



Healthcare
Improvement
Scotland

Inspections
and reviews
To drive improvement

UNDER REVIEW

Independent Healthcare Regulation

Provider Handbook

July 2024

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INTRODUCTION

You are now a provider of an independent healthcare service registered with Healthcare Improvement Scotland. We are the regulator for independent healthcare (IHC) services in Scotland. This includes:

- independent hospitals
- private psychiatric hospitals
- independent hospices
- independent clinics, and
- independent medical agencies.

Our regulatory functions include:

- registering independent healthcare services
- inspecting registered independent healthcare services to ensure providers are complying with legislation, operating within their conditions of registration, meeting standards of care and taking appropriate action to improve the quality of care and treatment where needed
- investigating complaints about registered independent healthcare services, and
- taking enforcement action where necessary.

About this document

This handbook sets out how Healthcare Improvement Scotland regulates independent healthcare services. It also describes what is expected of you as a provider and what you can expect from us. The handbook is designed as a practical guide and main point of reference about our regulatory processes. It outlines the important principles that guide us and contains links to other useful documents that together help answer the majority of frequently asked questions. Always check [Healthcare Improvement Scotland's website](#) for the most up-to-date guidance.

How we manage our relationship with you

The nature of our work means that our inspectors are often out of the office, so your first point of contact with Healthcare Improvement Scotland should be to email us at his.ihcregulation@nhs.scot.

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We will also contact you from time to time, for a number of reasons. For example, to request your self-evaluation or annual return, inform you about an update to our regulatory procedures or remind you of a regulatory requirement. Developing an ongoing relationship enables us to have a better understanding of the background and context of your service.

How we work with other regulators and professional bodies

We may share information about your service with other organisations, as part of information sharing agreements or as part of our regulatory duties.

- Care Inspectorate
- General Dental Council
- General Medical Council
- General Pharmaceutical Council
- Health and Safety Executive
- Human Fertilisation and Embryology Authority
- Independent Sector Complaints Adjudication Service
- Medicines and Healthcare products Regulatory Agency
- Mental Welfare Commission
- Nursing and Midwifery Council

To help improve patient safety and the general quality of care in the Scottish independent healthcare sector, we may also share appropriate information with national stakeholders including:

- British Association of Aesthetic Plastic Surgeons
- British Association of Cosmetic Nurses
- British College of Aesthetic Medicine
- British Dental Association (Scotland)
- Digital Clinical Excellence Forum (DiCE) UK
- Executive Clinical Leads in Hospice and Palliative Care Forum
- Independent Doctors Federation
- Independent Healthcare Providers Network
- Joint Council for Cosmetic Practitioners
- NHS boards
- NHS National Services Scotland (NSS)
- Royal College of General Practitioners

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- Royal Pharmaceutical Society
- Scottish Dental Clinical Effectiveness Programme
- Society of Occupational Medicine (SOM) Scotland

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ONGOING MONITORING

Following successful registration, we will request that you regularly submit information to help make sure our inspection process is intelligence-led, targeted, outcome-focused and efficient.

Self-evaluation

We will write to you periodically to ask you to complete a self-evaluation through the eForms portal. You must provide it within the deadline stated in the email. The self-evaluation is based on Healthcare Improvement Scotland's Quality Assurance Framework and asks you to tell us what you think you do well in your service, what improvements you think could be made and how you intend to make those improvements happen. You must read the [Guidance on completing your self-evaluation](#) at the time of completing your self-evaluation to help make sure you answer the questions appropriately and know what documents you need to upload. Your answers should be honest and you should have a quality improvement plan in place that highlights what you are doing to respond to the improvements you have identified. You should answer all questions objectively, constructively and with a focus on continuous quality improvement.

Annual return

We will write to you in December each year and ask you to complete an annual return for the previous year through the eForms portal. This process enables us to regularly review essential information about your service, such as your composition, activities, incidents and accidents, staffing details, etc. We use the information to inform our ongoing monitoring and inspection planning processes.

Notifications and Variations

You are **legally required** to notify certain matters to Healthcare Improvement Scotland. The current notification categories and required reporting timescales are listed in our [notifications guidance for service providers](#). It is **your responsibility** to submit the appropriate notification, within the right timescale. Some notification categories require a site visit and our written approval **before** you can continue to operate.

Guidance on how to use the eForms portal to submit a notification is available in our [how to access the online reporting portal](#) guidance.

