A competent workforce,

including recruitment practices in the centre and how staff are supported through education and training.

4. How a provider uses, collects, evaluates and responds to information, which is in turn is used to positively inform, improve and sustain a quality service.

5. How services respond to adverse incidents and whether there are appropriate systems in place to underpin safe care and oversight of the service.

6. Compliance with regulations. In all cases, if a service lacks any of the above components or there are deficiencies in any of them, providers

will be challenged to sustainably deliver a good-quality service.

At the end of this section, the reader will know if this is a well-run centre, is well resourced, has competent staff, uses information to improve the quality of the service and is compliant with the regulations, or whether there are areas that require immediate or longer-term improvements.

An associated regulation section — located underneath the findings — lists:

- the regulation numbers and the areas they relate to
- the findings against the regulations, with examples of the evidence
- the judgments made.

Quality and safety of the service

The section on quality and safety of the service is about life in the centre for residents or children.

In this section of the report, the inspector is telling the reader how residents or children are supported and encouraged to live a rewarding life — and how their wishes and choices are respected.

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 environment in which they live and what residents or children and their families say about the service.

This section makes a judgment on the critical elements that determine the quality and safety of services for residents or children and includes how residents and children are:

- always to the fore, can make choices and are actively involved in shaping the services they receive
- empowered to exercise their rights, achieve their personal goals, hopes and aspirations
- receiving evidenced and humanrights-based outcomes and effective person-centred care and support
- able to live in a safe, comfortable and homely environment
- receiving food and drink that is nutritious
- supported to be in good health
- protected from any harm or abuse
- supported to develop and maintain personal relationships and links with the community
- able to access educational, training and employment opportunities
- in a centre that promotes their welfare, including how it recognises and effectively manages its service when things go wrong.

The regulations reviewed, with the findings, examples of the evidence and the judgments made are again set out underneath this section.



Compliance plan

This section of the inspection report details how you will reach compliance. For more on compliance plans, see Step 5 of the fieldwork event on the following pages.

Risk rating

All non-compliances with regulations are now risk-rated and listed in this section of the inspection report. This section identifies the regulatory requirement, the judgment made, the risk rating of the judgment, and the deadline for reaching compliance given to the provider for those high-riskrated non-compliances.

Rights-based approach to regulation when making judgments

When we inspect and make judgments on compliance, we will check how the level of compliance protects the basic human rights of the people using the service. These rights include dignity, fairness, equality, respect, autonomy, freedom to control one's own life and to effectively take part in decisionmaking which impacts on one's life.

When we make judgments, we ensure the evidence used to inform our judgment has come from all our accumulated evidence and reflects the overall judgment. We triangulate (verify) evidence from a number of sources, including feedback from people who use services, their relatives and professionals.

Step 5. Generating an inspection report

Inspection reports are a summary of our findings. Inspection reports do not need to reference all of the information reviewed by the inspector during the inspection. They are used to inform the provider and person in charge of their level of compliance and are also used to inform the public about what it is like to live in that centre or receive a service. They also tell the public about the service's level of compliance.

We include our regulatory judgments in our inspection reports. We may also, where appropriate, write a summary overview report of our findings resulting from a regulatory programme completed by the Chief Inspector in relation to a registered provider.

Compliance plan

Where we identify non-compliance with the regulations, we will issue a compliance plan template to you after the on-site inspection, when we are issuing the draft inspection report. We will ask the provider at that point to tell us in the returned compliance plan how and when they will comply with the relevant regulation or regulations.

Providers are advised to focus their compliance plan actions on the overarching systems they have in place to ensure compliance with a particular regulation, under which a noncompliance has been identified. They should change these systems as necessary to bring them back into compliance — rather than focusing on the specific failing identified.

The provider's compliance plan should be **SMART** in nature:

- **S**pecific to that regulation
- Measurable so that it can monitor progress
- Achievable
- Realistic
- Time bound.

Providers should ensure that they return a satisfactory compliance plan by email only, replying to the relevant team⁺. If you are not submitting feedback on the draft inspection report, you must return your compliance plan within 21 calendar days. If you are submitting feedback, then you have will have 5 working days to return the compliance plan after receipt of the final inspection report that includes any changes based on your feedback. Later, as part of our continual monitoring to assess compliance, we may ask providers to update us about how they are implementing their compliance plans submitted to us.

Please note that feedback on the draft inspection report and compliance plans are separate issues. Even if you submit feedback on the draft report, you must submit a fully completed compliance plan and continue to take any necessary remedial actions required.

It is the provider's responsibility to ensure that it implements the actions in the compliance plan within the set time frames. We will determine if the provider's response adequately assures us that the provider understands the regulatory failings and can address them within the time frame provided. Inspectors will move designated centres to escalation if they are not assured by compliance plans received.

The inspector will also check that the returned compliance plan does not contain unnecessary personal data relating to residents, children, staff or others in the centre. If it does, it is immediately rejected and deleted, and the provider is informed that it must submit a new plan without such unnecessary personal data contained in it.

People with disabilities — <u>dcd@hiqa.ie</u>

⁺ The team email addresses are:

Older people — <u>dcop@hiqa.ie</u>

Special care units — <u>children@hiqa.ie</u>.

If the returned compliance plan contains commentary which is unrelated to addressing the noncompliance but does not contain personal data as outlined above, such commentary will be removed prior to publishing the compliance plan in the published inspection report.

Whenever the inspector is not assured about the provider's understanding of the regulatory failing and the provider's ability to address the failing within the time frames outlined by us, we can decide what if any regulatory activity needs to be taken. This can include, but is not limited to, increased monitoring or escalation activity.

We monitor compliance plans until providers have demonstrated that all identified non-compliances have been addressed, sometimes long after the on-site inspection has taken place.

Where we have made a judgment of not compliant, the provider or person in charge must take considerable action to comply with the relevant regulation. Where the non-compliance does not pose a high risk to residents using the service, we will risk-rate it as a moderate risk, and the provider must take action within a reasonable time frame to come into compliance. This will be reflected in the compliance plan.

Where the non-compliance is persistent or poses a high risk to residents, providers will be given a **compliance deadline** in the compliance plan template we issue to them.

Step 6. Quality assuring the report

Our aim is to ensure that every report written is:

- fit for purpose
- right first time
- adheres to the principles of plain English.

Fit for purpose

Our fit for purpose model aims to tell the reader: what it is like to live in the designated centre; whether or not it is a good centre or if it needs to improve; if it complies with the regulations; and if care and support is of high quality and is safe, among other elements.

Inspection reports are fair, balanced and reflect good practice in the centre and where improvements are required. They show how residents are supported and encouraged to live a rewarding life, and how their wishes and choices are respected.

Under our fit for purpose model, different sources of evidence are cross-referenced, although not all evidence that informs judgments and which has been gathered by inspectors will be mentioned in the inspection report. Our inspection

reports will also reflect the following elements:

- 1. Judgments have been made, and these are in line with how we describe compliance levels.
- 2. Judgments are supported by findings and the judgments are proportionate to the findings.
- 3. The findings cited are supported by sufficient evidence, which is relevant to the finding.
- 4. The evidence to support the findings is recorded clearly by inspectors.
- 5. We have the legal remit to make such a judgment.

Right first time means the report is fair and accurate and is validly backed by evidence. It is also vitally important that providers, staff, people using services and the public are able to understand the reports. Therefore, **adhering to plain English principles** means the language in every report is to a high standard and is written in a way that the intended audience of the report can readily understand.

Step 7. Issuing a report to providers

At the time of this updated handbook, all providers of designated centres receive a 'draft' inspection report and later a final inspection report. The inspection report process is as follows:

- Draft inspection report: report is issued to the provider for feedback (right of reply) following the inspection.
- Final inspection report: this is a copy of the final report which is prepared following the receipt and consideration of feedback, if received, from the registered provider. A decision on publication of the final report will be made by in line with our processes.

Issuing a draft report to providers shortly after an inspection informs providers of our findings and judgments and provides an opportunity for them to consider these findings. Preliminary findings will have been given verbally by the inspector or inspectors during the close-out meeting at the end of the inspection.

When the draft inspection report is issued to the provider, it will also include a feedback form and icompliance plan template, if such a plan has been issued to it. The draft inspection report will outline areas of good practice and those areas requiring improvement or areas of risk, if identified.

Providers have the right to provide feedback on perceived factual inaccuracies and on inspectors' regulatory judgments made in the report. Providers have 21 calendar days to provide feedback on a draft inspection report.

The feedback on a draft inspection report should not be used for matters which do not relate to factual accuracies or regulatory judgments in the draft inspection report, or matters dealt with under other processes.

Step 8. Managing feedback from centres

Feedback from a provider

The Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 amends the Health Act 2007 to set out a time frame of **21 calendar days** by which a provider can give written feedback on draft reports.

If you believe our regulatory judgments are incorrect or not proportionate to the evidence reviewed by the inspector or there are factual inaccuracies in the body of the draft report, you may choose to submit feedback to us. We welcome such feedback.

In the first instance, you should engage with the lead inspector and or author of the report (if they are different people) by phone or email to discuss your specific concerns or queries about the regulatory judgments in the draft inspection report. A single opportunity is provided to reply to the draft inspection report using a feedback form.

The feedback form and — where we identify non-compliance with the

regulations — the compliance plan template will be sent together in the same email when we are issuing the draft inspection report.

Following consideration of your formal written feedback provided on the feedback form, we may amend the report if deemed appropriate and in line with our standard operating procedure. If the provider does not engage in the feedback process, a final inspection report will be issued to it in due course.

Outside the scope of the feedback process

Any matters raised in the new feedback process that are unrelated to the findings of the inspection or judgments on compliance with the regulations will be rejected, such as the following:

- legal arguments or commentary about the provisions of the Health Act 2007 as amended and in particular section 2 or Parts 7 to 10 of the Health Act 2007 as amended
- any commentary not related to either factual inaccuracies or the regulatory judgments contained within the draft inspection report
- any feedback on a final inspection report
- any reference to any other designated centre, any other registered provider or third party adviser or consultant or to advice

provided by such adviser or consultant

 correspondence issued to a registered provider not related to the inspection and or correspondence issued to any other registered provider.

Matters dealt with under other processes:

- any matter which is or has been the subject of an independent inquiry or legal proceedings
- any matter relating to a third party who believes they are adversely mentioned in an inspection report; for example, a visiting health professional[±]
- any matter relating to the conduct of inspectors of social services (inspectors)[‡]
- any matter previously dealt with under the HIQA Complaints Policy
- any written representations made by a provider to a notice of proposed decision of the Chief Inspector under the Health Act 2007 (as amended)
- any submission from a provider's representative body on an issue of general concern
- any unnecessary personal data relating to a resident, a staff member or any other person. The

registered provider should ensure that all unnecessary personal data is removed from the feedback form prior to submitting it to the Chief Inspector.

If written feedback has been received, it is considered and may be accepted, rejected, or partially accepted. The draft inspection report may or may not be amended, including changes to judgments, arising from the feedback. The final report will then proceed for a decision on publication and be issued to the provider for information. At this stage, the provider cannot give any further feedback on the final report as the decision of the Chief Inspector, Deputy Chief Inspector or delegate is final.

Step 9. Approving the inspection report

Once we have considered the feedback from providers on the draft inspection report, we will finalise the report and the Chief Inspector, Deputy Chief Inspector or delegate will make a decision on publication.

Step 10. Publishing the report

We publish inspection reports and compliance plan response on our

[±] Any person who believes himself, herself or themself affected in this way should raise the matter directly with the inspector who is responsible for compiling the report.

⁺ These matters will be dealt with under HIQA's Complaints Policy.

website. An inspection report will not become publicly available until after it has undergone internal checks to ensure that the information contained is accurate, balanced and proportionate.

The length of time between the inspection and the report being published will be determined by a number of factors, making it difficult to give an exact date for any given centre. Providers should make reports available to residents or children and family members on request.

You will be notified by email when the report will be published. As we may have made changes to the reports issued to providers, the final report is issued to them for their information in advance of being published.

Inspection of your centre conclusion

The inspection of a designated centre is not just an on-site event that takes place in the designated centre over one, two or more days. It involves many steps, including desktop reviews of information and processes by the inspector, before, during and after the on-site inspection itself.

The inspection report outlines whether or not a centre is compliant with a regulation (or national standard in the case of a thematic inspection) and how this impacts on residents. The report strives to give greater voice to people using services and what it is like for them to live in the centre.

Meanwhile, under the Authority's Monitoring Approach, there are compliance plans, which remain actively monitored until you have addressed all identified noncompliances, in some cases long after the on-site inspection has taken place. The provider must implement the actions within the set time frames.

There are also processes in place to enable providers and staff to communicate with us, particularly around concerns they may have about our regulatory judgments. We promote fair and transparent regulation by operating a formal feedback process.

We will always prioritise the rights of people using services but believe our approach to the inspection and resulting inspection report is fair, proportionate, and accurately informs both the public and provider about compliance with the regulations and national standards.



Chapter 6. A guide to our escalation procedures



Introduction to our escalation procedures

We recognise things can go wrong in the delivery of social care. Therefore, our approach is focused on how providers respond to incidents, risk and non-compliances with the Health Act 2007 as amended, regulations and national standards and how they manage these issues.

This section of the handbook outlines how the Chief Inspector responds to circumstances which may reflect a regulatory risk to the safety and quality of life of people living in designated residential centres, arising from poor compliance with:

- the Health Act 2007 (as amended) (`the Act')
- regulations and national standards made under the Act.

What actions can be taken if a residential service is not safe?

