

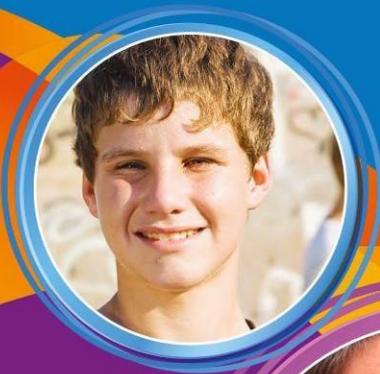


**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Guidance for Designated Centres

Enforcement Policy



About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is the independent Authority established to drive high quality and safe care for people using our health and social care services. HIQA's role is to promote sustainable improvements, safeguard people using health and social care services, support informed decisions on how services are delivered, and promote person-centered care for the benefit of the public.

The Authority's mandate to date extends across the quality and safety of the public, private (within its social care function) and voluntary sectors. Reporting to the Minister for Health and the Minister for Children and Youth Affairs, the Health Information and Quality Authority has statutory responsibility for:

- **Setting Standards for Health and Social Services** – Developing person-centred standards, based on evidence and best international practice, for those health and social care services in Ireland that by law are required to be regulated by the Authority.
- **Supporting Improvement** – Supporting health and social care services to implement standards by providing education in quality improvement tools and methodologies.
- **Social Services Inspectorate** – Registering and inspecting residential centres for dependent people and inspecting children detention schools, foster care services and child protection services.
- **Monitoring Healthcare Quality and Safety** – Monitoring the quality and safety of health and personal social care services and investigating as necessary serious concerns about the health and welfare of people who use these services.
- **Health Technology Assessment** – Ensuring the best outcome for people who use our health services and best use of resources by evaluating the clinical and cost effectiveness of drugs, equipment, diagnostic techniques and health promotion activities.
- **Health Information** – Advising on the efficient and secure collection and sharing of health information, evaluating information resources and publishing information about the delivery and performance of Ireland's health and social care services.

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1.0 Introduction

This policy outlines the legal and administrative framework¹ and principles within which the Health Information and Quality Authority² (hereafter 'The Authority') will operate should a registered provider fail to comply with Regulations and Standards.

In line with the principles of good public service administration, the policy aims to ensure, as far as is practicable, full transparency to providers, service users and the public of the legal and procedural options open to HIQA in dealing with non-compliance.

HIQA will remain open and transparent in the way it deals with identified non-compliance and the way in which it uses its legal powers. This will be done through the publication of the associated relevant policies and procedures and through the issue of updated guidance to registered providers and other relevant stakeholders (available on the Authority's website (www.hiqa.ie)).

In its Corporate Plan 2016-2018 HIQA is committed to four key outcomes. These are:

- care is improved
- people are safeguarded
- people are informed
- policy and service decisions are informed.

HIQA believes that the appropriate use of enforcement powers, including prosecution, is important, in achieving the above outcomes as well as securing compliance with legislation and minimum standards.

It is also vital that HIQA uses its powers reasonably, consistently and proportionately to ensure that registered providers are held to account for failures to safeguard the health, safety and welfare of service users where that is appropriate.

This framework sets out the general principles and approach that guides the Authority's approach to managing non-compliance, including enforcement and prosecution.

HIQA will ensure that all enforcement action will be undertaken in accordance with the relevant legislation, Regulations, Standards and policies.

¹ This document should not be relied upon for legal purposes – please refer to the original legislation - Health Act 2007 as amended.

² HIQA for the purposes of this policy means the Health Information and Quality Authority, a body corporate established under the Health Act 2007 together with the Chief Inspector, a statutory officer appointed under the Health Act 2007.

Action dealing with non-compliance is an essential element of the responsibilities of the Authority. The Act³ and our methodology set out a range of enforcement options to ensure compliance with regulations⁴ and minimum standards⁵, to effect improvements and to afford protection to service users.

A stepped approach to enforcement will normally be adopted. However, this stepped approach does not preclude HIQA moving directly to legal action, including prosecution, if the circumstances merit such action.