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Your service was registered on the basis of the information you provided at the time of registration. You **must** therefore operate according to your conditions of registration on your certificate of registration. If you wish to do anything that is not covered under your conditions of registration, you are **legally required** to formally request permission from Healthcare Improvement Scotland, by submitting an '*application to vary, add or remove a condition of registration*' notification through the eForms portal at least 28 days before the proposed change takes place. For example, if you wish to:

- introduce laser/intense pulsed light (IPL) treatments or surgical procedures (where not currently permitted)
- treat service users aged 17 and below (when currently only permitted to treat those aged 18 and above).

Further information on how to do this is available in our [notifications guidance for service providers](#).

We will review your variation application and request any further information deemed appropriate. In some circumstances, we may need to carry out a site visit to help inform our decision. If your application is approved, we will ask you to return your existing certificate of registration and we will issue a new one reflecting the changes to your conditions of registration.

Service Risk Assessment (SRA)

The Service Risk Assessment (SRA) is the operational planning tool we use to plan our inspection frequency. It provides us with a framework for monitoring services on an ongoing basis, so that our inspection approach is risk based and proportionate. Doing this helps us target our resources so that we reduce our inspections of services performing well and increase our inspection of services with poorer performance.

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The SRA includes our ongoing monitoring of five indicators:

Indicator		Description
1	IHC clinical risk category	We score your service based on the types of treatments and procedures you provide or whether you are a newly registered service awaiting its first inspection.
2	Annual return outcomes	We assess your responses in your annual return.
3	Complaint investigation and notification outcomes	We evaluate the type of notifications you submit, and the frequency and nature of complaints we have investigated about your service. We also assess how well you have engaged with the process and responded to investigation outcomes.
4	Inspection outcomes	We score your service according to its post-inspection grading, overall performance between inspections, any recent enforcement activity and how well you have engaged with the inspection process.
5	Significant risk or concern	We add an additional score where we identify a significant concern that we think has not been covered by indicators 1-4.

Once your service is registered, we will calculate an initial SRA score, which determines when we will carry out your first inspection. This will usually be 18 to 24 months following your registration date, or sooner if we deem appropriate. Following each inspection we will update your SRA, which determines when your next inspection will take place, as follows:

SERVICE RISK ASSESSMENT OUTCOME KEY		
TOTAL SCORE	SRA LEVEL	INSPECTION TYPE & FREQUENCY*
250 or above	Very High	FOLLOW-UP inspection within 3-6 months
200 – 245	High	FOLLOW-UP or FULL inspection within 12-18 months
150 – 195	Medium	FOLLOW-UP or FULL inspection within 2 years
100 – 145	Medium/Low	FULL inspection within 3 years
50 – 95	Low	FULL inspection within 4 years
0 – 45	Very Low	FULL inspection within 5 years

**We may undertake focused inspections outwith these frequencies if we receive intelligence that highlights a significant risk or concern. We will only undertake a focused inspection if our reason for inspecting is not within the parameters of a full or follow-up inspection. For example, an inspection to focus on how a service is managing the risks from Covid-19 or other infrequent topic directed by intelligence.*

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Records to be kept by registered independent healthcare services

You are **required** to keep a list of records that reflect the requirements of the following statutory instruments:

- National Health Service (Scotland) Act 1978 as amended by The Public Services Reform (Scotland) Act 2010
- The Healthcare Improvement Scotland (Requirements as to Independent Health Care Services) Regulations 2011, and
- The Healthcare Improvement Scotland (Applications and Registration) Regulations 2011

All records **must** be available to Healthcare Improvement Scotland when requested and located within the registered service, unless agreed in writing with Healthcare Improvement Scotland. Where it is not practicable to do this, for example if personnel records are kept in a centralised location, agreement must be sought with Healthcare Improvement Scotland to determine where and how these records can be accessed.

The list of records is provided in our [Records required by Healthcare Improvement Scotland](#) document. It is your responsibility to read this document and make sure these records are made available. This list of records is subject to change following review by Healthcare Improvement Scotland. In such circumstances, we will issue an amended list of records.

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INSPECTION

We have legal powers to enter and inspect your service, at any reasonable time. We have various inspection methods and types, as detailed in our [inspection methodology](#).

The foundations of our inspections

We monitor independent healthcare services regularly, using announced or unannounced inspections. The intelligence we gather from self-evaluations, annual returns, notifications, complaints, enforcement activity and other professional bodies helps to inform our risk-based and proportionate approach to regulation.

Our inspection process

- takes account of relevant legislation that providers must comply with
- is risk based, proportionate and uses information from multiple sources to inform our decision making
- asks providers to evaluate themselves against the [Quality Assurance Framework](#), identify improvements and tell us what actions they are taking to remedy these
- leads to published inspection reports with grades and clear information about the quality of independent healthcare being provided, and
- promotes the principle of involving people.

