



Healthcare
Improvement
Scotland

Inspections
and reviews
To drive improvement

Enforcement Policy

February 2021

© Healthcare Improvement Scotland 2021

Published February 2021

You can copy or reproduce the information in this document for use within NHSScotland and for educational purposes. You must not make a profit using information in this document. Commercial organisations must get our written permission before reproducing this document.

www.healthcareimprovementscotland.org

Foreword

This policy relates to:

- independent healthcare services that are not registered with Healthcare Improvement Scotland as required by *The National Health Service (Scotland) Act 1978*, and
- independent healthcare services registered under *The National Health Service (Scotland) Act 1978* as amended by the *Public Services Reform (Scotland) Act 2010* (“The Act”) and associated Regulations.

Introduction

Healthcare Improvement Scotland is the national health and social care improvement organisation for Scotland. We have many parts, with one single purpose to deliver our aim of better quality health and social care for everyone in Scotland. Part of our function is to act as the regulator for independent healthcare services in Scotland.

We have many tools at our disposal to drive improvement in independent healthcare. While we hope that this may never be required, we can use enforcement action to require improvement where we think there is a significant risk to the health and wellbeing of the users of independent healthcare services, for example, where standards of care fall substantially short of that required, are not improving or where people who use independent healthcare services are endangered.

This policy sets out the approach we will follow when using our enforcement powers under The Act.

Responsibility for the quality of the independent healthcare service provided lies with those who provide them.

This policy cannot be a substitute for professional judgement in individual cases. Decisions about whether to proceed with enforcement action will be based on the information available to us at that time.

Principles of the policy

We will follow the principles of good regulation set out in The Crerar Review (*The report of the Independent Review of Regulation, Audit, Inspection and Complaint Handling of Public Services in Scotland, Scottish Government, 2007 (The Crerar Report)*), which underpin good external scrutiny.

The following principles quoted from the Crerar Report are central to this policy and underpin our enforcement procedures.

(a) Public Focus

The needs and priorities of service users and the public must be the prime consideration in all external scrutiny. The public are the ultimate beneficiary of external scrutiny. As such, it is crucial that they are closely involved in both decisions about the use of scrutiny and any scrutiny activity.

(b) Independence

External scrutiny must be independent and must not be constrained by any party regarding its conclusions and publishing its findings. It must be free to make judgements about service delivery and report its findings into the public domain. It must be able to decide how it discharges its responsibilities, once its focus has been agreed.

(c) Proportionality

The use of external scrutiny within the wider public accountability system must be proportionate to the particular issue, policy context or environment. Proportionality must apply at two levels. Firstly, in deciding whether it is appropriate to use scrutiny and second, in deciding its nature, scope and duration.

(d) Transparency

External scrutiny must be transparent in all its activities, its focus, decision making criteria, business processes, assessments and reporting. There should be a transparent decision making framework for regulatory intervention. It is essential that the processes and mechanisms which support the use of external scrutiny are transparent, so that all parties understand the particular purpose for which it is being used at any given time. For external scrutiny to be credible, its reports must be clear, independent and consistent.

(e) Accountability

External scrutiny must be able to account for its use of resources. It must demonstrate and report on the impact of its activities on services scrutinised, on the direct and indirect cost implication and it must demonstrate value for money. Its assessments and findings must be fair and capable of being defended.

The purpose of enforcement

The purpose of enforcement, up to and including prosecution, is to secure compliance with legislation and minimum standards and ensure that registered providers are held to account for failures to safeguard the health, safety and welfare of service users.

All independent healthcare providers are required to comply with:

- the National Health Service (Scotland) Act 1978 (“The Act”)
- regulations associated with the above primary Act, and
- service specific conditions imposed by Healthcare Improvement Scotland (registered providers only).

This policy provides the framework and principles within which we will operate.

Part 1 – Offences in relation to unregistered providers of independent healthcare services

Offences

Under Section 10Z9 of The *National Health Service (Scotland) Act 1978*, it is an offence to:

- provide an independent healthcare service while it is not registered with us.
- pretend that an independent healthcare service is registered with us.

Our approach to enforcement action

The purpose of taking enforcement action is to ensure independent healthcare services operate to an appropriate standard and to protect the people who use them from the risk of harm.

We will normally advise a provider (in writing) of the requirement to register and work with them to achieve registration. However, in the following circumstances we will take immediate enforcement action:

- If we have grounds to believe that a provider is intentionally choosing not to register.
- If we have grounds to believe that a provider is intentionally deceiving the public that an independent healthcare service is registered with us.
- If an unregistered provider places people at risk of harm.

Prosecution

We will report providers to the Crown Office and Procurator Fiscal Service (COPFS) for prosecution in order to hold service providers to account for failing to comply with legal requirements.