If our inspectors find that the residential service is not safe or the regulations and national standards are not being met, we can take a number of steps including:

- attaching additional conditions to registration of a designated centre
- varying existing conditions of registration
- requiring changes be made and checking that these are carried out
- cancelling the registration of the designated centre
- prosecuting for offences under the Act.

Monitoring

We define monitoring as the routine oversight and regulation of designated centres to assess compliance with regulations and standards. This includes reviewing, analysing and riskrating information in order to assess compliance with regulations and or standards.

What is escalation?

The Chief Inspector defines escalation as increased regulatory activity up to and including the decision to take enforcement action due to:

- concerns about the quality and safety of care being delivered to residents or people using services
- poor compliance by providers with their obligations under the Act and associated regulations and or standards.

Principles of good escalation

We closely consider the impact on people using services from our escalation measures. Fundamental to any decision we make on regulatory activity is proportionality. Therefore, the principles underpinning our escalation processes are that:

- we deal swiftly with noncompliance
- our regulatory activity is proportionate to the risk profile
- we recommend the most appropriate action
- we ground our decisions in evidence
- our decisions are based on sound, reasoned judgment of all evidence related to a designated centre where there is a concern
- our response is the most appropriate activity to undertake in order to 'answer' questions our inspectors have about a centre.

Internal escalation and external escalation

Escalation is twofold: **internal** and **external**.

Internal escalation is how designated centres or services of concern are discussed within the Office of the Chief Inspector of Social Services in order to determine the best course of regulatory action to bring the provider back into compliance.

It includes deciding on the appropriate regulatory activities needed in order to prevent centres drifting away from complying with the regulations and national standards.

External escalation is the Chief Inspector's interaction with registered providers when there is concern about poor compliance. It covers potential or actual actions the Chief Inspector intends to take. It is also about how inspectors may inform other interested parties of risk within a designated centre or service.

Guide to internal escalation

There are six steps which the Chief Inspector will take in deciding on an internal escalation response. These are:

- 1. Risk profile of the designated centre.
- 2. Internal 'case-review' meeting to critique concerns about a centre.
- 3. Increased regulatory activity.
- Monitoring, reviewing and making judgments on responses from a provider.
- 5. Making recommendations to take enforcement action if the problem is not resolved.
- 6. Reconvening a case review to close the escalation or move to enforcement.

These steps are discussed in more detail below.

1. The centre's risk profile

The Chief Inspector maintains an upto-date regulatory risk profile of all designated centres — in effect, the overall risk rating of a centre — which is fundamental to our decision-making on regulatory interventions, including escalation of a centre at risk.

Based on the risk profile, and in line with our risk-based approach to regulation, we target our resources where they are needed most. (See Chapter 3 on *Governance and a riskbased approach to regulation* for more on risk.)

Regulatory plan

Every designated centre has a regulatory plan which includes how often we will inspect it and how often we will seek information from it, such as compliance plan updates or annual quality reviews. The regulatory plan is determined by the level of regulatory risk the centre poses. In other words, how well the centre is governed and how compliant the provider is with the regulations and standards.

Lower-risk centres

Designated centres that the Chief Inspector has determined to be lower risk are managed by the case-holding inspector and are routinely discussed with their regional managers. Regional managers will in turn assure their line managers that they are satisfied that these centres:

- are being risk-rated appropriately
- have appropriate regulatory and monitoring plans in place
- are implementing these plans.

Moderate-risk centres

Designated centres that are determined to be of moderate risk face increased regulatory activity, the nature of which will be decided at case review meetings by the case-holding inspector and their regional manager. We provide regular assurance about these moderate risk-rated centres to our Deputy Chief Inspectors, which will include:

- these centres or services being discussed at a case-review meeting
- regulatory activity, which is proportionate to the risk, being started or is under way
- recommendations on next actions with a clear time frame for review.

High-risk centres

Designated centres that are determined to be high risk will be subject to automatic case review by inspectors and senior managers.

2. Case review

Designated centres that are deemed to be moderate to high risk are reviewed and discussed at an internal casereview meeting. At these meetings, inspectors discuss concerns about a centre in order to:

- draft a time-bound regulatory plan (such as seeking a compliance plan update) or
- make a regulatory decision, such as:
 - attaching conditions to registration or enforcement
 - deciding to take a prosecution
 - taking no further action and closing the case-review process.

We take into account all information about the centre or service when deciding on a regulatory plan (see Chart 5), which will contain actions that the provider must take within set time frames. In due course, the inspector will review the progress made by the provider against these actions and will reconvene the case review.

The actions we take aim to ensure the centre complies with the regulations and standards and will improve the safety and quality of life for people using its services. When issues are resolved, the centre will return to routine oversight and regulation.

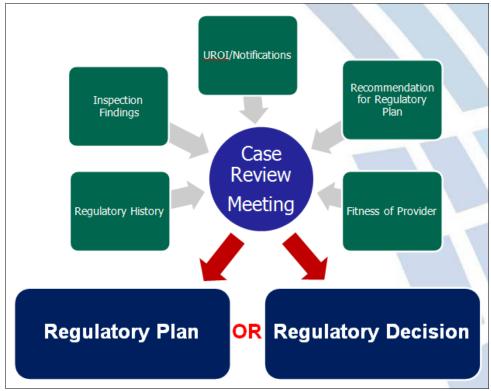


Chart 5. Case review

UROI = unsolicited receipt of information.

3. Increased regulatory activity

In deciding whether to start increased regulatory activities, such as escalation, our main focus is to bring about compliance and ensure the safety of residents or children. Our escalated regulatory activity options include:

- carrying out a risk-based inspection
- seeking further information, such as a compliance plan update or assurance report
- inviting the provider to attend:
 - a cautionary provider meeting
 - a warning provider meeting
- issuing a warning letter
- asking the provider for information under the Chief Inspector's statutory powers under section 65 of the Act
- reassessing the fitness of the provider or persons participating in the management of the designated centre.

These are discussed further in the section on **External escalation**.

Referring a centre or service to other agencies

During the course of our work, the Chief Inspector may have concerns that should also be notified to other relevant agencies or regulators, for example, An Garda Síochána (Ireland's National Police and Security Service) or the Health and Safety Authority.

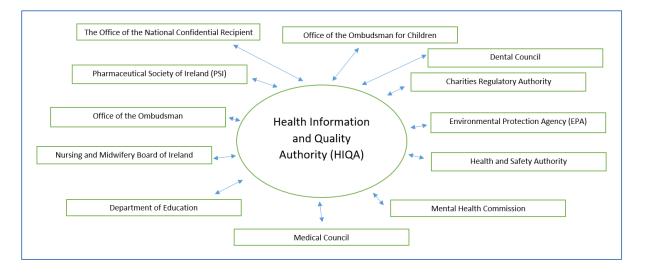
In such cases, inspectors will make these referrals to other agencies in line with data protection law and any information sharing or cooperation arrangements which HIQA has in place with other agencies (see Chart 6).

Confidential information

Wherever possible, the Chief Inspector will anonymise information before sharing it with other agencies. In circumstances where the personal data of a service user (such as a resident) is shared as part of a referral, we will only do so with the consent of the person.

We do not require the consent of a health and social care professional when we make referrals to, or raise concerns with, another regulator regarding the person's fitness to practise or whenever we share personal data about that individual when doing so. However, in such circumstances, we will inform in writing the person who is the subject of a fitness-to-practise referral or concern to another agency that we have done this.

Chart 6. Sample of information sharing arrangements under memorandums of understanding (MOUs) between HIQA and other agencies



Monitor, review and make a judgment on provider's responses and information

After the inspector, regional manager and Deputy Chief Inspector (as required) decide on a regulatory plan (activity) or make a regulatory decision, inspectors monitor and reassess the risk associated with the non-compliances. This will be based on the responses by the provider or any additional information obtained.

Our inspectors will reconvene a casereview meeting in order to agree a recommendation on the next steps. Where we are not satisfied with the response or information from the provider, the centre or service will remain in escalation or a regulatory decision will be made.

5. Making a recommendation to take enforcement action

Where a provider has failed to improve the service or if any improvements made were ineffective, a decision on enforcement action may be taken. Enforcement action is used to improve services in order to protect residents or children and to hold the provider and others working in the centre to account for their past failure to comply with the Act, regulations or a condition of registration. See Chapter 7 for more on enforcement.

6. Closing a case review

The Chief Inspector will reconvene a case review to close the escalation or move to enforcement. A case review is closed when the regulatory risk assigned to that centre has reduced.

Guide to external escalation

Introduction to external escalation

External escalation refers to how the Chief Inspector tells providers that their level of compliance with the Act and or the regulations and standards is poor and that their centre or service has been placed on an escalation pathway. This can be done in a number of ways, including:

- verbally during the preliminary feedback process at the end of an inspection
- during a cautionary provider meeting
- in writing through a warning letter.

Depending on the circumstances and the assessment of risk, the regulatory actions available as escalation options[#] are set out in Table 7.

Table 7. Escalation options available to the Chief Inspector for centres ofrisk

Regulatory activity or action	What does this mean for you?
Focused risk-based inspection	 A risk-based inspection will focus on non-compliances and will include follow up on all high or moderate risk- rated non-compliances. This activity is chosen where: there are concerns as to the level of compliance with the regulations or national standards a provider's compliance plan indicates that improvements have been made and a focused risk- based inspection is required to verify this. Providers will be verbally advised of poor compliance at the end of an inspection.
Cautionary provider meeting	This is a meeting between a case-holding inspector and his or her regional manager from the Chief Inspector and a provider. Its purpose includes communicating the risk and the required actions to be taken.
Warning provider meeting	This is a meeting between the relevant Deputy Chief Inspector and or regional manager; the case-holding inspector; and the provider. This meeting has a number of purposes, including to communicate the risk and the required actions to be taken and to issue a formal warning letter to the provider.

[#] This is not a hierarchy of options nor is each activity mutually exclusive.

Regulatory activity or action	What does this mean for you?
Warning letter	The warning letter reiterates the actions required and explicitly outlines the measures that will be taken if the provider does not implement the required changes within the stated time frame. All warning letters have a specified time frame.
Section 65 request for information	This is used where the provider has failed to submit previously sought information to the Chief Inspector or where the information is sought urgently in response to risks. The Health (Miscellaneous Provisions) (No. 2) Act 2024 has amended section 65 of the Health Act 2007. Now, the registered provider must submit information under section 65 in such manner and form as the Chief Inspector requires.
Provider-assurance report	A provider-assurance report or Regulation 23 quality and safety annual report (where applicable) may be sought from the provider. This is done where the provider has made some progress but the Chief Inspector requires further assurances. It can be used where the provider has demonstrated compliance previously but the degree of risk requires an assurance response. See below for further details.
Recommendation to take enforcement action	Enforcement action will be recommended by the Chief Inspector wherever a provider has failed to improve practice sufficiently and in a way that ensures the safety and welfare of residents.
Refer to other agencies	Sometimes, we may notify our concerns to other agencies that have a statutory responsibility for a particular area; for example, An Garda Síochána, the Health and Safety Authority and so on.

Provider-assurance report

A centre does not have to be in escalation for us to request a provider-assurance report.

However, in escalation, we may request such a report where the provider has made some progress and has demonstrated compliance previously, but the information is of such a serious risk that further assurances are required.

We will issue the provider with a provider-assurance report template detailing the regulations and or standards where assurances are required. We will set out the frequency of how often such a report should be returned to us and the date or dates they should be sent to us.

The provider is asked to explain how it will comply with the regulations and standards listed by the inspector.

Satisfactory providerassurance reports

If we are satisfied with the provider's assurance report and believe it will address the identified non-compliances in a timely manner and areas where quality improvement is needed, the centre will revert back to routine monitoring after discussion at a casereview meeting.

Unsatisfactory providerassurance reports

If we believe the provider-assurance report fails to quickly address noncompliances and areas which need to improve, we will convene a further case-review meeting. The centre will remain on an escalation pathway and further actions may be taken.

Overview of cautionary provider meetings

At cautionary provider meetings, providers are given a verbal warning when the Chief Inspector is dissatisfied with the provider's actions to reduce identified risks or to comply with the regulations and or national standards.

At these meetings, the Chief Inspector is represented by the case-holding inspector and his or her manager. These meetings aim to:

- inform the registered provider of the exact nature of the continued non-compliance and areas of concern
- put the registered provider on notice of the possible legal consequences of the continued non-compliance
- tell the registered provider what needs to be done and the time frame that it needs to be completed in
- ask a registered provider to submit an updated compliance plan with deadlines in order to comply with regulations and national standards
- give the registered provider a fair opportunity to put its case forward before the Chief Inspector's representatives.

The Chief Inspector will issue a note of this cautionary provider meeting including any actions agreed between the provider and inspectors — to the registered provider within **five working days** of the meeting.

Overview of warning provider meetings

We issue providers with a formal written warning at these meetings. These meetings are attended by the case-holding inspector; the relevant Deputy Chief Inspector and or regional manager; and the provider. A senior representative of the Chief Inspector chairs the meeting. The purpose of the warning provider meeting is to:

- tell the provider that enforcement action will be started should the provider fail to address the noncompliances and areas of risk
- outline the relevant provisions in the Act to ensure that the registered provider is:
 - fully aware of its legal obligations
 - fully aware of the consequences of continued non-compliance
- set out and explain the exact nature of the non-compliances
- ensure the registered provider understands the issue being communicated
- give the registered provider a fair opportunity to respond to the issues outlined
- hand the formal warning letter to the provider during the meeting.