Who we involve in our inspections

To understand the quality of care delivered, we need to know the views of:

- those receiving care, and
- those delivering care.

During our inspections, we focus on people who use the service and promote ways that providers can improve people's experience of using the service. We talk with patients, carers, their families using the service and those delivering the service.

Our inspections focus mainly on outcomes for patients, such as the care they received and how that care affected their lives. We also evaluate the processes in place to ensure care and treatment is delivered safely. The Quality Assurance Framework helps us to maintain this focus.

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What we look at during inspections

The [Quality Assurance Framework](#) contains seven 'Quality Domains' which are grouped into three 'Key Focus Areas'. Under each domain, there are several 'Quality Indicators'. We use these key focus areas, domains and indicators to assess how well care and treatment is delivered.

Requirements and recommendations

A requirement is a statement which sets out what is required of an independent healthcare provider to comply with the National Health Service (Scotland) Act 1978, regulations or a condition of registration. Where there are breaches of the Act, regulations or conditions, a requirement must be made. Requirements are enforceable.

A recommendation is a statement which sets out what a service should do in order to align with relevant standards and guidance.

Ongoing monitoring

We ask providers to submit regular information to us to make sure our inspection process is efficient and effective. This includes self-evaluation, annual returns and notifications.

Inspection frequency

Inspection frequency is determined by the service's SRA, which is regularly updated. This means that inspection frequencies flex up and down depending on regulatory activity.

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ENFORCEMENT

Legal powers

If the care you provide harms your patients or puts them at risk of harm, we can take enforcement action to protect them. We do this to ensure you make improvements to prevent any further harm or risk of harm.

We will take immediate enforcement action if we have grounds to believe that you are:

- intentionally choosing not to register an independent healthcare service
- intentionally deceiving the public that an independent healthcare service is registered with Healthcare Improvement Scotland, or
- putting patients at risk of harm.

Unless we think your patients are at immediate risk of harm, we will take a graduated approach to enforcement, in keeping with the principles set out in our [Enforcement Policy](#). This policy provides the framework and principles under which we operate.

Legislation

In providing your service, you are required to comply with:

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

Your duty to inform patients about enforcement action

As a provider, you have a duty to inform your patients of any enforcement action we take in regard to your service. In addition, where we believe there is a risk of harm to your patients, we will inform them directly of our enforcement action. We will treat each case according to individual circumstances and part of our assessment will be a consideration of your co-operation in accurately informing your patients about the enforcement action we have taken and why.

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Publishing of enforcement action and outcomes

Details of all enforcement action we take will be published on our website.

We also have a statutory obligation to share the outcome of our enforcement action with NHS boards, Scottish Government, local authorities and other relevant scrutiny bodies.

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.

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COMPLAINTS

Your complaints handling procedure

You **must** have a complaints procedure that describes how you will acknowledge, investigate and respond to complaints made to you by your patients. We will look at how you handle complaints during our inspections. We will draw on different sources of evidence to understand how well you listen to, respond and learn from complaints. For example, your complaints policy and indicators such as your complaints backlog and staff survey results. We will also speak with patients and staff and review case notes from investigations. A service that is safe, person-centred and well led will treat every complaint as an opportunity to improve and will respond to complaints openly and honestly.

Healthcare Improvement Scotland's duty to investigate complaints

Healthcare Improvement Scotland has a duty to investigate complaints it receives about your service.

We can investigate complaints that relate to:

- ✓ the quality of care and/or treatment experienced
- ✓ care environment or equipment issues
- ✓ poor treatment by a member of staff
- ✓ operational and procedural issues
- ✓ inadequate standard of service
- ✓ delays to treatment
- ✓ failure to provide an agreed service, without good cause
- ✓ dissatisfaction with an organisation's policy
- ✓ environmental or domestic issues
- ✓ communication issues with a service or provider
- ✓ the service/provider's failure to follow the appropriate process, and
- ✓ lack of information provision by the service/provider.

We cannot investigate complaints that relate to:

- ✗ services that are not registered with us (that we do not regulate)
- ✗ events that occurred more than 6 months prior to the complaint being made
- ✗ refunds for treatment/care received
- ✗ fees charged for treatment/care

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- × clinical decisions (ie informed decisions made by a healthcare professional) about treatment/care received
- × a request for a second opinion relating to treatment/care
- × ethical standards of an individual registered healthcare professional
- × issues about the functions of one service/provider, raised by another
- × matters relating to contracts of employment
- × issues that fall under the responsibility of another regulator, professional body or public agency
- × issues that are currently/have already been investigated and responded to by Healthcare Improvement Scotland
- × issues that are currently being investigated by a third party adjudication service (such as the Independent Sector Complaints Adjudication Service (ISCAS)), and
- × issues that are currently subject to legal proceedings.