HIQA will take into account the likely impact of regulatory or enforcement action on people who use services, their carers, families and the wider community when deciding what kind of action to take.

This policy will be underpinned by the Authority's assessment and monitoring approach.⁶

³ The Health Act 2007 as amended (The "Act")

⁴ 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, 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 2015.

⁵ National Quality Standards for Residential Care for Older Persons in Ireland,

⁶ HIQA has adopted a common 'Authority Monitoring Approach' (AMA) in order to carry out its functions as required by the Act. Application of AMA will ensure the consistent and timely assessment and monitoring of compliance with Standards and Regulations, managing regulation and risk.

2.0 Regulatory response

Our regulatory response is informed by, among other things, the provisions of the Act, the Regulations and the Standards. It should be noted that these provisions place specific and general duties on registered providers. They also provide HIQA with powers to monitor and inspect regulated services and to gather information about whether relevant requirements are being met.

HIQA will employ a Judgment Framework which will:

- help its inspectors to reach judgments about a registered provider's compliance with the essential standards
- set out how we go about determining our regulatory response and how we will make decisions taking into account the impact on people using the service.

The Authority's monitoring process of compliance with the Act, Regulations and Standards include:

- the process of inspection, within which requirements are clearly articulated in an Action Plan
- the requirement of the provider to submit an Action Plan within a preset timeframe
- validation of the provider's actions against the Action Plan.

The aim of HIQA is to regulate for improvement. HIQA will encourage improvement and provide, when appropriate, accessible advice on methods of improvement wherever possible thus ensuring the best possible outcome for service users.

Where a registered provider fails to comply with the requirements of the Act, the Regulations and Standards and demonstrate sustained improvements, HIQA will take action based on the seriousness of the breach and the risk posed to the service users.

In circumstances where providers fail to implement improvements to comply with the regulatory requirements and depending on the circumstances and assessment of risk, HIQA has a range of options available.

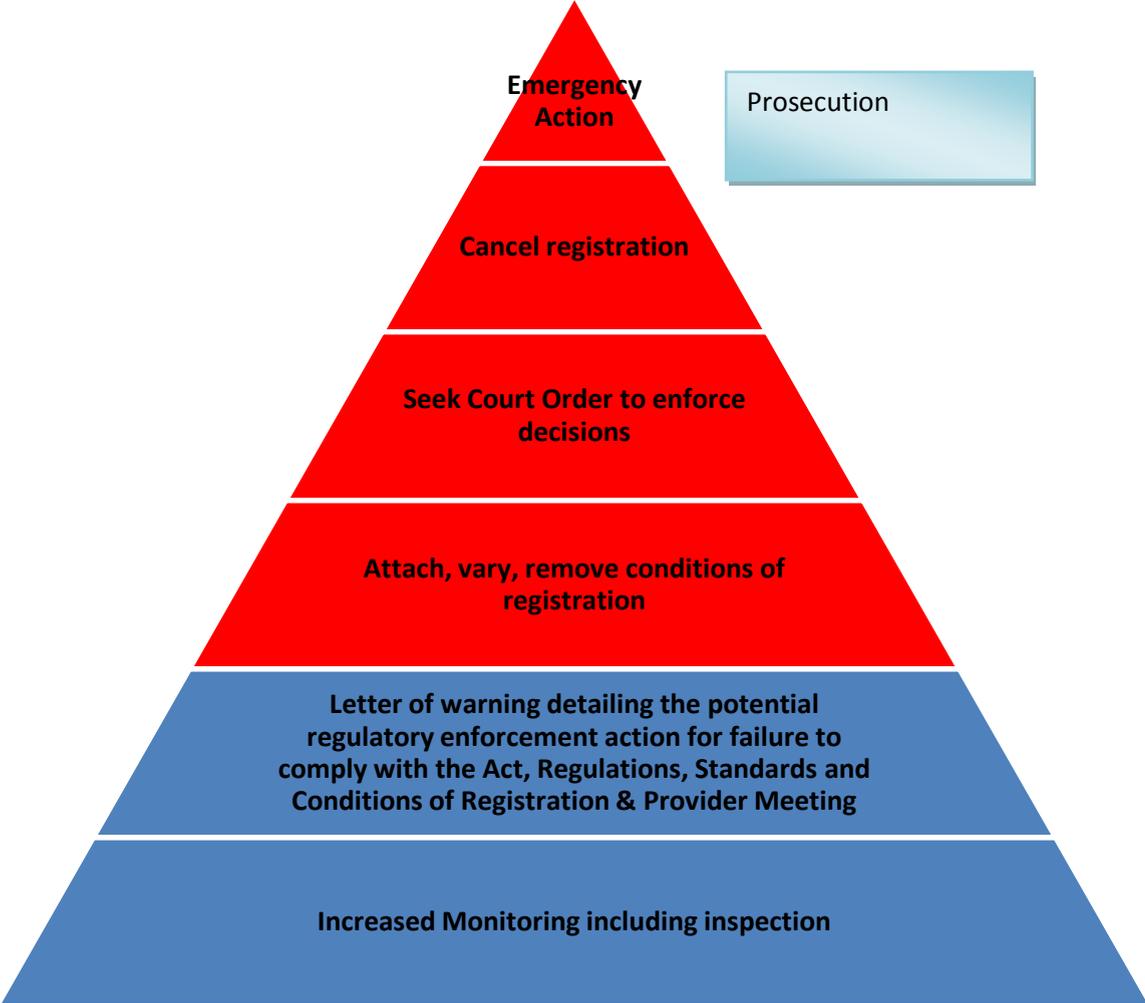
Options include increased monitoring, immediate Action Plans⁷, provider meetings and warning letters (Table 1).