The Chief Inspector will issue a note of this warning meeting — including any actions agreed between the provider and inspectors — to the registered provider within **five working days** of the meeting.

The warning letter

A warning letter is used by the Chief Inspector to clearly inform providers that they are failing to meet their obligations under the Act and or regulations.

The warning letter will detail what specific regulations are not being met. It will spell out the legal consequences of providers not satisfactorily addressing an identified noncompliance, such as attaching a condition to the provider's registration.

Time-bound actions that the provider must take are contained in the warning letter. We will follow up on this meeting by carrying out a scheduled reassessment of the actions taken or not taken.

Assessing if a provider is making progress

Inspectors will assess the progress that the provider is making against the actions and timelines in the warning letter. They will do this by seeking updates from the provider or conducting an inspection.

Section 65 requests for information

Under section 65 of the Health Act 2007 (as amended), a provider shall give the Chief Inspector information which is considered necessary to

support the Chief Inspector's functions. However, we will only request information that is necessary and is reasonable to request.

These requests will be in letter format by registered post and may also be issued by email. The Health (Miscellaneous Provisions) (No. 2) Act 2024 has amended section 65 of the Health Act 2007. Now, the registered provider must submit information under section 65 in such manner and form as the Chief Inspector requires.

Section 65 is only used in limited circumstances and only when certain criteria are met. We will send a request for specific information under section 65 when:

- the request directly relates to the functions of the Chief Inspector
- no response has been received from the registered provider to a previous request to submit information.

Under section 79(2) of the Act, it is an offence for a registered provider to fail to provide information requested under section 65 of the Act.

Additional information that may be requested from a provider

Annual review report

The older people care and welfare regulations, disability care and support regulations, and special care unit care and welfare regulations all require providers of designated centres to produce an annual review of the quality and safety of care and support in the centre.

In addition, the 2013 disability regulations and the 2017 special care unit regulations require registered providers, or a person nominated by them, to carry out an unannounced visit to the designated centre at least once every six months and prepare a report on the visit.

The report of these requirements is called the 'annual report'. During escalation, inspectors will review the annual report along with a providerassurance report where the provider has made some progress, but we still require further assurances.

To assist providers in undertaking the annual review, we have created report templates for them to use for this purpose. These were updated in April 2023 to include the date range for the annual review period. These templates are available on our website as follows:

 Disabilities — Annual Review Report: Assessing performance against the national standards for residential services for children and adults with disabilities: Regulation 23(1)(d):

<u>https://www.hiqa.ie/reports-and-</u> publications/guide/annual-reviewreport-regulation-23d-disability</u>

- Older people Annual Review Report: Assessing performance against the national standards for residential services for older people in Ireland: Regulation 23(d): <u>https://www.hiqa.ie/reports-andpublications/guide/annual-reviewreport-regulation-23d-older-people</u>
- Special Care Annual Review Report: Assessing performance against the national standards for Special Care Units: Regulation 24(d): <u>https://www.hiqa.ie/reports-and-</u> publications/awido/org.assessing

publications/guide/scu-assessingperformance-against-nationalstandards-special-care.

We have also developed templates for the six-monthly unannounced visits by the registered provider (or a delegate) to designated centres for people with disabilities or special care units, which are available on our website as follows:

 Regulation 23: Six-monthly unannounced visit to designated centre — Report on the quality and safety of care and support and plan to address any concerns with regard to the standard of care and support in residential services for children and adults with disabilities. Regulation 23(2)(a)(b): https://www.hiqa.ie/sites/default/files/ 2017-02/Reg-23-six-montly-visit-DCD.pdf

 Regulation 24: Six-monthly unannounced visit to designated centre — Report on the quality and safety of care and support and plan to address any concerns with regard to the standard of care and support in special care units for children. Regulation 24(3)(a)(b): https://www.hiqa.ie/sites/default/files/ 2018-07/Reg-24-six-montly-visit-DCSC_0.pdf.

In addition, registered providers of nursing homes are required to make the annual report available to residents and the Chief Inspector. The registered provider is also required to develop and implement a quality improvement plan to address issues highlighted by the annual review.

Escalation conclusion

The Chief Inspector deploys a range of proportionate escalation measures to ensure the safety and quality of life of people living in regulated designated centres — giving providers ample opportunity to comply with regulations and standards.

At all times, we will clearly communicate with providers about our regulatory response. Therefore, when there is a drift away from compliance

with regulations and national standards, we will clearly tell providers what they need to do, when they need to do it, and why they need to do it.

Providers must meet the requirements of the Act and regulations. They must be aware of the legal consequences of continued non-compliance with these requirements, up to and including refusal or cancellation of registration or being prosecuted for an offence under the Act.

However, the Chief Inspector is mindful of the need to avoid unnecessary distress to people using

Your notes

services as a result of such drastic measures and will always work with providers to ensure that escalation works to reduce immediate risks and bring about sustainable improvements into the future.

It is important to stress that compliance with the regulations by providers is a minimum requirement. In order to improve the quality and safety of social care services, service providers are encouraged to look beyond the regulations and to continually try to improve their services to residents or children.

Your notes

Your notes

Chapter 7. Guide to powers of enforcement



Introduction to enforcement

If we come across a situation where there is a serious risk to residents or to children in a special care unit which the provider is unwilling or unable to rectify without delay, we can take enforcement action. This may ultimately result in a decision by the Chief Inspector to close a designated centre.

This section of the handbook will outline the Chief Inspector's powers of enforcement and identify the grounds for exercising these powers. It will also set out how we communicate with providers in such cases. Because proportionality is fundamental to our approach to regulation, the level of enforcement action taken:

 will reflect the risk to residents and children associated with the noncompliance

- is deemed to be the most balanced and appropriate response
- is based on evidence related to that centre or service.

Definition of enforcement

We define enforcement as using our statutory powers to:

- bring about improvements in order to protect people using services
- prevent a provider from continuing to provide a service that is non-compliant with regulations and national standards and is not safe and
- hold a provider (or other people involved in the management of a centre) to account for noncompliances with the Act or regulations.

The Chief Inspector is committed to working with providers in the best interests of people living in designated centres and will support providers to

reach and exceed compliance with the regulations. With this in mind, a stepped approach to enforcement will normally be adopted.

However, this stepped approach does not preclude the Chief Inspector from moving directly to legal action, including prosecution, if the circumstances warrant such action. We will take a firm but fair approach in carrying out our enforcement activities when all other means of bringing about improvements in the designated centre have failed or there is a serious risk to the health and welfare of residents or children.

The Chief Inspector will take into account the likely impact of regulatory action (to include enforcement action) on people who use services, their carers, families and the wider community when deciding what kind of action to take. We will enforce in a way that is:

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

As described in Chapter 6, we will take a number of regulatory actions to bring about improvements. These include:

increased monitoring[^] and focused inspections

- seeking provider-assurance reports
- convening warning meetings and issuing warning letters
- making requests for information under section 65 of the Act.

However, we are likely to take enforcement action if:

- the failure of the provider to comply with regulations is having a serious impact on the health, safety or quality of life of people living in the centre
- the failure of the provider to comply with regulations poses an unacceptable risk to residents or children
- the provider has persistently failed to comply with the regulations and national standards
- the provider is carrying on the business of a designated centre outside of the conditions of registration.

We have statutory powers under the Act to take a prosecution, if necessary, and can seek a court order to enforce decisions of the Chief Inspector (under section 58 of the Act). Following a decision of the court, we will closely monitor the level of care in the centre against the regulations and national standards. A number of our regulatory decisions and enforcement powers, and the legal basis for them, are summarised in Table 8.

[^] Where the Chief Inspector refers to 'monitoring' in this handbook, it includes: inspection, review of information submitted by the centre, information held about the centre and ongoing review of

information. This is all taken into account when the Chief Inspector is assessing compliance with regulations and standards.

Table 8. Statutory enforcement actions that can be taken by the ChiefInspector

Regulatory decisions and enforcement powers	Legal basis under the Health Act 2007 (as amended)
Refuse to register or renew the registration of a designated centre	Section 50
Vary or remove a centre's condition of registration	Section 51
Attach an additional condition of registration	Section 51
Cancel a centre's registration	Section 51
Issue a Compliance Notice	Section 78A
Apply to the district court for an order to enforce a decision under section 50, 51 or 52 (section 52 deals with applications by providers to vary or remove a registration condition)	Section 58
Urgent application to the district court (with notice to the provider) to cancel registration or vary, remove or attach additional conditions of registration	Section 59
If the risk is immediate, ex parte emergency application to the district court (without notice to the provider) to cancel or vary, remove or attach additional conditions of registration	Section 60
Sets out the offences under the Act	Section 79
Allows the Chief Inspector to bring summary proceedings for an offence	Section 80

Table 9 sets out enforcement measures that are used to protect people using services by bringing about improvements through the use of our legal powers. Enforcement action can also be taken to hold the provider and other people participating in the management of a centre to account for failures to comply with the Act and regulations, and these measures are also included in Table 9.

Table 9. Enforcement action using legal powers to secure improvementsand to hold the provider and others to account for non-compliancewith the Act and regulations

Regulatory decision to take enforcement action	Circumstances where we recommend a regulatory decision
Section 49 of the Health Act 2007 (as amended)	Under the Health (Miscellaneous Provisions) (No. 2) Act 2024, the Health Act 2007 is amended to allow the Chief Inspector to include on the public register details of any fines or other penalties imposed on a registered provider under the Health Act 2007.
Section 50 of the Health Act 2007 (as amended) Refuse to register or renew the registration of a designated centre	 Where the Chief Inspector is not satisfied that: the registered provider or intended registered provider and each person who will participate in the management of the designated centre is fit to be the registered provider and to participate in its management and that the application will comply with or, if for renewal, is in compliance with: the national standards the regulations any other enactment that appears to be relevant, and is cited by the Chief Inspector.
Section 51 of the Health Act 2007 (as amended) Vary or remove conditions of registration	Where there is a moderate or high risk-rating as a result of non-compliance with the regulations and the variation or removal of the condition will bring about the necessary improvements to reduce risk and to safeguard the safety and welfare of residents or children.
Section 51 of the Health Act 2007 (as amended) Attach a new condition of registration	Where there is a moderate or high risk-rating as a result of non-compliance with the regulations, an additional condition may be attached to limit what the provider can do or provide in order to bring about compliance.
Section 51 of the Health Act 2007 (as amended)	The power to cancel the registration of a designated centre is only relied on when the level of risk to the residents or children is unacceptable because:
Cancel registration	 the provider has failed (despite being given an opportunity) to improve its service in order to comply with the regulations and national standards

Regulatory decision to take enforcement action	Circumstances where we recommend a regulatory decision
	 the provider or person participating in management is no longer considered to be a fit person under the Chief Inspector's assessment of fitness processes the provider has been convicted of an offence under the Act.
Section 58 of the Health Act 2007 (as amended) Enforcement order	If the Chief Inspector believes on reasonable grounds that any person is carrying on the business of a designated centre in contravention of a decision under:
	 Section 50 or 52 to refuse an application Section 50 or 52 to grant an application subject to any conditions Section 51 to cancel, vary or remove any condition to the registration or attach an additional condition to the registration,
	the Chief Inspector may apply to the district court under section 58 of the Act where the court may issue an order to enforce a decision of the Chief Inspector.
Sections 59 and 60 of the Health Act 2007 (as amended) Urgent and immediate	These are applications to the district court to cancel registration or to vary, remove or attach additional conditions of registration. These actions will be taken where there is evidence of a risk to the life of residents or children or a serious risk to the health and
action	welfare of residents or children because of any act, failure to act or negligence by the provider or a person acting on the provider's behalf.
	These actions may be taken on notice to the provider (section 59) if urgent, or taken ex parte (without notice to the provider) (section 60) if the risk is immediate.
Section 73A of the Health Act 2007 (as amended)	Under the Health (Miscellaneous Provisions) (No. 2) Act 2024, the Health Act 2007 is amended to give the right of entry and inspection for unregistered designated centres.

Regulatory decision to take enforcement action	Circumstances where we recommend a regulatory decision
Section 78A and B of the Health Act 2007 (as amended)	Under section 78A of the Act, the Chief Inspector may issue a compliance notice to the registered provider of a designated centre for older persons or a designated centre for persons with disabilities, where there are non-compliances with regulations or with certain sections of the Act. The compliance notice will set out the nature of the non-compliance and will contain directions from the Chief Inspector for the provider to carry out certain actions, or to refrain from certain actions by a specified date. The provider will have 14 calendar days to to appeal the compliance notice to the district court. Failure to comply with the compliance notice by the specified date is an offence under the Act. Under Section 78B, the Chief Inspector can maintain and publish a list (a register) of compliance notices. These new provisions include any associated fines or other penalties.
Sections 79 and 80 of the Health Act 2007 (as amended)	The Chief Inspector has the power to prosecute under section 80 for certain offences outlined in the Act and the regulations made under it.
Offences and prosecution	Prosecution is a serious enforcement action, and it holds registered providers and any person to account for not complying with legal requirements. It aims to punish wrongdoing, to avoid a reoccurrence and to act as a deterrent to others.

Section 51 — Administrative enforcement

Cancelling, varying, removing or imposing new registration conditions on registered designated centres



We now look at section 51 of the Health Act 2007 (as amended), which gives the Chief Inspector powers under certain circumstances to cancel a designated centre's registration, vary or remove conditions of registration, and or attach new conditions of registration to the centre.

Scope of section 51

Section 51 allows the Chief Inspector to take administrative enforcement action. Section 51 enforcement actions can be to:

1. Vary an existing condition of registration.

- 2. Attach a new condition of registration.
- 3. Remove a condition of registration.
- 4. Cancel the registration of a designated centre.

