



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Monitoring and Regulation
of Healthcare Services

HIQA's monitoring approach against the *National Standards for Safer Better Healthcare*

April 2022

Safer Better Care

About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent statutory authority established to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public.

HIQA's mandate to date extends across a wide range of public, private and voluntary sector services. Reporting to the Minister for Health and engaging with the Minister for Children, Equality, Disability, Integration and Youth, HIQA has responsibility for the following:

- **Setting standards for health and social care services** — Developing person-centred standards and guidance, based on evidence and international best practice, for health and social care services in Ireland.
- **Regulating social care services** — The Chief Inspector within HIQA is responsible for registering and inspecting residential services for older people and people with a disability, and children's special care units.
- **Regulating health services** — Regulating medical exposure to ionising radiation.
- **Monitoring services** — Monitoring the safety and quality of health services and children's social services, and investigating as necessary serious concerns about the health and welfare of people who use these services.
- **Health technology assessment** — Evaluating the clinical and cost-effectiveness of health programmes, policies, medicines, medical equipment, diagnostic and surgical techniques, health promotion and protection activities, and providing advice to enable the best use of resources and the best outcomes for people who use our health service.
- **Health information** — Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information on the delivery and performance of Ireland's health and social care services.
- **National Care Experience Programme** — Carrying out national service-user experience surveys across a range of health services, in conjunction with the Department of Health and the HSE.

About this document

This document sets out a summary of the Health Information and Quality Authority's (HIQA's) monitoring approach against the *National Standards for Safer Better Healthcare* in healthcare services in Ireland.

Under the Health Act 2007, HIQA has a function to monitor the safety and quality of health services.

In April 2022, HIQA announced a new programme of inspections was commencing in healthcare services to monitor against the *National Standards for Safer Better Healthcare*. These inspections are informed by an assessment judgment framework, a guide to which has been published on www.hiqa.ie.

About the *National Standards for Safer Better Healthcare*

The *National Standards for Safer Better Healthcare*, published in 2012 by HIQA, aim to drive improvements in the quality and safety of healthcare services in Ireland.

The standards set out what should be in place for safe and effective day-to-day service delivery.

The standards are designed to apply to all public healthcare services, settings and locations. All healthcare service providers can use the standards to improve the quality and safety of the care they provide.

HIQA uses these standards to assess the quality and standard of care in Irish healthcare services.

Under current law, healthcare services provided by or on behalf of the HSE (excluding mental health) are monitored to make sure they are following these standards.

The assessment judgement framework for the *National Standards for Safer Better Healthcare*

The assessment judgement framework sets out how HIQA will monitor and inspect healthcare services against the *National Standards for Safer Better Healthcare*. In order to consistently carry out its functions, HIQA has adopted the 'Authority Monitoring Approach'.

All HIQA inspection staff adhere to this approach to ensure:

- a consistent and timely assessment when monitoring compliance with national standards
- a responsive and consistent approach to the assessment of risk within healthcare services
- a focus on improving the service being inspected through the application of the inspection process.

The process provides HIOA inspectors with a range of steps, approaches and tools to assist them in carrying out their functions.

When HIOA inspectors conduct an inspection, they check to confirm that each healthcare provider being inspected has put in place a range of measures which would indicate compliance with the *National Standards for Safer Better Healthcare*.

In order to do this fairly and consistently, inspectors use what is known as an assessment judgement framework as a tool to aid each inspection. The assessment judgement framework is used to ensure the assessment of compliance against the national standards is timely, consistent and responsive to any risks identified within the services.

A resource for inspectors and for healthcare providers

This framework aims to support HIOA inspectors in gathering information when monitoring or assessing a service and to make judgments on compliance as well as providing service users information about how HIOA carries out its work. Healthcare providers can also use it as a resource to self-assess their own services against the national standards.

The assessment judgement framework provides a guide on how each standard will be reviewed, including the lines of enquiry (questions to be asked to assist with checking compliance) that may be explored by inspectors in order to assess compliance.

The framework also provides direction to providers on what evidence of compliance with national standards looks like.

HIOA's risk-based approach to inspection

HIOA uses a risk-based approach to monitoring compliance against the national standards. This means that monitoring activities are prioritised and that resources relating to inspection are organised based on an assessment of regulatory risk. This risk-based approach informs how frequently HIOA will inspect any service, and the focus and type of inspection carried out. In addition, this approach ensures that HIOA can tailor its monitoring activities so they are responsive and proportionate to regulatory risk and assessment can be made against any *National Standards for Safer Better Healthcare* dependent on the risk identified.

As part of the rollout of this new programme of monitoring, this will incorporate a 'floor-to-board approach' which means that inspectors will focus on everyday practice and the experiences of people using the healthcare service, and less time speaking with managers of the services we monitor.