It should be noted that regulation approaches may not follow a linear order even in the event of an identified breach of legal requirements, as every breach is judged on an individual basis and our response to it is proportionate to the risk for people who use services (Diagram 1).

The Chief Inspector has the right to exercise discretion in determining the regulatory response to any breach of requirements.

⁷ The decision to issue an immediate action plan is an exceptional regulatory activity. An immediate action plan is only used when inspection findings indicate that there is an immediate risk to the welfare of residents as a result of significant non-compliance with the regulations that requires the registered provider to take immediate action to address the risk

Diagram 1- Regulatory Responses⁸



⁸ Note: this is not a linear process and the Chief Inspector may take one or a combination of any the actions outlined above.

3.0 Principles of enforcement

Prior to using its statutory enforcement powers, HIQA will employ other means of seeking compliance with the registered provider. However, if a registered provider/person in charge fails or continues to fail to fulfill his/her legal obligations or to bring about necessary changes to the service they provide enforcement action may be taken.

All registered providers should be aware that enforcement is a legal process and may result in court proceedings and/or prosecution.

In deciding to take any enforcement action HIQA will balance the consequences of taking enforcement action against the risks of taking no action.

1. HIQA will be fair and proportionate in how it works with registered providers and persons in charge in order to ensure compliance with the Act, Regulations and Standards.
2. HIQA will be consistent in how it uses its enforcement options. Consistency does not mean that HIQA will use the same enforcement option every time a particular legal requirement is not met. It means that we will use the same criteria and approach when deciding how to respond to non-compliance.
3. HIQA will be guided by the ARI (attitude, risk, impact) principle.
 - Attitude: HIQA considers whether the attitude and knowledge of the provider is appropriate. In particular, HIQA assesses whether the provider has understood the issue and shown a willingness to put things right.
 - Risk: HIQA assesses the risk to residents from any non-compliance and takes action higher up the regulatory response escalator (Table 2) where residents are at risk.
 - Impact: HIQA assesses the impact of the concerns on outcomes for residents and whether the enforcement action will bring about the necessary improvement. HIQA will take the most appropriate action matched to the degree of risk identified.
4. HIQA will take enforcement action depending on the seriousness of any breaches of the law.
5. Where any given enforcement action does not bring about the required improvements HIQA may escalate the enforcement action.
6. HIQA will ensure that the resources employed in any regulatory or

enforcement action will be used in the most effective and efficient manner.