Section 51A allows the Chief Inspector to remove conditions of registration where it is appropriate in the circumstances and where it will not adversely affect residents living in the designated centre, or young people temporarily living in special care units. For more information relating to section 51A, please refer to Chapter 2 above.

Grounds for using section 51 powers

The grounds for using the powers under section 51 to vary, remove or attach new conditions of registration or cancel a designated centre's registration are as follows:

- Ground 1: the provider or person participating in management has been convicted of one or more of the following:
 - an offence under the Act
 - an offence under any law deemed to be relevant and cited by the Chief Inspector and noted on the registration certificate
 - an offence under the Child Care Act, 1991
 - an offence against the person.
- Ground 2: that in the opinion of the Chief Inspector, the provider or person participating in management is not a fit person to be the provider or to be involved in managing the centre.
- Ground 3: the centre is being run, or has been run at any time, contrary to:
 - any requirement or operating condition imposed by or under the Act or
 - other statutory provisions that the Chief Inspector considers to be relevant.

Information relating to the above grounds may become apparent to the Chief Inspector at any stage of the registration cycle; for example, while inspecting a centre; from information received in notifications or from the public; or through assessing compliance with regulations and standards.

Section 51 versus section 50 powers

While both sections contain some similar powers, these sections are separate and distinct from each other, including the legal grounds for exercising those powers. Section 50 only applies when there is an active application to renew registration or to register for the first time. In such circumstances, section 50 gives the Chief Inspector the power to:

- grant registration
- refuse registration
- attach conditions to registration.

In contrast, section 51 allows the Chief Inspector to cancel registration, vary, remove or add extra registration conditions to designated centres which are **currently**^{*} registered. Therefore, these powers may be exercised **at any time** within the registration cycle of a registered centre — but only after any one or more grounds for exercising the powers have arisen.

^{*} Including any centres registered under the provisions of the transitional registration (section 69).

Sometimes, the powers contained in sections 50 and section 51 may be exercised at the same time, but there are distinct differences between these two sections.

For example, under section 50, a condition may be attached to a registration if the Chief Inspector believes it is appropriate in relation to the designated centre concerned. However, under section 51, a condition may only be attached to a registration if any of the grounds are met.

Applying section 51 powers fairly

We will use our section 51 powers fairly and in line with the principles of natural justice. Any decision to cancel registration or vary, remove or attach an additional condition will be related to a non-compliance or noncompliances identified within the designated centre.

Cancelling the registration of a designated centre will only be used when variation, removal or attachment of additional conditions of registration are not appropriate or where the risk to residents or children is unacceptable.

We will take the most proportionate action based on the level of risk and non-compliance. We will consider **all of the available evidence** in the decision-making process. For example, if the provider has recently hired new or additional staff or will invest in the centre.

Informing providers about section 51 decisions

Whenever the grounds exist for using section 51, the pathway for informing providers of decisions under this section is the same as that used for registration or registration renewal decisions. We will tell providers in two stages about decisions we make under section 51:

- Initially, we will advise them that we *propose* to make a decision and that they can make a representation about it.
- 2. Secondly, we will *confirm a decision* and their right to appeal.

Written notice of *proposed* decision under section 51

The registered provider will receive written notice of *proposed* decisions to cancel registration or make changes to registration conditions under our section 51 powers — similar to the information flow around decisions we make on applications to register or renew registration.

This notice will be clear, specific and unambiguous so that the provider can understand and consider the decision. Ahead of this, we will keep the

provider informed of our assessments of fitness, compliance with regulations and conditions of registration.

Any notice of *proposed* decision will state that the registered provider may make written representations to the Chief Inspector about the proposed decision. When you receive this proposed decision, you can either:

- accept it and inform the Chief Inspector that you do not intend to make representations or
- make representations in writing within 14 calendar days after the notice is given.

Representations following receipt of a section 51 proposal notice

Registered providers can make written representations to the Chief Inspector after receiving a notice of *proposed* decision under the Act. This must be done within **14 calendar days** after the notice is given (specified in the notice of *proposed* decision). The Chief Inspector shall not make a final decision until:

- this 14-day period has elapsed, or
- the registered provider confirms it does not intend to make representations, or

• a written representation is received.

We will carefully consider any representation received, which may lead to the proposed decision being changed, not progressed or confirmed. We may decide to inspect the centre if an inspection is the only way to:

- verify the actions said to be taken by the provider as outlined in the representations by the registered provider, or
- to verify the mitigating action by the provider in response to a proposed condition.

If this inspection is required, it will be carried out within **15 working days** of receipt of the representation.

Where the Chief Inspector's decision following a representation is different from the notice of *proposed* decision originally sent to the provider, we will issue a new notice of *proposed* decision to the provider. The provider will be able to make representations on any such new notice.

Written notice of decision under section 51

The registered provider must be given written notice of any decision made under section 51 to cancel registration or to vary, remove or attach new conditions. Such notice of decision does not take effect until **14 calendar days** after the notice is given.

The notice of decision will give the provider sufficient information on the

decision and the reasons for it, so that the provider can consider it. The Act provides that a written notice of a decision made under section 51 should also inform registered providers of their right to appeal.

Appeals to decisions made under Section 51

Under section 57 of the Act, registered providers have the right to appeal a notice of decision made under section 51 to the district court. Section 57 of the Health Act 2007 has been amended by the Health (Miscellaneous Provisions) (No. 2) Act 2024. Where a registered provider brings an appeal to the court, it must:

- make such an appeal within 14 calendar days (previously 28 days) after receiving written notice of the decision, and
- give written notice of the provider's appeal to the Chief Inspector within 14 calendar days (previously 28 days) after the notice is given.

When does a section 51 decision take effect?

The decision will not take effect until the date specified in the notice or until an appeal has been heard if the provider appeals the decision to the district court.

How section 51 notices are issued

Notices issued under section 51 will be sent by registered post to the registered address of the registered provider or, if urgent, may be delivered by hand.

Notification of cancellation decisions to the HSE or Tusla

If the Chief Inspector cancels the registration of a designated centre under section 51 **and** the cancellation takes effect, we will immediately notify the Health Service Executive (HSE) or the Child and Family Agency (Tusla).

We will ensure that the HSE or Tusla has adequate notice of **any** proposed decisions which might affect either organisation.

Applying to the district court under section 59

Section 59 of the Act allows the Chief Inspector to apply to the district court for an order to:

- cancel the registration of a designated centre
- vary or remove a condition of registration or
- attach new conditions of registration.

Section 59 powers can be used when the Chief Inspector has reasonable

grounds to believe that there is a risk to the lives or a serious risk to the health or welfare of residents living in the centre or children because of any act, failure to act or negligence by a registered provider or a person acting on its behalf.

Whenever grounds exist for relying on section 59, the Chief Inspector may proceed to apply to the district court. The court may make an order as requested by the Chief Inspector or as the court considers appropriate.

Applications under section 59 are made to the appropriate district court where the designated centre is located. This application is made on notice to the registered provider under section 59. We can also make an emergency application for these orders ex parte (without notice to the provider) under section 60 when the risk is immediate.

Prosecution

The Chief Inspector has the power to prosecute for certain offences outlined in the Act and the regulations made under it.

Prosecution of a person for an offence under the Act holds registered providers and other people participating in management to account for not complying with legal requirements. It aims to punish wrongdoing, to avoid a reoccurrence and to act as a deterrent to others.

It can be sometimes appropriate to prosecute at the same time as taking

other enforcement action; for example, cancellation of registration and or imposing conditions on registration.

The Chief Inspector will not begin prosecution proceedings unless satisfied that:

- it is in the public interest
- there is sufficient, admissible and reliable evidence that an offence has been committed
- the evidence meets the standard for a criminal prosecution
- there is a realistic prospect of conviction.

Under section 51, as mentioned, the grounds for cancelling an existing registration, varying or removing conditions or attaching extra conditions include operating the designated centre contrary to any requirements or conditions imposed on the centre by or under the Act.

Section 79 of the Act contains a list of offences which may be prosecuted under the Act, which can be divided into those that can be committed by:

- any person (for example, a registered provider and or a person participating in management)
- a registered provider only, such as failing to comply with a condition of registration.

Table 10 sets out a list of offences outlined in section 79 of the Act.

Table 10. List of offences

Section 79 offences	Reference to section contravened	Details of the offence
79(1)(a)	69(3)	A person fails to notify the Chief Inspector that they are carrying on the business of a designated centre.
79(1)(b)	46	A person carrying on an unregistered centre.
79(1)(b)	47	Prohibition against false or misleading information by a person
79(1)(b)	77	Obstruction by a person.
79(1)(b)	77B	Obstruction by a person when an inspector is inspecting a designated centre that is unregistered.
79(2)(a)	56(1)	Failure by a registered provider to affix certificate of registration in a conspicuous place.
79(2)(a)	65	Failure by a registered provider to submit to the Chief Inspector such information at such time as the Chief Inspector considers necessary to enable the Chief Inspector to carry out the Chief Inspector's functions.
79(2)(b)	56(2)	The registered provider carrying on the business of a designated centre shall not, in an application under section 52 for the variation or removal of any condition of the registration of the designated centre, knowingly make a statement which is false or misleading in a material respect.
79(2)(b)	56(3)	Unless registration as a designated centre of a particular description has been effected under this Part in respect of a premises, undertaking or organisation, a person shall not, with intent to deceive another person, (a) apply a name to the premises, undertaking or organisation that in any way describes it as a designated centre

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Section 79 offences	Reference to section contravened	Details of the offence
		of that description, or (b) hold out the premises, undertaking or organisation as a designated centre of that description.
79(2)(b)	56(4)	The registered provider carrying on the business of a designated centre shall not describe or hold out the designated centre as able to — (a) provide a service, the provision of which would be in contravention of a condition of the registration of the designated centre, or (b) do anything else, the doing of which would be in contravention of a condition of the registration of the designated centre.
79(2)(b)	66(1)	The registered provider carrying on the business of a designated centre shall not cease to carry on its business and close the designated centre unless the registered provider first gives the Chief Inspector written notice, of such period as may be prescribed, of the intention to do so as of a date specified in the notice.
79(2)(c)	n/a	Fails to discharge a duty to which the registered provider is subject under a provision of the regulations.
79(2)(d)	n/a	Registered provider contravenes a provision of the regulations.
79(2)(e)	n/a	Registered provider fails to comply with a condition of the registration of the designated centre.

Previous convictions

We will be aware of an offence committed under the Act which we have successfully prosecuted. In addition, details of any other convictions should be outlined on a completed Garda vetting disclosure submitted to us as part of a registration or notification process.

Duty to disclose all convictions during vetting

The Criminal Justice (Spent Convictions and Certain Disclosures) Act 2016 (see https://www.irishstatutebook.ie/eli/201 6/act/4/enacted/en/html) provides that, in certain circumstances, after seven years have passed since the date of certain minor convictions, a conviction may be regarded as being 'spent'.

In most cases, a person will not be required to disclose a spent conviction. However, one of the **exceptions** to non-disclosure of spent convictions relates to cases where a person applies for, seeks or is offered work in a designated centre within the meaning of section 2 of the Act.

Therefore, registered providers, intending registered providers and people who intend to participate in the management of a designated centre as well as all other staff working in or seeking a job in a designated centre must disclose **all** convictions on the Garda National Vetting Form.

The Chief Inspector views Garda vetting as an important safeguarding measure.

A photocopy of a report from the National Vetting Bureau of the Garda Síochána (police) for providers and persons participating in the management of the centre must be dated within six months of submission to the Chief Inspector. However, if a previous version submitted to us is dated within the last two years, you do not need to submit an updated copy of a vetting disclosure with your application for renewal of registration.

'One of the **exceptions** to non-disclosure of spent convictions relates to people seeking to work in — or who are offered work in — designated centres. Therefore, registered providers or intending registered providers and people who intend to manage designated centre, as well as all other staff or intending staff of the centre, must disclose **all** convictions on the Garda National Vetting Form.'

Appropriate international police vetting is needed for nurses who have lived outside of the Republic of Ireland or Northern Ireland for more than six months. However, people in this situation will still be required to complete Garda vetting for any time spent as a resident in Ireland.

To help avoid any potential vetting delays, you should speak to the liaison person in your organisation who handles Garda vetting. If you are the liaison officer, you could contact the Garda National Vetting Bureau and discuss it with them. Since the introduction of eVetting, Garda vetting is now much more efficient and timely.

Liability for prosecution of directors, managers and others

Section 80(4) of the Act lists people involved in designated centres who may be prosecuted when an offence under the Act is committed by a body corporate; a person purporting to act on behalf of the body corporate; an individual; or an unincorporated body of persons.

Where it has been proven that the offence was committed with his or her consent or knowledge, or through his or her neglect, a director, member of a committee of management or other controlling authority of the body concerned or its manager or secretary or other officer can be prosecuted.

Possible prosecution for operating an unregistered designated centre

You cannot run a designated centre until it is registered and unless you are its registered provider. A person in charge, whether a registered provider or someone else, shall not manage the centre in any capacity unless the centre is registered under the Act.

Section 46 of the Health Act 2007 (as amended) requires that:

1. A person shall not carry on the business of a designated centre unless the centre is registered under the Act and the person is its registered provider.

2. The person in charge of a designated centre, whether that person is the registered provider or another person, shall not manage or participate in the management of the centre unless the centre is registered under the Act.

Section 79(1)(b) of the Act further provides that a person is guilty of an offence if the person contravenes section 46.