As part of the initial phase of monitoring, HIOA's core assessment will include 11 standards (listed in Appendix 1) relating to:

- Governance, leadership and management,

- Support of Workforce,
- Person centred care,
- Effective care
- Safe care (protecting patients from harm), with a particular focus on four key risk areas
 - Infection prevention and control
 - Medication safety
 - Transitions of care (into the hospital, within the hospital and discharges out of the service)
 - Assessment of the deteriorating patient including use of early warning scores and assessment of sepsis.

Inspections

All services will receive a minimum of two inspections in each three-year cycle. As part of the risk-based approach, HIQA may carry out the following types of inspection:

Announced inspection

A standard announced inspection will generally take place **once in every three years**. It can be expected to take place over one to two days, dependent on the size of the healthcare facility, types of services provided and inspection findings on the day.

An announced inspection will involve monitoring compliance against a core assessment of a selection of the *National Standards for Safer Better Healthcare*.

Unannounced inspection

This type of inspection will generally take place **once in every three years**, or more often if determined necessary by HIQA. With unannounced inspections, healthcare service managers will not be notified by HIQA in advance of the inspection.

This inspection will usually be of shorter duration and will take place over one day and can last for six to eight hours. The purpose of each unannounced inspection will be to follow-up and review progress made in relation to any areas that were not in compliance with national standards during the standard announced inspection.

It also allows HIQA inspectors to evaluate progress with the implementation of compliance plans following standard announced inspections.

Targeted inspection in response to regulatory risk

If HIQA becomes aware of a specific risk within a service, a targeted inspection may be carried out in response. These inspections are in addition to the two routine inspection types described above.

These inspections will be individually designed to align to the risk issue to be investigated. This will be done by applying HIQA's assessment judgment framework in one or more of the 45 national standards, and applying relevant lines of enquiry as required by the nature of the risk issue to be explored on inspection.

These type of inspections will generally be unannounced. However, they may also be short-notice announced inspections, where typically 48 hours' notice will be given to facilitate meeting with key hospital or service personnel.

How HIQA assesses compliance

The accompanying document *Guidance on the assessment-judgment framework for the National Standards for Safer Better Healthcare* aims to guide inspectors on reviewing each standard and sets out the lines of enquiry (the questions) to be explored by inspectors in order to assess compliance with the standards.

Before an inspection, HIQA reviews information on the service to inform what needs to be examined during the inspection.

In order to make judgments about compliance, HIQA may:

- communicate with people who use the service, whenever it is appropriate, to find out about their views and experience of the service
- talk with staff and management to find out how they plan, deliver and evaluate care and services; these conversations may concentrate on:
 - the structures and processes in place
 - how care is delivered and how outcomes are measured and monitored
 - other aspects of their role, such as their experience and training
- observe practice to see if it reflects what is outlined in relevant documents, such as national guidelines and local policies
- review documents to see if appropriate records are being kept which reflect practice and what people have stated.

What compliance with standards looks like

Details on 'what compliance with this standard looks like' are described and aligned with the lines of enquiry as set out in the *Guidance on the assessment-judgment framework for the National Standards for Safer Better Healthcare*. HIQA recognises that service providers may be seeking other ways to improve the quality of their services and outcomes for people using the service, however, compliance with the standards is the overall responsibility of the service provider.

Healthcare services are expected to continually review and self-assess their services against the national standards and put measures in place to comply with the standards.

Examples of the information and evidence that may be reviewed and how this may be done

Inspectors will gather evidence and information to assist with assessing compliance. They will gather this under the headings of:

- observation
- communication
- documentation.

Guidance on the assessment-judgment framework for the National Standards for Safer Better Healthcare will support HIOA inspectors to plan an inspection, gather information before, during and after an inspection and make judgments about compliance. It also informs providers of what to expect during the inspection and provides direction to providers on what evidence of compliance with national standards looks like.

The types of information reviewed will be determined by the service's history of compliance, specific areas of risk identified and the outcome of inspection.

Making judgments on compliance with standards

Once inspectors have gathered the required information and evidence, a judgment will be made on the level of compliance found against each standard reviewed. Inspectors will judge whether the provider has been found to be compliant, substantially compliant, partially compliant or non-compliant with the standards as outlined in the assessment judgment framework.

A judgment of non-compliance indicates that the standard of compliance has not been met resulting in a risk for those using the service. Risks will be escalated to the relevant manager during the inspection fieldwork and or following completion of the inspection fieldwork to the General Manager/Chief Executive Officer/Clinical Director/Master, or hospital group Chief Executive Officer if deemed appropriate.

Reporting the findings of inspections

The inspector will give feedback to the service or hospital manager or their delegate on the preliminary findings from the inspection on completion of the on-site inspection.