7. HIQA will inform registered providers of their right of reply and representation under the law and ensure that these rights are upheld.
8. HIQA will adhere to the rules of natural justice in all of its activities.
9. Where there is an immediate threat to the safety and welfare of residents the Chief Inspector may decide to take urgent enforcement action that has immediate effect.
10. HIQA will work with other statutory agencies when undertaking enforcement action taking cognizance of any associated or other relevant legislation.
11. HIQA will monitor its use of enforcement action to ensure that enforcement action is appropriate and proportionate and ensure that any lessons from its use are learned and applied into practice.

4.0 Enforcement actions under the Health Act 2007 (as amended) - statutory enforcement actions

The Chief Inspector has a number of enforcement provisions available should a registered provider fail to comply with the Act. These powers are detailed below.

The specific powers are detailed within the relevant sections in the Act which can be access at (www.irishstatutebook.ie).

How HIQA will proceed with these matters will be listed in the associated procedures.

4.1 Refusal of Registration (Section 50)

Each application under Section 48 of the Act for the registration or renewal of the registration of a designated centre is considered under four tests.

These include:

- 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 Standards
 - The Regulation
 - Any other enactment that appears to the Chief Inspector to be relevant and is cited by the Chief Inspector.

If the Chief Inspector is not so satisfied, the application for registration shall be refused.

Additional options

Registered providers and persons in charge have a legal obligation to remain compliant with the Act, Regulations and Standards. Should the Chief Inspector at any time consider that this is not the case; the following options can be considered.

4.2 Court orders enforcing certain decisions (Section 58)

If the Chief Inspector believes on reasonable ground 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 a condition an additional conditions 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.

Court Order for Cancellation or variation registration (Section 59)

If the Chief Inspector believes, on reasonable grounds that there is a risk to the life, or a serious risk to the health or welfare, of residents in a designated centre, because of any act, failure or negligence on the part of the registered provider or a person acting on behalf of the registered provider, the Chief Inspector may apply to the Court for an Order to:

- Cancel the registration of the designated centre
- Vary or remove a condition of registration or
- Attach an additional condition of registration.

4.3 Ex Parte application to the District Court (Section 60)

The Chief Inspector may make an application under Section 59 may be made ex parte and without notice for an interim order, if having regard to the circumstances of the particular case, the court considers it necessary or expedient to make the order immediately in the best interest of the residents.

5.0 Prosecution for specified offences (Section 79)

The Chief Inspector has the power to prosecute for certain offences defined in the Act and the Regulations made under it.

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 recurrence 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 list of offences is set out in Appendix 2, Table 2.

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.

6.0 Working with other organizations

Where HIQA and another enforcement body (e.g. An Garda Síochána, or the Health and Safety Authority) have the power to take action, HIQA will Endeavour to work with the other enforcement body to ensure coordination of their respective powers. HIQA has memoranda of understanding with several other regulators.

Appendix 2: Table 2 - List of Offences

All offences are identified and listed below.

Section 79(2) offences	Reference to section contravened	Details of the offence
79 (1)(a)	69 (3)	Failure to notify the Chief Inspector
79 (1)(b)	46	Carrying on an unregistered centre
79 (1)(b)	47	Prohibition against false or misleading information
79 (1)(b)	77	Obstruction
Section 79(2) offences	Reference to section contravened	Details of the offence
79 (2)(a)	56(1)	Failure to affix Certificate of registration in conspicuous place.
79 (2)(a)	65	A registered provider shall 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.
Section 79(2) offences	Reference to section contravened	Details of the offence
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 organization, a person shall not, with intent to deceive another person, a) apply a name to the premises, undertaking or organization that in any way describes it as a designated centre of that description, or (b) hold out the premises, undertaking or organization as a designated centre of that description.
Section 79(2) offences	Reference to section contravened	Details of the offence
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	Contravenes a provision of the Regulations.
79 (2)(e)	n/a	Fails to comply with a condition of the registration of the designated centre.

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