Therefore, if the Chief Inspector believes that an unregistered designated centre is being operated by a person, and if a person in charge is managing the centre, they may be prosecuted by the Chief Inspector.

How we may become aware of a possible offence

The Chief Inspector may become aware of an unregistered centre operating in a number of ways; for example:

- while inspecting a registered designated centre, the inspector may receive information (either verbally or through a review of documentation)
- on receipt of solicited or unsolicited information
- information in the public domain.

Regulatory action when a centre is being operated without being registered

If we believe a person is operating an unregistered centre, we may take the following steps:

- We may enter and inspect this premises at any time.
- We may set up a case-review meeting to discuss the suspicion that an offence is being or has been committed.
- We may decide whether or not to commence a criminal investigation.

 If we decide to start a criminal investigation, we will prepare an investigation strategy.

Prosecution of offences

Where it is alleged an offence has been committed under section 79 of the Act, which includes running an unregistered centre under section 46, it may be dealt with summarily (heard in the district court without a jury) or on indictment (in the circuit court before a judge and jury).

The Chief Inspector may prosecute most of the offences contained under section 79 of the Act, while HIQA may prosecute offences in certain, limited circumstances.[±] Where a prosecution is taken by the Chief Inspector or HIQA, summary proceedings will be issued in the district court jurisdiction where the alleged offence was committed.

Prosecutions on indictment Where a case is deemed too serious for the district court, the Director of Public Prosecutions (DPP) may decide to prosecute the case on indictment (in most cases, tried before a judge and jury), in which case the DPP will prosecute the case in the appropriate circuit court.

[±] Specifically, HIQA may prosecute offences where a person has contravened section 77 of the Act by refusing to allow an authorised person to monitor

compliance with national standards or conduct an investigation.



Prosecution time limits

Prosecutions for offences under the Act must be commenced within certain time limits. The Act requires that proceedings to prosecute are commenced:

1. Within 12 months of the date of the commission of the alleged offence.

For example, if a person refuses to allow a person who is monitoring compliance under section 73 to enter a premises on 1 January 2016, then any summary proceedings in relation to this alleged offence should be started by 31 December 2016.

 If we are unaware of the alleged offence until a later date, then a prosecution can be taken within two years of the date of the alleged offence. In such cases, a prosecution **must be started** within six months after we first become aware of evidence of the alleged offence. For example, if a person is alleged to be operating an unregistered designated centre on 1 January 2016 in contravention of section 46, and we only become aware of it on 1 March 2017, then we must start proceedings by 31 August 2017 (that is to say, within six months after the evidence comes to our knowledge).

However, if we only become aware of the alleged offence on 10 September 2017, we must start summary proceedings by 31 December 2017 (that is to say, within two years from the date of the alleged commission of the offence on 1 January 2016).

Offences tried on indictment

Conversely, there is generally no time limitation on starting proceedings in relation to indictable offences.

Conclusion to enforcement

The Chief Inspector has significant regulatory powers which are applied fairly and proportionately when addressing non-compliances. As can be seen, we are required to give providers ample time to consider and respond to our proposed decisions and final decisions under these powers.

The Chief Inspector is responsible for registering and inspecting designated centres and assessing whether the registered provider complies with the regulations and national standards.

Each registered provider and person who participates in the management of designated centres must ensure they are delivering a safe and effective service that complies with, and ideally exceeds, the requirements of regulations, national standards and any other relevant legislation.

In order to carry out its functions, the Chief Inspector has adopted a common Authority Monitoring Approach (AMA), which provides a consistent framework for inspectors to use their professional judgment and which supports them to do this.

Enforcement action will follow our escalation procedures in circumstances where providers are failing to bring themselves into compliance and where these failures are placing residents or children and people using services at risk of serious harm or neglect.

We will always strive to minimise disruption and anxiety for people living in designated centres whenever there is the possibility of enforcement action. However, it is our duty to use our powers fairly to ensure safe and highquality services are provided in designated centres.

Your notes

Your notes

Appendices

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Appendices



Appendix 1 — Summary of published guidance for providers of designated centres^{¥‡}

ADVISORY

Please note that guidance may be updated and that published website links may change over time. If a website link no longer works, please search online using the title of the document. If you cannot locate a document from the list below, it may have been replaced, superseded or removed from our website.

Name of guidance	Publication date	Location on <u>www.hiqa.ie</u>
General gui	dance for	all designated centres
Lexicon for Social Care	21 June 2024	https://www.hiqa.ie/areas-we-work/lexicon- social-care
Registration handbook: Guidance on making applications, providing prescribed information and submitting registration notifications	July 2023	https://www.hiqa.ie/reports-and- publications/guide/registration-handbook- guidance-making-applications-providing
What is a designated centre? A guide to understanding the definition of designated centres: June 2022	Summer 2022	https://www.hiqa.ie/reports-and- publications/guide/what-designated-centre
Guidance on the assessment of fitness for designated centres	2018	https://www.hiqa.ie/reports-and- publications/guide/guidance-assessment- fitness-designated-centres

⁴ Current at the time of preparing this handbook. Please note that websites addresses may change over time and that guidance may be updated.

⁺ In cases where national standards and regulations cited in published guidance have been superseded, the overarching guidance still applies.

Name of guidance	Publication date	Location on <u>www.hiqa.ie</u>
Guidance on	Published on 29	https://www.hiqa.ie/reports-and-
managing notifiable	June 2022	publications/guide/guidance-managing-
events in Designated		notifiable-events-designated-centres
Centres: Guidance		
for registered		
providers and		
persons in charge of		
designated centres Fire Safety	26 Jan 2021	https://www.higa.ie/reports-and-
Handbook: A guide	20 Jan 2021	publications/guide/fire-safety-handbook-guide-
for providers and		registered-providers-and-staff
staff of designated		
centres		
Guidance on a	13 Nov 2019	https://www.higa.ie/reports-and-
Human Rights-based		publications/guide/guidance-human-rights-
Approach in Health		based-approach-health-and-social-care-
and Social Care		services
Services		
HIQA Provider Portal	Updated on 20	https://www.hiqa.ie/reports-and-
- user guide for	May 2020	publications/guide/higa-provider-portal-user-
providers		<u>guide-providers</u>
Questionnaire for	13 March 2018	https://www.hiqa.ie/reports-and-
residents		publications/guide/questionnaire-residents
Guidance for	5 November	https://www.higa.ie/reports-and-
providers of health	2015	publications/quide/quidance-communicating-
and social care	2015	plain-english-adults
services:		
Communicating in		
plain English (Adults)		
Guidance -	5 November	https://www.hiqa.ie/reports-and-
Communicating in	2015	publications/guide/guidance-communicating-
plain English for		plain-english-children
Children		
Guidance on	3 September	https://www.hiqa.ie/reports-and-
information	2012	publications/health-information/guidance-
governance for		information-governance-health-and-social-care
health and social care services in		
Ireland		

Appendix 1 Summary of published guidance			
Name of guidance	Publication date	Location on <u>www.hiqa.ie</u>	
What you should know about Information Governance. A Guide for health and social care staff	25 October 2011	https://www.hiqa.ie/reports-and- publications/health-information/what-you- should-know-about-information-governance- guide	
Special car	e units		
Annual Review Report — Assessing performance against the National Standards for Special Care Units: Regulation 24(d)	Published on 18 January 2019 Updated on 26 April 2023	https://www.higa.ie/reports-and- publications/guide/scu-assessing-performance- against-national-standards-special-care	
Monitoring notifications handbook: Guidance for persons in charge of children's special care designated centres	Published on 30 January 2019	https://www.higa.ie/reports-and- publications/guide/monitoring-notifications- handbook-scu	
Special Care Units Regulation 24 Six Monthly Unannounced Visit	Published 5 July 2018	https://www.hiqa.ie/reports-and- publications/guide/special-care-units- regulation-24-six-monthly-unannounced-visit	
Guidance on the Statement of Purpose for Special Care Unit (SCU)	Published 12 March 2018; updated October 2019	https://www.hiqa.ie/reports-and- publications/guide/guidance-statement- purpose-special-care-unit-scu	
Guidance for the assessment of special care centres (SCU)	Published 5 February 2018; updated September 2020	https://www.hiqa.ie/reports-and- publications/guide/guidance-assessment- special-care-centres-scu	

	Appendix 1 — Summary or published guidance				
Name of guidance	Publication date	Location on <u>www.hiqa.ie</u>			
Assessment judgment framework for special care units (SCU)	Published 5 February 2018; updated June 2022; updated October 2022	https://www.hiqa.ie/reports-and- publications/guide/assessment-judgment- framework-special-care-units-scu			
Designated of	centres for	older people			
Safeguarding assessment- judgment framework for designated centres for older people.	June 2024	https://www.hiqa.ie/reports-and- publications/guide/guidance-assessment- designated-centres-older-people-dcop			
Guidance on safeguarding for designated centres for people with disabilities and for older people.	June 2024	https://www.hiqa.ie/reports-and- publications/guide/guidance-assessment- designated-centres-older-people-dcop			
Guidance for the assessment of designated centres for older people	Updated January 2024	https://www.hiqa.ie/reports-and- publications/guide/guidance-assessment- designated-centres-older-people-dcop			
Assessment- judgment framework for designated centres for older people	Updated January 2024	https://www.hiqa.ie/reports-and- publications/guide/assessment-judgment- framework-designated-centres-older-people- dcop			
Assessment- judgment framework for infection prevention and control and antimicrobial stewardship in designated centres for older people	Published January 2024	https://www.hiqa.ie/reports-and- publications/guide/assessment-judgment- framework-designated-centres-older-people- dcop			

Name of guidance	Publication date	Location on <u>www.hiqa.ie</u>
Are you ready for assessment of the application to register:- Guidance and checklist: Designated Centres for Older People	Published on 30 August 2021	https://www.hiqa.ie/reports-and- publications/guide/are-you-ready-assessment- application-register-guidance-and-0
Guidance on promoting a care environment that is free from restrictive practice: Older People's Services: Effective June 2023	Published on 22 March 2019 Updated on 13 April 2023	https://www.hiqa.ie/reports-and- publications/guide/guidance-restrictive- practice-dcop
Self-assessment questionnaire: Restrictive practice thematic programme: Older People's Services	Published on 22 March 2019 Updated on 13 April 2023	https://www.hiqa.ie/reports-and- publications/guide/guidance-restrictive- practice-dcop
Restrictive Practice Thematic Programme Quality Improvement Plan: Designated Centres for Older People	Published on 22 March 2019 Updated on 13 April 2023	https://www.higa.ie/reports-and- publications/guide/guidance-restrictive- practice-dcop
Assessment judgment framework for thematic inspections of restrictive practices: Older People's Services: Effective June 2023	Published on 22 March 2019 Updated on 13 April 2023	https://www.hiqa.ie/reports-and- publications/guide/guidance-restrictive- practice-dcop

Name of	Publication	
guidance	date	Location on <u>www.hiqa.ie</u>
Guidance on the Statement of Purpose for designated centres for older people (DCOP)	5 February 2018	https://www.hiqa.ie/reports-and- publications/guide/guidance-statement- purpose-designated-centres-older-people-dcop
Monitoring notifications handbook for designated centres for older people (DCOP)	February 2018	https://www.hiqa.ie/reports-and- publications/guide/monitoring-notifications- handbook-designated-centres-older-people
Annual Review Report, regulation 23(d), Older People (guidance and annual review report template).	29 June 2016	https://www.hiqa.ie/reports-and- publications/guide/annual-review-report- regulation-23d-older-people

Designated centres for people with disabilities

Safeguarding	June 2024	https://www.hiqa.ie/reports-and-
assessment-		publications/guide/guidance-assessment-
judgment framework		centres-persons-disabilities-dcd
for designated		
centres for people		
with disabilities.		
Version 1: June 2024		
Guidance on	June 2024	https://www.hiqa.ie/reports-and-
safeguarding for		publications/guide/guidance-assessment-
designated centres		centres-persons-disabilities-dcd
for people with		
disabilities and for		
older people.		
Guidance for the	Updated January	https://www.hiqa.ie/reports-and-
assessment of	2024	publications/guide/guidance-assessment-
designated centres		centres-persons-disabilities-dcd
for people with		
disabilities		

Name of guidance	Publication date	Location on <u>www.hiqa.ie</u>
Assessment- judgment framework for designated centres for people with disabilities	Updated January 2024	https://www.hiqa.ie/reports-and- publications/guide/assessment-judgment- framework-disability-services-dcd
Assessment- judgment framework for infection prevention and control and antimicrobial stewardship in designated centres for people with disabilities	Published January 2024	https://www.hiqa.ie/reports-and- publications/guide/assessment-judgment- framework-disability-services-dcd
Are you ready for assessment of the application to register:- Guidance and checklist: Designated Centres for people with disabilities	Published on 30 August 2021	https://www.hiqa.ie/reports-and- publications/guide/are-you-ready-assessment- application-register-guidance-and-checklist
Regulation 14: Person in Charge of a Designated Centre for Disability: April 2021	Published 1 May 2016; updated 19 April 2021	https://www.hiqa.ie/reports-and- publications/guide/regulation-14-person- charge-designated-centre-disability
Guidance on promoting a care environment that is free from restrictive practice: Disability Services: Effective June 2023	Published on 22 March 2019 Updated on 13 April 2023	https://www.hiqa.ie/reports-and- publications/guide/guidance-restrictive- practice-dcd
Self-assessment questionnaire: Restrictive practice thematic programme: Disability Services	Published on 22 March 2019 Updated on 13 April 2023	https://www.hiqa.ie/reports-and- publications/guide/guidance-restrictive- practice-dcd