Penalties

Successful prosecution may lead to a fine or imprisonment. The Sheriff decides on the penalty to be imposed on the service provider. They may impose a prison sentence as well as or instead of a fine. The current maximum court fines are:

- maximum fine: up to £5,000.
- maximum prison sentence: up to 3 months.

Publication of enforcement action and outcomes

We will give notice of prosecutions taken in relation to individual service providers to local authorities, NHS boards, Scottish Government and other relevant scrutiny bodies. This is in accordance with statutory reporting obligations set out in the Act and Regulations, and within the memoranda of understanding established between these organisations and us.

Details of successful prosecutions taken in relation to individual service providers will be published on our website.

Referral to Professional Bodies

We will report the relevant individuals from the provider to their professional body (GMC, NMC, GDC). This is in accordance with statutory reporting obligations set out in the Act and Regulations, and within the memoranda of understanding established between these organisations and us.

Part 2 – Registered providers of independent healthcare services

Our approach to enforcement

The purpose of taking enforcement action against registered independent healthcare services is to ensure they operate to an appropriate standard and to protect the people who use them from the risk of harm. Unless people who use the independent healthcare service are at immediate risk of harm, we will take a graduated approach to enforcement, in keeping with the principles set out above.

The range of options we have are not mutually exclusive and we may take a variety of enforcement actions at the same time. This will be proportionate and related to the level of risk to service users and the seriousness of the non-compliance. We will follow up enforcement action to ensure that quality improvements are achieved.

In most cases the steps below will be followed:

Step 1: Escalation of concerns identified by us to independent healthcare service providers

We will work with independent healthcare service providers to make improvements where we have identified areas of concern.

If we do not receive a satisfactory response from the independent healthcare service provider, we may move to Step 2.

Step 2: Condition Notice (Section 10U)

We may serve a Condition Notice on the service provider where Step 1 has not succeeded in bringing about improvement, or where circumstances are sufficiently serious that formal enforcement is necessary.

This Condition Notice sets our intention to vary, remove or impose an additional condition of registration on the service provider.

Conditions imposed will be designed to ensure that the service is safe to continue to be provided and that it complies with the Act and relevant Regulations.

We will provide details of the service provider's right to make representations against the imposition of the condition(s). In most cases we will meet with the service provider prior to the Condition Notice being issued.

Step 3: Improvement Notice (Section 10R)

We may serve an Improvement Notice on an independent healthcare service provider where there is evidence of a breach of Regulation(s) or conditions that justifies the cancellation of an independent healthcare service's registration. We may also undertake this step where the imposition of a condition has not succeeded in bringing about improvement.

Conditions may be imposed at the same time as Improvement Notices and an Improvement Notice may also be justified without a condition having been imposed. This Improvement Notice sets out our intention to cancel the independent healthcare service's registration, unless significant improvement is demonstrated within a stated timescale. The Notice will detail the nature of the improvement required, the legal basis for this action, the timescale for implementation and our intentions in the absence of improvement.

We will provide details of the independent healthcare service provider's right to make representations against the contents of the Notice. In most cases we will meet with the service provider prior to the Improvement Notice being issued.

Step 4: Cancellation of Registration Notice (Section 10S)

We may serve a Cancellation of Registration Notice, where the timescale for meeting an Improvement Notice has expired without compliance.

This Cancellation of Registration Notice details the legal basis of the action and details of the independent healthcare service provider's rights to make written representations against cancellation. In most cases we will meet with the service provider prior to the Cancellation of Registration Notice being issued.

Emergency Procedures

Emergency procedures provide important safeguards but they will not be required routinely. For that reason, they do not form part of the normal graduated system of enforcement as outlined above. In each case where an emergency procedure is being considered, we will seek legal advice from Central Legal Office (CLO) without delay.

Emergency Condition Notice – Section 10V

We may impose an Emergency Condition Notice at any time if we believe not to do so would pose a serious risk to people’s life, health or wellbeing.

Such a Notice would come into effect immediately on its receipt by the independent healthcare service provider. It would give the reason and explain the rights of the independent healthcare service provider to make written representations concerning any matter in dispute.

We will take account of any such written representations in deciding whether to leave the condition in place, vary or remove it and notify the independent healthcare service provider of our decision. If the condition remains in place the Notice will explain the independent healthcare service provider’s rights of appeal to the Sheriff.

Emergency Cancellation of Registration Order (Section 10T)

We may apply to the Sheriff to request the cancellation of an independent healthcare service’s registration at any time, where we believe there is a serious risk to people’s life, health or wellbeing.

The sheriff will grant an Emergency Cancellation of Registration Order where they agree that there would be a serious risk to people’s life, health or wellbeing unless the registration is cancelled.