The inspector then writes up an inspection report to summarise the findings. In order to summarise these findings, the standards are grouped in the inspection report under the two overarching elements of care:

- Capacity and capability – consideration of governance, leadership and management arrangements in place in the service, how people who work in the service are recruited and supported through education and training, and

whether there are appropriate systems in place to underpin the safe delivery and oversight of the service.

- Quality and safety – consideration of the experiences, care and support people receive on a day-to-day basis. It is a check on whether this is a good quality and caring service and is a service which ensures people are safe. It includes information about the environment in which they are cared for.

As part of the quality improvement approach for service providers to address instances of non-compliances, each service will be required to submit a compliance plan or quality improvement plan where the standard of compliance has not been met resulting in a risk for those using the service.

Applying the assessment judgment framework to other types of monitoring in healthcare settings

HIQA may also conduct other types of monitoring activities in healthcare settings.

HIQA may seek to conduct a more detailed evaluation of a service's approach to ensuring compliance with the standards under Section 8 of the Health Act 2007 through, for example, conducting a regulatory governance review. Such reviews may take a number of months to conclude.

HIQA may also initiate a statutory investigation into services in accordance with Section 9 of the Health Act 2007.

Monitoring against the national standards in these scenarios will again relate back to HIQA's assessment judgment framework. For each review or investigation, a selection of one or more standards that align with the areas of risk that have prompted the review will be selected from the assessment judgement framework to form the assessment approach.

A guidance document outlining the approach and standards to be assessed will be published at the start of each review or investigation.

Benefits of the new approach for healthcare services and service users

This new monitoring programme places emphasis on a forward-facing approach to monitoring which aims to drive quality improvement while also continuing to respond to concerns as they arise. The new monitoring programme will enable a pro-active, consistent and effective approach to monitoring of compliance. It also aims to:

- Increase agility in monitoring compliance against any of the *National Standards for Safer Better Healthcare* where required

- Be adaptable to new and expanding roles for healthcare services, including under the Sláintecare Programme and other legislative changes
- Facilitate integration in a new information and communications technology (ICT) system will help improve dialogue between services, people using services and HIOA.

Summary

The guide to the assessment judgment framework for the monitoring of healthcare services against the *National Standards for Safer Better Healthcare* acts as the key document for HIOA in assessing compliance against the standards. The assessment judgment framework will be used going forward to inform HIOA's monitoring work across healthcare settings. It has been published to also act as a resource for providers to help them in their efforts to enhance levels of compliance against the national standards by giving transparency to the inspection process.

From the perspective of people using services, the approach is intended to assess the key areas of risk in health services and appraise the real-time experiences of those using healthcare services.

Appendix 1- Core set of standards to be assessed as part of routine monitoring

Person Centred Care

Standard 1.6 Patient Privacy, Dignity and Autonomy

Standard 1.7 Culture of Kindness, Consideration and Respect

Standard 1.8 Complaints and Concerns are responded to promptly, openly and effectively

Effective Care

Standard 2.7 Physical environment supports high quality, safe and reliable care

Standard 2.8 Effectiveness of healthcare is systematically monitored, evaluated and continuously improved

Safe Care

Standard 3.1 Providers protect patients from the risk of harm through the design of services

Standard 3.3 Providers effectively identify, manage, respond to and report on Patient Safety Incidents

Leadership, Governance and Management

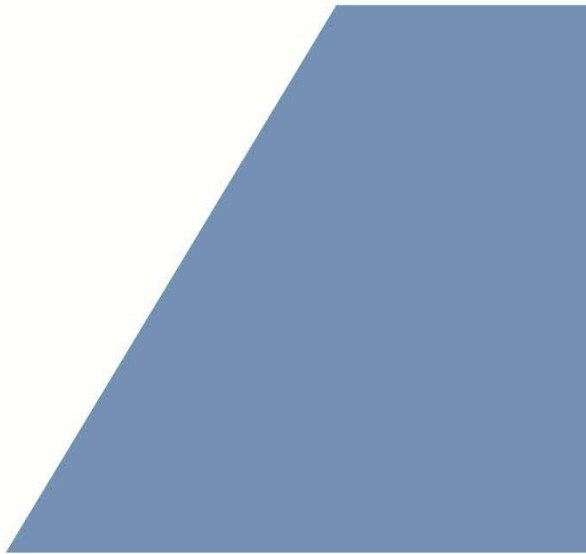
Standard 5.2 Providers have formalised governance arrangements for assurance of high quality, safe and reliable care

Standard 5.5 Providers have effective management arrangements

Standard 5.8 Providers have systematic monitoring arrangements to identify opportunities to continually improve

Workforce

Standard 6.4 Service providers support their workforce in delivering high quality safe and reliable healthcare



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