Name of guidance	Publication date	Location on <u>www.hiqa.ie</u>
Restrictive Practice Thematic Programme Quality Improvement Plan: Designated Centres for People with Disabilities	Published on 22 March 2019 Updated on 13 April 2023	https://www.hiqa.ie/reports-and- publications/guide/guidance-restrictive- practice-dcd
Assessment judgment framework for thematic inspections of restrictive practices: Disability Services: Effective June 2023	Published on 22 March 2019 Updated on 13 April 2023	https://www.hiqa.ie/reports-and- publications/guide/guidance-restrictive- practice-dcd
Guidance on the Statement of Purpose for designated centres for children and adults with disabilities (DCD): V2.0	Published 5 February 2018; updated October 2019	https://www.hiqa.ie/reports-and- publications/guide/guidance-statement- purpose-designated-centres-children-and- adults
Monitoring notifications handbook for disability (DCD)	Updated October 2024 Published 5 February 2018	https://www.hiqa.ie/reports-and- publications/guide/monitoring-notifications- handbook-disability-dcd
Regulation 23 Six Monthly Unannounced Visit (guidance and report template, people with disabilities)	Published 1 July 2016 Updated on 11 March 2025	https://www.hiqa.ie/reports-and- publications/guide/regulation-23-six-monthly- unannounced-visit
Annual Review Report, regulation 23(d), Disability	Published on 29 Jun 2016 Updated on 26 April 2023	https://www.hiqa.ie/reports-and- publications/guide/annual-review-report- regulation-23d-disability

Appendix 1 — Summary of published guidance				
Name of guidance	Publication date	Location on <u>www.hiqa.ie</u>		
Guidance on	e on Published			
Directory of	1 June 2015	https://www.hiqa.ie/reports-and-		
Residents (for		publications/guides/guidance-directory-		
Children and Adults		residents		
with Disabilities)				



Appendix 2 — Summary of statutory monitoring notifications and related regulations for designated centres for people with disabilities, older people and children living in special care

Submit to Provider Portal or send NF01–09s to notify@hiqa.ie and NF39s and NF40s to the relevant team.[‡]

Notification	Title of monitoring	Related regulations			
form number	notification required	Care and support regulations for designated centres for people with disabilities	Care and welfare regulations for designated centres for older people	Care and welfare regulations for children in designated special care units	
Forms NF01	to NF09 must be submitte	ed as follows:			
 within 	three working days for disabil	ity centres and special care	units		
 within 	two working days for designa	ted centres for older people			
NF01	The unexpected death of a resident in designated centres for older people or disability centres. The death of a child, including the death of a child following his or her transfer to hospital from the special care unit, and the circumstances and cause of death when established.	Regulation 6: Health care	Regulation 6: Health care Regulation 13: End of life care	Regulation 8: Health care	

⁺ The contact email addresses for our teams are:

- NF39 and NF40 for older people <u>dcop@hiqa.ie</u>
- NF39 and NF40 for people with disabilities <u>dcd@hiqa.ie</u>
- NF39 for special care units <u>children@hiqa.ie</u>.

Notification	Title of monitoring	Related regulations			
form number	notification required	Care and support regulations for designated centres for people with disabilities	Care and welfare regulations for designated centres for older people	Care and welfare regulations for children in designated special care units	
NF02	Outbreak of any notifiable diseases as identified and published by the Health Protection Surveillance Centre	Regulation 6: Health care Regulation 27: Protection against infection	Regulation 6: Health care Regulation 27: Infection control	Regulation 8: Health care	
NF03	Any serious injury to a resident in a disability centre or child in a special care unit that requires immediate medical or hospital treatment Any serious incident or injury to a resident in a nursing home that requires hospital admission or resulted in death	Regulation 6: Health care Regulation 7: Positive behavioural support	Regulation 6: Health care Regulation 7: Managing behaviour that is challenging	Regulation 8: Health care Regulation 11: Positive behavioural support (including restraint and single separation)	
NF05	Any unexplained absence of a resident from the designated centre. Where a child is removed, absconds, fails to return, is prevented from returning, is missing or is otherwise absent from the special care unit. See Appendix 5 for further information on reporting absconsions from special care units.	Regulation 26: Risk management procedures	Regulation 26: Risk management	Regulation 25: Risk management Regulation 7: Programme of Care Regulation 9: Education, individual needs, religion, ethnicity, culture and language Regulation 12: Protection	

Notification	Title of monitoring		Related regulations	
form number	notification required	Care and support regulations for designated centres for people with disabilities	Care and welfare regulations for designated centres for older people	Care and welfare regulations for children in designated special care units
NF06	Any allegation, suspected or confirmed abuse of any resident or a child in a special care unit (see Appendix 5 for further information on special care unit NF06s) Any incident of alleged or confirmed abuse of any	Regulation 8: Protection	Regulation 8: Protection	Regulation 12: Protection
NF07	resident in a nursing home Any allegation of misconduct by the registered provider or by staff	Regulation 21: Records	Regulation 21: Records	Regulation 14: Staff members and others working in the special care unit Regulation 22: Record of a person employed in the
NF08	Any occasion where the registered provider becomes aware that a member of staff is the subject of a review by a professional body	Regulation 21: Records	Regulation 21: Records	special care unit Regulation 14: Staff members and others working in the special care unit

Notification	Title of monitoring		Related regulations	
form number	notification required	Care and support regulations for designated centres for people with disabilities	Care and welfare regulations for designated centres for older people	Care and welfare regulations for children in designated special care units
	For nursing homes, any occasion where the registered provider becomes aware that the person in charge is the subject of a review by a professional body			Regulation 22: Record of a person employed in the special care unit
NF09	Designated centres for older people and designated centres for people with disabilities: any fire, any loss of power, heating or water, and any incident where an unplanned evacuation of the centre took place. Designated special care unit: any fire or unplanned evacuation of the designated special care unit.	Regulation 17: Premises Regulation 28: Fire precautions	Regulation 17: Premises Regulation 28: Fire precautions	Regulation 17: Accommodation Regulation 26: Fire precautions

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Appendix 2 — Summar	v or statutory	v monitorinc	1 notifications and	n related redulations
	y or statutor	y monitoring	g nouncations and	a relaced regulations

Notification	Title of monitoring		Related regulations	
form number	notification required	Care and support regulations for designated centres for people with disabilities	Care and welfare regulations for designated centres for older people	Care and welfare regulations for children in designated special care units
NF39 A–E (submit quarterly on certain dates)	Any time restraint is used in a disability centre and any time a restrictive practice is used in a nursing home, including the type of restrictive practice used and the number of residents affected Any instance of restraint and or single separation in a special care unit	Regulation 7: Positive behavioural support	Regulation 7: Managing behaviour that is challenging	Regulation 11: Positive behavioural support (including restraint and single separation) Regulation 25: Risk management Regulation 7: Programme of Care Regulation 9: Education, individual needs, religion, ethnicity, culture and language
	Operation of fire equipment other than a drill Recurring pattern of theft or burglary (centres for older people and centres for people with disabilities, notification form NF39C [†])	Regulation 28: Fire precautions Regulation 8: Protection Regulation 12: Personal possessions	Regulation 28: Fire precautions Regulation 8: Protection	Regulation 26: Fire precautions N/A

⁺ Please note that in designated centres for older people and people with disabilities, quarterly NF39C forms relate to any recurring pattern of theft or burglary; while in special care units, NF39C is used to notify any loss of power, heating or water.

Notification	Title of monitoring	Related regulations					
form number	notification required	Care and support regulations for designated centres for people with disabilities	Care and welfare regulations for designated centres for older people	Care and welfare regulations for children in designated special care units			
NF39 A–E (submit	Non-serious injury to a resident [¥]	Regulation 6: Health care	N/A	Regulation 8: Health care			
quarterly on certain	Any death other than notified in NF01 [¥]	Regulation 6: Health care	Regulation 13: End of life care	N/A			
dates)	Pressure area care (designated centres for older people only)	N/A	Regulation 6: Health care	N/A			
	Any loss of power, heating or water (designated	N/A	N/A	Regulation 17: Accommodation			
	special care unit notification form NF39C) [≠]			Regulation 26: Fire precautions			
NF40 (submit every six months) [‡]	within the preceding six mor for all incidents covered by c	Nil return: in older persons and disability centres only, when there were no incidents that needed to be notified within the preceding six months (such as 'recurring pattern of theft or burglary'). Only submit one nil return form for all incidents covered by other notification forms. This is not required in special care units. At the end of each half year (end of June and end of December), a nil return should be submitted to us.					

[¥] In designated centres for older people, form NF39D is used for any death/s other than those notified within two working days under NF01, while in designated centres for people with a disability or designated special care units, form NF39D is used for reporting any injury to a resident that did not require notification within three days (which is not required for DCOP).

^{*} Please note that in designated centres for older people and people with disabilities, quarterly NF39C forms relate to any recurring pattern of theft or burglary; while in special care units, NF39C is used to notify any loss of power, heating or water.

⁺ For Period 1 (January, February, March, April, May and June) and Period 2 (July, August, September, October, November and December).

Appendix 3 — Quick guide to registration notifications

Appendix 3 — Quick guide to registration notifications

Registration notifications received by the Chief Inspector will inform renewal of registration applications and will be considered as part of the assessment of fitness in terms of the provider complying with the regulations.

Notification required and form number	Older people	Disability	Special care
Legal basis for notification	2015 registration regulations for residential services for older people	2013 registration regulations for residential services for people with disabilities	2017 registration regulations for designated special care units for children
	Regulation 6, Schedules 1, 2 and 3	Regulation 7, Schedule 3	Regulation 6, Schedules 2 and 3
Change of person in charge	NF30A	NF30A	NF30A
 Absence of person in charge Disability centres and special care units: 28 calendar days and longer Designated centres for older people: 42 calendar days and longer (and appointment of deputy person in charge) 	NF30B	NF30B	NF30B

Appendix $J = Quick guide to registration notifications$	Appendix 3 —	Quick guide to	registration notifications
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Notification required and form number	Older people	Disability	Special care
Return of the person in charge after an absence	NF30C	NF30C	NF30C
Change of person participating in management	NF31	NF31	NF31
Change to the ownership of a body corporate (disability and special care units [‡])	N/A	NF32	NF32 [‡]
Changes to information supplied (applicant details) for registration purposes: changes to company, partnership, unincorporated personnel and contact information [^]	NF33–37C	NF32–37C	
Declaration of bed occupancy. Timeframe 1–15 January; 1– 15 May; 1–15 September	NF60	N/A	NF60

 ^{*} Not applicable to special care units at the time of writing.
 ^ Not applicable to special care units at the time of writing.

Notification required and form number	Older people	Disability	Special care
	Regulation 9 (older people)	Regulation 11(1) (disabilities)	Regulation 10 (special care)
Notice to be given by a registered provider of a designated centre of intention to cease carrying on the business and close the designated centre. Following receipt of a notice from the registered provider of its intention to cease carrying on the business of a designated centre and close the centre, the Chief Inspector, in line with the regulations, [¥] will note this information in the official public register of centres published on the HIQA website.	have to carry out a site visit after receiving a NF35 notification.	NF35 This notification is only for when the designated centre ceases and closes — the NF35 is not required when a provider is selling a business which provides residential centre services for people with disabilities. The Chief Inspector does not have to carry out a site visit after receiving a NF35 notification.	NF35 This notification is only used in the event of the designated special care unit ceasing operation and being closed by the current statutory provider. Submitting an NF35 would not be required if a future potential provider were to sell a business providing special care unit services. The Chief Inspector does not have to carry out a site visit after receiving a NF35 notification.

Appendix 3 — Quick guide to registration notifications

⁴ Regulation 3(5) of the Health Act 2007 (Registration of Designated centres) (Special Care Units) Regulations 2017; Regulation 4(5) of the Health Act 2007 (Registration of Designated Centres for persons (Children and Adults) with Disabilities) Regulations 2013 (as amended); Regulation 3(2) of the Health Act 2007 (Registration of Designated Centres for Older People) Regulations 2015 (as amended).

Appendix 3 — Quick guide to registration notifications

Your notes

Appendix 4 — Registration notification time frames

Registration notifiable event and associated timelines

Registration notification form	Notifiable event	What should the provider submit?	Type of this app	designated lies to	l centre	When is the notification required?
NF30	NF30A: Change of the person in charge	NF30A form and prescribed information	Older persons	Disability	Special care units	Within 10 calendar days
	 NF30B: Absence of the person in charge, longer than: 28 calendar days disability and SCU 42 calendar days nursing homes (and deputising arrangements)[‡] 	NF30B form	Older persons	Disability	Special care units	One month in advance (or, in the case of an emergency, as soon as it becomes apparent)
	NF30C: Return of the person in charge (following an absence) [‡]	NF30C form	Older persons	Disability	Special care units	Within three calendar days

⁺ These are notifications which are managed by our registration teams, rather than our Notification Team.

Registration notifiable event and associated timelines							
Registration notification form	Notifiable event	What should the provider submit?	Type of designated centre this applies to			When is the notification required?	
NF31	Change of person participating in management	NF31 form and prescribed information	Older persons	Disability	Special care units	Within 28 calendar days	
NF32	Change to the ownership of a body corporate	NF32 form	N/A [#]	Disability	N/A^	Not less than eight weeks in advance	
NF33	Change of company personnel and or company contact information	NF33 form	Older persons	Disability	N/A^	Not less than eight weeks in advance	

[#] Not applicable to designated centres for older persons.