We will seek legal advice in drafting any formal enforcement notices and formal pleadings required for any court proceedings.

Right to make representation

We are required to give registered independent healthcare service providers the opportunity to make formal representation about any notice we serve on them.

We will set out the arrangements for responding to a formal representation at the time of serving a notice.

Enforcement reports

We will prepare an enforcement report prior to formal enforcement being taken, to ensure we have considered all relevant facts. This report will set out the background to the proposed action, an evaluation of other options considered and reasons for the proposed enforcement action.

We will use this report as the basis for discussion with legal advisors when formal action is being considered and prior to formal enforcement notices being issued. In the case of emergency procedures, this enforcement report will inform the content of the application to the Sheriff which will be drafted by the legal advisors.

In circumstances where we decide to directly inform people who use a service of formal enforcement action we take, we will state the reason for doing so in the enforcement report. We will also update the report with our assessment of the service provider's progress in complying with enforcement action and whether any further action is necessary.

Where formal enforcement action has been taken we will review the service's regulatory support assessment and grades awarded. When planning our inspections we will consider any previous formal enforcement action taken as part of our ongoing assessment of the independent healthcare service provider.

Compliance with formal enforcement will be checked through inspection and will be reported publicly.

Publication of enforcement action and outcomes

We will give notice of any formal enforcement action we take to local authorities, NHS boards, Scottish Government and other relevant scrutiny bodies. This is in accordance with statutory reporting obligations set out in the Act and Regulations, and within the memoranda of understanding established between these organisations and Healthcare Improvement Scotland.

Details of formal enforcement actions we take in relation to individual independent healthcare service providers are also publicly available on our website.

Although we make this information publicly available as set out above, service providers have the primary duty to inform people who use their service of any formal enforcement action we have taken in regard to their service. However, if an inspector believes there is a risk of harm to people who use the service, we will inform them and/or their carers directly of such formal enforcement action.

We will treat each case according to individual circumstances. Part of our assessment will be a consideration of the level of cooperation from the service provider in accurately informing people who use their service of the measures being taken and reasons why.

Where enforcement relates to the fitness of a registered manager or any staff of a registered service, we will advise the relevant professional body of any action we take.

Quality Assurance

Policy Framework

This policy framework requires us to act flexibly and fairly. It requires each situation to be carefully considered on its own merits. Therefore, we will use professional judgment and evidence based assessments to protect people who use healthcare services and ensure improvement.

Our staff will be conversant with and refer to “*Right First Time*”, *Scottish Government, March 2010*, prior to taking any formal enforcement action. This guidance sets out four essential steps in any such decision making process: prepare, investigate, decide and notify. They sit well with this Enforcement Policy.

We will give consideration to current circumstances and relevant regulatory history of services prior to taking formal enforcement action. For example, we will consider the service’s quality of management and leadership, self-assessment submission and the extent to which the service has addressed any previous recommendations, requirements and enforcement notices.

To promote consistency in the application of this framework, and to ensure the quality of decision making, the following definitions are used in all assessments, reporting, correspondence and decision making:

- **Formal Enforcement**
Refers to formal actions set out in the Act which we can use to change the conditions of registration, require improvements or cancel a registration. Healthcare Improvement Scotland has statutory powers to take legal action and service providers have legal rights of review and appeal against such action.
- **Requirement**
Is a statement that sets out what is required of a service provider. It relates directly to the Act, Regulations or orders made under the Act or a condition of registration and must be complied with. Requirements are legally enforceable at the discretion of Healthcare Improvement Scotland.
- **Recommendation**
Is a statement that sets out what a service provider should do in order to improve or develop the quality of the service. However, failure to do so will not directly result in enforcement action. Recommendations are based on the Health and Social Care Standards and other relevant best practice guidance.

Governance

In accordance with the principles of good governance we will make regular reports on our enforcement activity, the outcomes and related key performance indicators to our Board and Scottish Government.

You can read and download this document from our website. We are happy to consider requests for other languages or formats. Please contact our Equality and Diversity Officer on **0141 225 6999** or email his.contactpublicinvolvement@nhs.scot



www.healthcareimprovementscotland.org

Edinburgh Office: Gyle Square | 1 South Gyle Crescent | Edinburgh | EH12 9EB
Telephone: 0131 623 4300

Glasgow Office: Delta House | 50 West Nile Street | Glasgow | G1 2NP
Telephone: 0141 225 6999

The Healthcare Environment Inspectorate, the Scottish Health Council, the Scottish Health Technologies Group, the Scottish Intercollegiate Guidelines Network (SIGN) and Scottish Medicines Consortium are part of our organisation.