We have a [complaints procedure](#) that we follow to ensure we investigate complaints consistently and effectively.

Complaints about Healthcare Improvement Scotland

You can make a complaint about us if you feel:

- we have provided you with an inadequate standard of service
- you have experienced difficulties communicating with us
- you have received poor treatment by or attitude from a member of our staff
- we have not followed our operational procedures
- we have failed to follow appropriate process, or
- dissatisfied with our policy.

If you wish to make a complaint about a member of our staff, you should follow the procedure set out in [Healthcare Improvement Scotland's Complaints Handling Procedure](#).

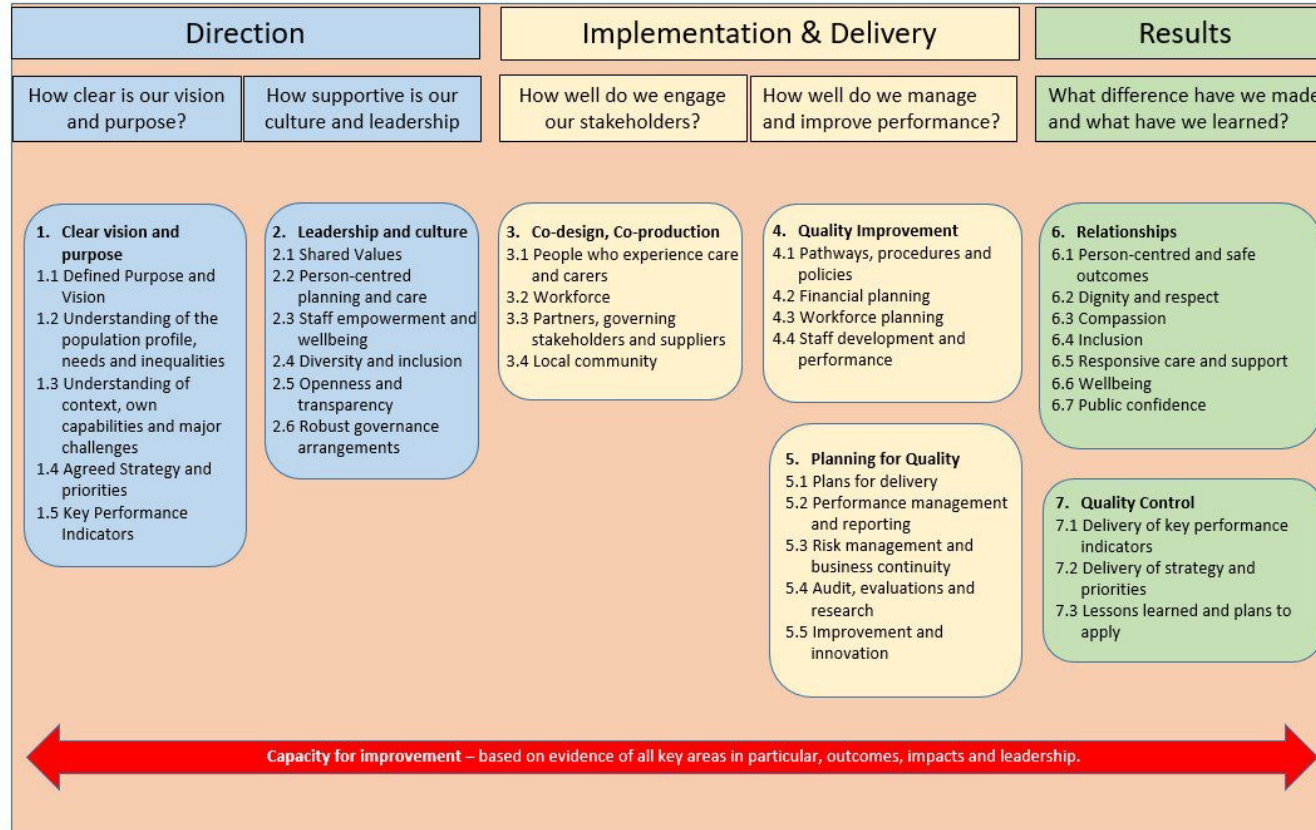
There are two stages to the procedure and if you remain dissatisfied following the second stage, you can ask the [Scottish Public Services Ombudsman](#) (SPSO) to consider your complaint.

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APPENDIX 1: Quality Assurance Framework



Quality Assurance Framework



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