 $^{^{\}mbox{\circ}}$ Not applicable to special care units at the time of writing.

Registration notification form	What should the provider submit?	the provider this applies to		centre	When is the notification required?	
NF35	Ceasing to carry on the business of the designated centre and closing the centre	NF35 form	Older persons	Disability	Special care units	Not less than six months in advance for designated centres for older people, disability and specia care. Following receipt of a notice from the registered provider of its intention to cease carrying on the business of a designated centre and close the centre, the Chief Inspector, in line with the regulations, [¥] will note this information in the official public register of centres published on the HIQA website.

⁴ Regulation 3(5) of the Health Act 2007 (Registration of Designated centres) (Special Care Units) Regulations 2017

Regulation 4(5) of the Health Act 2007 (Registration of Designated Centres for persons (Children and Adults) with Disabilities) Regulations 2013 (as amended) Regulation 3(2) of the Health Act 2007 (Registration of Designated Centres for Older People) Regulations 2015 (as amended).

Registration notifiable event and associated timelines						
Registration notification form	Notifiable event	What should the provider submit?	Type of designated centre this applies to			When is the notification required?
NF36	Change of partner and or partnership contact information	NF36 form	Older persons	Disability	N/A [^]	Eight weeks in advance
NF37	Change of members and or unincorporated body contact information	NF37 form	Older persons	Disability	N/A^	Eight weeks in advance
NF60	Declaration of bed occupancy	NF60 form (via Provider Portal website or email for designated centres for older people; via email for special care)	Older persons	Not applicable to disability	Special care units	1–15 January 1–15 May 1–15 September

Appendix 5 — Information for all designated centres

Appendix 5 — Additional useful information

The following section has been compiled from queries we have received from providers and the public about regulation in designated centres. We believe it would be beneficial for staff in designated centres and providers of these centres to discuss some of the issues raised in order to support compliance with regulations and national standards. While this information is divided into the different types of designated centres, staff in centres may benefit from reviewing all areas covered.

All designated centres

Advocacy services

The regulations for designated centres for older people, residential centres for people with disabilities and designated special care units for children all require providers to help residents access advocacy services.

While we are not intrinsically an advocacy service, through the course of our work, we do seek to advocate for the rights and dignity of residents and clients of these services.

There are a number of areas where this happens frequently, such as the requirement by providers to respond to our compliance plans as part of the inspection process (see Chapter 5 on inspection of your centre).

We have worked with various advocacy groups to help inform national standards in children's residential services, designated centres for older people, and residential services for children and adults with disabilities.

We also value the role of advocacy services for adults and children in designated centres for people with disabilities and for older people, and advocacy services for children and young people temporarily living in special care units.

New regulations for providers of designated centres for older people came into effect from 1 March 2023. These changes aim to support a positive complaints culture and support residents in private nursing homes by providing access to advocacy services.

Healthcomplaints.ie provides information on how to make a complaint or give feedback about health and social care services in Ireland.[‡] You can obtain a list of advocacy services at the following link: https://www.healthcomplaints.ie/resou rces/where-to-get-help-and-advocacy/.

⁺ Homepage,

https://www.healthcomplaints.ie/.

Appendix 5 — All designated centres

Animal-assisted therapy in designated centres

The quality of life and potential health benefits arising from animal-assisted therapy for people living in residential care settings or attending other health and social care services has been indicated in a number of studies.[^] There is no regulatory prohibition on having pets in a designated centre.

However, when considering introducing pets, you should consider a number of factors, including that the residents' and or children's wishes inform any decisions and that the provider's policy be clearly communicated with existing or new residents and children in the centre.

There should be a risk assessment and control measures in place to mitigate any identified risks to residents or children. Staff in centres should also establish whether potential pets have been socialised and are suitable for residents or children. A number of designated centres in Ireland have pets and many centres use a pet visitation service. Family members also often take pets in to visit their relatives and some residents take their own pet in with them as they move into residential care.

Record retention in designated centres

Providers should be aware that different regulatory requirements are in place for the retention of records relating to residents, children and staff in the different types of designated centres: centres for older people, disability centres and special care units.

In designated centres for adults with disabilities and in designated centres for older people, providers must keep residents and staff members' records for **at least seven years** after the resident has ceased to live in the designated centre and after the staff member has last worked there.

Records related to children living in designated centres for people with disabilities shall be **kept in perpetuity (forever)** and transferred to the Health Service Executive (HSE) not later than seven years from the date on which the child ceased to live in the designated centre.

In special care units, the regulations stipulate that all records (bar one specifically listed exception) shall be **retained in perpetuity**. The record retention periods are set out in the respective regulations for designated centres for older people, people with disabilities and special care units.

Richeson, N. E. (2003). Effects of animal-assisted therapy on agitated behaviors and social interactions of older adults with dementia. American Journal of Alzheimer's Disease & Other Dementias®, 18(6), 353–358. Available online from: https://doi.org/10.1177/153331750301800610.

[^] Banks, MR and Banks, WA. The Effects of Animal-Assisted Therapy on Loneliness in an Elderly Population in Long-Term Care Facilities. The Journals of Gerontology: Series A, Volume 57, Issue 7, 1 July 2002, Pages M428–M432. Available online from: <u>https://doi.org/10.1093/gerona/57.7.M428</u>;

Appendix 5 — Designated centres for people with disabilities

Designated centres for people with disabilities



Qualifications to work in a designated centre for people with disabilities

We are not prescriptive about the qualifications of staff working in designated residential centres for people with disabilities. Therefore, while it is usual to see staff having a particular qualification, such as a QQI/FETAC[#] Level 5 award, this is not a requirement of the regulations.

Schedule 2 of the Health Act 2007 (Care and Support of Residents in Designated Centres for Persons (Children and Adults) with Disabilities) Regulations 2013 sets out the information and documents to be obtained about staff currently and previously employed there. Section 1(f) of Schedule 2 requires providers to keep records of relevant current registration status with professional bodies for nursing and other health and social care professionals employed. Inspectors may review a sample of employee files during an inspection to ensure all the required information is available.

If this file belongs to a nurse, we would expect to see active registration status with current PIN[¥] in place. However, inspectors do not review all staff files, as it is the responsibility of the provider to ensure all required documentation is in place and that it is operating in compliance with regulations and national standards.

Qualifications of the person in charge of a disability centre

The qualifications of the person in charge of a designated centre for people with disabilities are solely the responsibility of the registered provider. We are not prescriptive about such qualifications and this is not precisely specified in the regulations.

[#] QQI = Quality and Qualifications Ireland is an amalgamated entity which in 2012 replaced the Further Education and Training Awards Council (FETAC), the Higher Education and Training Awards Council (HETAC), the National Qualifications Authority of Ireland (NQAI) and the Irish Universities Quality Board (IUQB). Source: https://www.qqi.ie/.

[¥] The Nursing and Midwifery Board of Ireland (NMBI) issues all registered nurses and midwives with a unique personal identification number (PIN) when they first register with NMBI. This PIN number is printed on all subsequent certificates issued by NMBI to the registrant. For more information, see: https://www.nmbi.ie/FAQ-Repository.

Appendix 5 — Designated centres for people with disabilities

The regulations say that the post of person in charge shall be full-time and that the person in charge shall have the qualifications, skills and experience necessary to manage the designated centre, taking into consideration its size, statement of purpose, and the number and needs of the residents.

In addition, from 1 November 2016, all newly appointed persons in charge of designated centres for people with disabilities (as opposed to those already in a specific person in charge role when the regulations were enacted) must have:

- an appropriate qualification in health or social care management at an appropriate level and
- a minimum of three years' experience in managing or supervising in health or social care.

However, if you were in a specific person in charge role prior to 1 November 2016 but take on the same role in another designated centre, while still being in your original post, or if you move to another centre to carry out this role, then you must meet these additional requirements.

The regulations do not give a specific qualification type.

Generally, providers of residential disability services put their own arrangements in place to enable them to demonstrate that they are meeting the regulations in the appointment of a person in charge and to ensure the best outcomes for residents. We ask providers to demonstrate this.

To assist providers and people interested in working as a person in charge of a designated centre, we have produced a guidance document on the role of the person in charge in designated centres for people with disabilities.



Search online for *Regulation 14: Person in Charge of a Designated Centre for Disability: Guidance on Regulation 14 – Person in Charge, Health Act 2007 (Care and Support of Residents in Designated Centres for Persons (Children and Adults) with Disabilities): April 2021* or go to <u>https://www.hiqa.ie/sites/default/files/</u> <u>2017-05/Provider-guidance-on-</u> <u>Regulation-14-PIC.pdf</u>.

Appendix 5 — Designated centres for people with disabilities

Assessment of need in disability centres

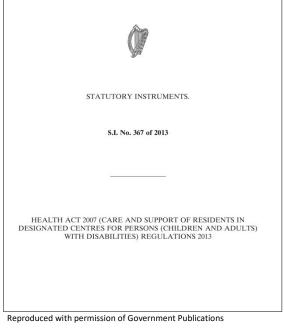
Our function is to register designated centres for people with disabilities and to assess ongoing compliance with regulations and national standards in these centres. We do not have a regulatory remit in relation to how or who carries out assessments of need for people with disabilities using these services.

However, in the *National Standards for Residential Services for Children and Adults with Disabilities*, Standard 2:1 advocates the use of personal plans for residents; while Standard 4:1 calls for the health and development of each person to be promoted.

Standard 4.2 says people with disabilities should receive a health assessment and be given appropriate support to meet any identified need. The features of this standard say health assessments should be timely, comprehensive and multidisciplinary, and be regularly updated and reviewed.

Disability building requirements

The requirements for the premises housing a designated centre for people with disabilities is set out in Regulation 17 and Schedule 6 of the 2013 care and support regulations for designated centres for people with disabilities.



In addition, Standard 2.2 of the *National Standards for Residential Services for Children and Adults with Disabilities* (2013) advocates homely and accessible premises which promote the privacy, dignity and safety of each resident.

Features 2.2.1 to 2.2.19 of the standards illustrate ways that centres can meet the requirements of Standard 2.2. We have not published any specific guidance documents about building requirements for designated centres for people with disabilities.

Designated centres for older people



Qualifications of healthcare assistants in centres for older persons

We are not prescriptive about the qualifications required for care staff to work in centres for older people, but the regulations require the registered provider to ensure that there is an appropriate number and skill-mix of staff to meet the assessed needs of the residents.

It is the provider's responsibility to ensure that staff have the know-how to be able to deliver the care and support required by residents. However, if the person is employed as a nurse, we do require a current PIN for nurses to be kept on file, which will show their qualification discipline.

There is no specific requirement in the regulations that stipulates a particular minimum qualification to work as a healthcare assistant in centres for older people. In addition, the regulations do not specify any particular training or qualification or the level required. In our inspections, we consider whether the provider can demonstrate that staff are appropriately trained to meet the needs of residents in that service. The 2016 *National Standards for Residential Care Settings for Older People in Ireland* do refer to the required competencies necessary to provide a person-centred, effective and safe services to all residents.

These are:

- Standard 7.2: Staff have the required competencies to manage and deliver person-centred, effective and safe services to all residents.
- Standard 7.3: Staff are supported and supervised to carry out their duties to protect and promote the care and welfare of all residents.
- Standard 7.4: Training is provided to improve outcomes for all residents.

Respite care in centres for older persons

While we regulate designated centres for older people, services in these centres, such as respite care and short-term residential care, are a matter between residents and their families and the centres — once the centre meets its conditions of registration.

However, the regulations require that residents are clearly communicated with in relation to the services they receive, including matters relating to charges. Only fees set out in the contract of care can be charged by the registered provider.

This contract of care must be agreed between the resident and the service provider within one month of admission to the centre for older people. Providers should always provide clear information to families about residential care options in centres for older people.

Fees in centres for older people

The Chief Inspector of Social Services is not a financial regulator and has no role in relation to the fees charged by providers of designated centres for older people. While our inspectors review the contract of care in line with the regulations to check whether it is transparent and provides choice, the regulatory framework does not allow our inspectors to review the amount of additional money that a resident may have to pay.

Nonetheless, we have also engaged with the Competition and Consumer Protection Commission (CCPC) to inform guidance for registered providers in the development and use of contracts of care and have raised this issue with the Department of Health.*

There is a specific regulation requiring the provider to have a contract for providing services in place when a resident is admitted to a centre for older people. Regulation 24(1) of the 2013 care and welfare regulations for designated centres for older people states:

Regulation 24(1)

The registered provider shall agree in writing with each resident, on the admission of that resident to the designated centre concerned, the terms on which that resident shall reside in that centre.

Regulation 24(2)

The agreement referred to in paragraph (1) shall relate to the care and welfare of the resident in the designated centre concerned and include details of—

(a) the services to be provided, whether under the Nursing Homes Support Scheme or otherwise, to the resident concerned,

(b) the fees, if any, to be charged for such services,

(c) where appropriate, the arrangements for the application for or receipt of financial support under the Nursing Homes Support Scheme, including the

[•] Chief Inspector addressing the Oireachtas Joint Committee on Health, 4 October 2023.

arrangements for the payment or refund of monies, or

(d) any other service of which the resident may choose to avail but which is not included in the Nursing Homes Support Scheme or to which the resident is not entitled under any other health entitlement.

This regulation requires the provider to have a contract for providing services in place and this contract must be agreed in writing with the resident. The contract should be transparent about fees being charged and how much the resident will pay for extra services which they choose to avail of.

Residents should be clearly communicated with about the services they receive, including fees. The registered provider can only charge the fees set out in the contract of care. This contract must be agreed between the resident and the service provider within one month of being admitted to the centre for older people.

The lived environment in centres for older people

The lived environment is more than the square footage of a centre. It is about whether the premises is designed and laid out to improve people's abilities, promote their independence and support active living and enjoyment to ensure positive outcomes for the people living in the designated centre.

To provide a comfortable living environment for residents, providers should not rely solely on meeting the requirements of the regulations on premises, but should consider other regulations and national standards that may impact on the lived environment for residents.

The regulations and national standards on the premises require that the design and layout of a designated centre is suitable for its stated purpose. This means that all areas within the premises must ensure the privacy, dignity and wellbeing needs of each resident are met.

Therefore, the privacy, dignity and wellbeing of the residents must always be at the centre of the layout, design and organisation of the living and recreational accommodation for residents.

The national standards place the privacy, dignity and wellbeing of residents at the core of the lived environment. Equally, poorly designed living accommodation, or its poor usage, can have a significant negative impact on the privacy, dignity, wellbeing and independence of residents.

It is essential, therefore, that providers have an understanding of the concepts of privacy, dignity and wellbeing.

Key prerequisites to maintaining a person's privacy in a designated centre for older people include:

- the person's right to his or her personal privacy
- the freedom to be alone if he or she so chooses
- the freedom from unwanted or undue intrusion or disturbance in his or her life or affairs
- not be made to feel embarrassed when receiving care and support
- not to feel embarrassed or upset when other people are receiving care and support
- his or her personal information being confidential and not being shared without the person's permission.

Key prerequisites to maintaining a person's dignity in a designated centre for older people include:

- a service that ensures the person living there is always seen, heard, listened to and treated fairly, and with courtesy and kindness
- the person is always recognised, understood and feels safe
- irrespective of a person's physical or cognitive abilities, there is an inherent understanding of the value and worth of the person
- the person is treated with respect and is offered every opportunity to contribute to society

- the person's spiritual or religious beliefs are respected and facilitated
- the services provide people and their carers with adequate information for them to make informed choices about their care
- the person is able to undertake activities in private without fear of impinging on others.

Key prerequisites to maintaining a person's wellbeing in a designated centre for older people include:

- preserving the person's selfrespect and self-esteem through enhanced staff engagement
- the person is enabled to maintain contact and links to the community in which they formerly lived, and their social networks and family connections are fostered
- the continuity of staff working in the centre is developed and maintained
- the person has good opportunities to pursue meaningful activities
- the person has sufficient personal space.

When a person moves into a designated centre, they leave behind a home filled with memories: personal possessions, mementoes, souvenirs and photographs that tell their life story. Therefore, the care environment is one that encourages people to retain items that are dear to them.

If residents wish, they should be encouraged to be involved in how their room is decorated with their personal

possessions. Sufficient space is provided for private personal use, which includes personal storage and secure storage for the safe-keeping of valuables and money, and residents are happy with these arrangements.

Shared bedrooms must be of an adequate size for shared occupancy and ensure the comfort, privacy and dignity of each resident. Residents should be given a choice of who they share their rooms with. Where residents share rooms, intimate personal care must be discreetly provided, not causing embarrassment to either the person receiving care or to their fellow residents.

For example, if residents need to use the bathroom, if unable to get there independently, they are assisted to the bathroom. It is never appropriate that residents should have to go to the toilet on a commode beside their bed, especially if other residents are in the room. Inspections will focus on these kinds of issues in shared accommodation in the designated centre.

A centre must have a written visitor policy which promotes the privacy, dignity and wellbeing of residents and ensures that visitors (when there are no public health restrictions in place) are welcome and residents are supported to maintain their personal relationships, in accordance with their wishes. These relationships can further enhance the wellbeing of residents.

Since 31 March 2025, the nursing home visitor policy must include the

process for access during an outbreak of a communicable disease, and epidemic or a pandemic, and arrangements for residents to receive nominated support persons, amongst other requirements.

The lived environment and staff working in this environment should both be welcoming. They should afford residents the opportunity to meet their visitors in communal areas or in a private area (other than the resident's room) if they so wish or for their visitors to join them and their fellow residents in communal areas.

Evaluation of the effectiveness of the facilities, decor, design and layout of the premises to ensure the privacy, dignity and wellbeing of residents comprises an element of the continual quality improvement cycle, which in turn forms part of the annual review.

Therefore, the lived environment is not solely about the premises and is not determined by the size of the rooms. Rather, it is about the homeliness and the experience of the person living in that residential service. We of course take into account how accessible the environment is and also the space provided for residents.

However, when we make a regulatory judgment on the standard of privacy, dignity and wellbeing experienced by people living in designated centres, we are reporting on their experience of life in the centre. Our regulatory judgment includes a wider and more holistic view of the totality of the environment. Appendix 5 — Designated special care units

Designated special care units



Records retention in special care

Case records held about each child placed in special care are held in perpetuity (forever). The same rule applies to any residential centre in which a child is placed on a statutory basis.

This is to ensure there is an accurate account of each child's time in care so that whether as a child or an adult, a person can know their own history.

This may be something which could be taken for granted by people who remain in their family home for their childhood, but it is very important for people who have spent time out of the family environment.

Notifying an absconsion (NF05)

There are times when a child placed in a special care unit may abscond. This means that they have left or have not returned to the unit without permission from unit staff. Persons in charge of designated special care units are required to notify these incidents to the Chief Inspector within three days. These notifications allow us to monitor the ongoing safety of these vulnerable children and to assess the ongoing security of these units.

The Chief Inspector defines absconsion as a time when a child is outside of the sight and supervision of a unit staff member without permission.

Notifying an allegation of child abuse (NF06)

Staff working in special care units may have or become aware of a concern about a child's safety or welfare. The staff themselves may also be the subject of an allegation of abuse made by a child or other persons connected to the child.

Special care units have several reporting requirements in relation to concerns about a child. The first is to

Appendix 5 — Designated special care units

report any child protection or welfare concern to Tusla (child protection and welfare notification). These reports include welfare concerns that may not necessarily be an allegation of abuse.

Secondly, special care units report specific incidents to the child's allocated social worker and others (such as a Tusla monitoring officer), using the 'significant incident' reporting system. This system allows Tusla to monitor and respond to risk to a child.

The third requirement is the reporting of child abuse allegations to the Chief Inspector (NF06).

It is important for providers of special care units to ensure that an NF06 is submitted only when there is an actual allegation of abuse. All other concerns about a child's welfare should be reported to Tusla in line with the Children First Act 2015 and *Children First: National Guidance for the Protection and Welfare of Children*, (2017), and through any other reporting systems that Tusla has put in place.

Appendix 6 — References and resources*

Please note that the accuracy, quality, relevance and currency of these works are not guaranteed or uniform. More recent information may have superseded these works. It does not include all the resources that may be relevant to service providers. It is up to each service provider to identify the best available evidence relevant to their activities. For further information on guidance we have published for providers of designated centres, see Appendix 1.

Legislation

Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023. Dublin: Government Publications; 2023. Available online from: <u>https://www.irishstatutebook.ie/eli/2023/act/10/enacted/en/html</u>.

Health (Miscellaneous Provisions) (No. 2) Act 2024. Dublin: Government Publications; 2024. Available online from:

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^{*} All online resources were accessed at the time of preparing this handbook. Please note that web addresses may change over time and that the Chief Inspector of Social Services is not responsible for external website content. Any possible omissions of external sources are inadvertent and will be corrected in future editions. We acknowledge the previous work of our staff teams whose internal guidance material and previously published guidance were essential in the drafting of this handbook.

Criminal Justice (Spent Convictions and Certain Disclosures) Act 2016. Dublin: Government Publications Office; 2016. Available online from: <u>http://www.irishstatutebook.ie/eli/2016/act/4/enacted/en/html</u>.

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http://revisedacts.lawreform.ie/eli/2007/act/21/front/revised/en/html.

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Regulations

Designated centres for people with disabilities

Health Act 2007 (Care and Support of Residents in Designated Centres for Persons (Children and Adults) with Disabilities) Regulations 2013. Dublin: The Stationery Office; 2013.

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Overview reports

To view our overview reports on the regulation of designated centres for older people and people with disabilities, and our overview reports on the regulation and monitoring of children's services, visit the <u>Key Reports and Investigations section</u> of <u>www.hiqa.ie</u>.

General resources

Health Information and Quality Authority (HIQA). The impact of COVID-19 on nursing homes in Ireland: July 2020. Dublin: HIQA; 2020. Available online from: <u>https://www.hiqa.ie/reports-and-publications/key-reports-and-investigations/impact-covid-19-nursing-homes-ireland</u>.

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Your notes

Appendix 7 — Revision history

Revision Date	Summary of main changes
May 2025	 Version 4.1 Edited to simplify references to amended regulations for designated centres for older people, designated special care units, and designated centres for people with disabilities. These are now referred to as: Health Act 2007 (Care and Welfare of Residents in Designated Centres for Older People) Regulations 2013 (as amended) Health Act 2007 (Registration of Designated Centres for Older People) Regulations 2015 (as amended) Health Act 2007 (Care and Welfare of Children in Special Care Units) Regulations 2017 (as amended) Health Act 2007 (Registration of Designated Centres for Persons (Children and Adults) with disabilities) Regulations 2013 (as amended). Updated images of guidance issued by the Chief Inspector.
March 2025	No other change to contents. Version 4
	 Reflect changes in the regulation of nursing homes arising from: Health Act 2007 (Care and Welfare of Residents in Designated Centres for Older People) (Amendment) Regulations 2025, in relation to: appointing a person deputising for the person in charge whenever the person in charge is absent deputising arrangements for key management roles implementing quality improvements identified in the annual review amending the definition of 'family' throughout the regulations to include 'a close friend' among other examples arrangements for residents to have access to the Internet new provision to further support residents with communication difficulties visiting arrangements when visting in a nursing home is restricted provision of information on access by residents to inspection reports qualification and experience requirements for deputy persons in charge limit on the number of centres that a person in charge may manage at any one time facilitating staff to raise concerns about the quality and safety of the care and support provided to residents additional infection control and risk management requirements in nursing homes. Section 78A of the Health Act 2007 (as amended) commencement of compliance notices for designated centres for older people and people with disabilities Section 78B of above Act — commencement providing that the Chief Inspector shall maintain a list of all registered providers on whom a fine or other penalty is imposed by a court under Section 78A and that the

Regulation handbook: A guide for providers and staff of designated centres

October 2024	Version 3
	Reflect changes to Health Act 2007 arising from:
	 Health (Miscellaneous Provisions) (No. 2) Act 2024, in relation to:
	 new provisions for the collection and maintenance of information from specified designated centres
	 allowing the Chief Inspector to remove a condition of registration where it is appropriate in the circumstances and will not adversely affect people living in the designated centre.
	 a reduction in representation timelines from 28 to 14 days and a reduction in appeal time frames from 28 to 14 days for all proposed decisions and decisions
	 additional measures under section 65 requirement to submit information in such manner and form as the Chief Inspector requires
	 powers of inspection of unregistered designated centres and right to seek a warrant from a court to enter an unregistered centre
	 proposed new power of compliance notice, once commenced, publication of these, and related offences and penalties for not complying
	 adding to the public registers of designated centres the details of any fines or other penalties imposed on a provider under the Health Act 2007.
	Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023.
	 New requirement under section 28 of this Act to notify the Chief Inspector of notifiable incidents involving residents in designated centres.
	 Sets out the time frame by which a provider can give feedback on a draft report (21 days). This means that the Chief Inspector's submission process will be retired.
	 Once the relevant section of the Patient Safety Act is commenced, the Chief Inspector will have a new discretionary function to review specified incidents in nursing homes.
	Formatting throughout, and updates to resources section to reflect removal of obsolete guidance from www.hiqa.ie and publication of new guidance, including the <i>Lexicon for Social Care</i> .

January 2024	Version 2.2
January 2024	 Providing further clarity in relation to the submission process, in
	line with updated procedure, and making judgments
	 Reference to new <i>Registration handbook</i> and removal of
	references to related obsolete guidance
	 Removal of requirement to include a signed floor plan declaration
	when submitting floor plans
	 Change of HIQA banking details for payment of annual and registration force
	registration fees
	Updated guidance in Appendix 1 and updated references and
	resources in Appendix 6
	 In Appendix 5, reference to new older people regulations in
	relation to complaints and advocacy.
	Removal of references to obsolete COVID-19 assurance framework
	for registered providers
	 Updating of website links and amendments to references.
	 Remove obsolete glossary of terms.
July 2022	Version 2.1
,	 welcome from the new Chief Inspector
	 updates to reflect further clarity when applying to vary conditions
	when new extensions increase the footprint of a designated centre
	 new entry on emailed scanned copies of acceptance of NOPDs and
	NODs
	 updated fitness guidance (including assessment-of-fitness
	interviews by video conferencing)
	 updated guidance on understanding the definition of a designated
	centre
	 new advice on marketing cookies for viewing portal videos
	 new guidance on managing notifiable events
	 amendments to hyperlinks, guidance and resources in appendices
	 additional MOU and updated MOU
	 various style and grammar amendments throughout.
August 2021	Version 2 published.
	Various amendments including in relation to:
	 changes to footprint of a centre
	 registered provider's representative
	 new application to register
	 site visit and self-assessment
	 floor plans of centres
	 applications to vary or renew
	 publication of:
	 fire safety guidance
	 assurance programme on infection prevention and control
	 — safeguarding standards
	 time frames for draft Portal notifications
	 visiting and public health restrictions inclusion of additional resource material
October 2019	inclusion of additional resource material
	First published

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