



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Health Information
and Standards

Stakeholder involvement report
informing the amendment of the scope
of the *National Standards for Safer
Better Healthcare*

September 2024

About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent statutory body 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.

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 of Social Services 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 permanent international protection accommodation service centres, health services and children’s social services against the national standards. Where necessary, HIQA investigates serious concerns about the health and welfare of people who use health services and children’s social 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 and social care services, with the Department of Health and the HSE.

Visit www.hiqa.ie for more information.

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1. Introduction and background

The commencement of the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 (the Patient Safety Act) expands the scope of the standard setting and monitoring functions of the Health Information and Quality Authority (HIQA) to private hospitals and future prescribed private health services. The amended *National Standards for Safer better Healthcare* were approved by the Minister for Health in August 2024, for commencement on 26 September 2024.

An amendment to the scope of the standards was required to enable HIQA to take on this expanded remit on commencement of the Patient Safety Act. To enable this, HIQA has amended the scope of the *National Standards for Safer Better Healthcare*, to include private hospitals and has conducted a public consultation on this amendment. This amendment to the scope of the *National Standards for Safer Better Healthcare* is an immediate measure to ensure the standards can be used for monitoring of private hospitals on commencement of the Patient Safety Act.

The original *National Standards for Safer Better Healthcare* were approved by the Minister for Health in 2012 and contain 45 standards. The scope of these standards include all healthcare services (excluding mental health) provided or funded by the HSE, and were developed through extensive stakeholder engagement and review of research evidence. These standards provide a framework for healthcare providers for the continual development of person centred, safe and effective healthcare services. The standards have been used by HIQA since 2012 in investigation, review and monitoring programmes.

In preparation for the commencement of the Patient Safety Act, HIQA conducted a due diligence of the *National Standards for Safer Better Healthcare* to assess the applicability of each individual standard to private hospitals. This due diligence concluded that the standards are suitable for use in private hospitals, but the scope of the standards would need to be amended to include private hospitals. This amendment will ensure that consistent, quality care is provided to all patients in both public and private hospitals.

In line with the notification and consultation requirements set out in the Patient Safety Act and HIQA's standards development process, HIQA has engaged with stakeholders in a targeted way to help inform the amendment to the scope of the standards. This targeted engagement has helped to ensure that the amendment to the scope of the standards is clear and appropriate, and that providers would be able to put the standards into practice.

The ways in which HIQA’s project team* engaged with stakeholders to inform the amendment to the scope of the *National Standards for Safer Better Healthcare* are set out in this document. These include a public consultation survey on the amendment to the scope of the standards to include private hospitals, and focus groups with senior representatives from private hospitals to obtain their views on the amendment. The project team also attended a number of targeted stakeholder consultation sessions with private hospitals. These sessions were facilitated by HIQA’s Healthcare Regulation Directorate and focused on HIQA’s expected monitoring role against the *National Standards for Safer Better Healthcare*. These sessions were also used to raise awareness of the public consultation and to encourage private hospitals to take part in the public consultation.

The following report of stakeholder involvement outlines the process and outcome of the following consultation stages:

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| Public consultation survey on amendment to scope of standards | 4 March – 12 April 2024 (six weeks) | nine written submissions |
| Targeted focus groups during public consultation | 13 and 21 March 2024 | 30 participants from private hospitals |

The feedback received from the public consultation survey and focus groups is set out in sections 2 and 3. Additional feedback was also received relating to monitoring, inspection and the process for reporting notifiable incidents. While this feedback is outside the scope of this public consultation on the amendment to scope of the standards, a brief overview is provided in section 4. This feedback has also been documented by the project team and will be used to inform any future update of the *National Standards for Safer Better Healthcare*, or other national standards, as appropriate.

* A project team was established within HIQA’s standards development function to work on the amendment to scope of the *National Standards for Safer Better Healthcare*.

2. Public consultation

This section presents an overview of the analysis of responses received during the public consultation and how HIQA used this information to inform the amendment to the scope of the standards to include private hospitals.

2.1 Public consultation process

The public consultation ran for a six-week period from 1 March to 12 April 2024. Ahead of the start date of the consultation, HIQA notified the Minister for Health of its intention to conduct the public consultation. A consultation form was developed to assist people to respond to the consultation. Responses could be made via an online survey tool, and the form was also available to download on www.hiqa.ie. Responses could also be emailed to a dedicated email address or posted to HIQA.

In order to reach as wide a range of stakeholders as possible, the public consultation was advertised in HIQA's newsletter and on its website. A press release about the public consultation was issued, and the consultation was advertised periodically via HIQA's social media channels, including X (formerly Twitter), LinkedIn, Facebook and Instagram. To ensure key stakeholders were reached, targeted emails were also sent to each of the private hospital groups to inform them of the public consultation and invite them to take part in the focus groups. In addition, a briefing document outlining further details on the commencement of the Patient Safety Act and the expansion of HIQA's standards setting and monitoring functions to private hospitals was published alongside the public consultation document on the HIQA website.

The consultation asked people for their views on amending the scope of the standards to include private hospitals. The consultation included the following questions:

- Is the proposed scope of the standards clear?
- On commencement of the Patient Safety Act, the *National Standards for Safer Better Healthcare* will apply to private hospitals. Do you think there will be challenges implementing the standards in the new settings?
- Is there any additional information or guidance needed to support the implementation of these standards in private hospitals?

In total, nine written responses were received over the course of the public consultation. All responses were considered by the project team and were used to inform the amendment to the scope of the standards.

2.2 Results of the public consultation

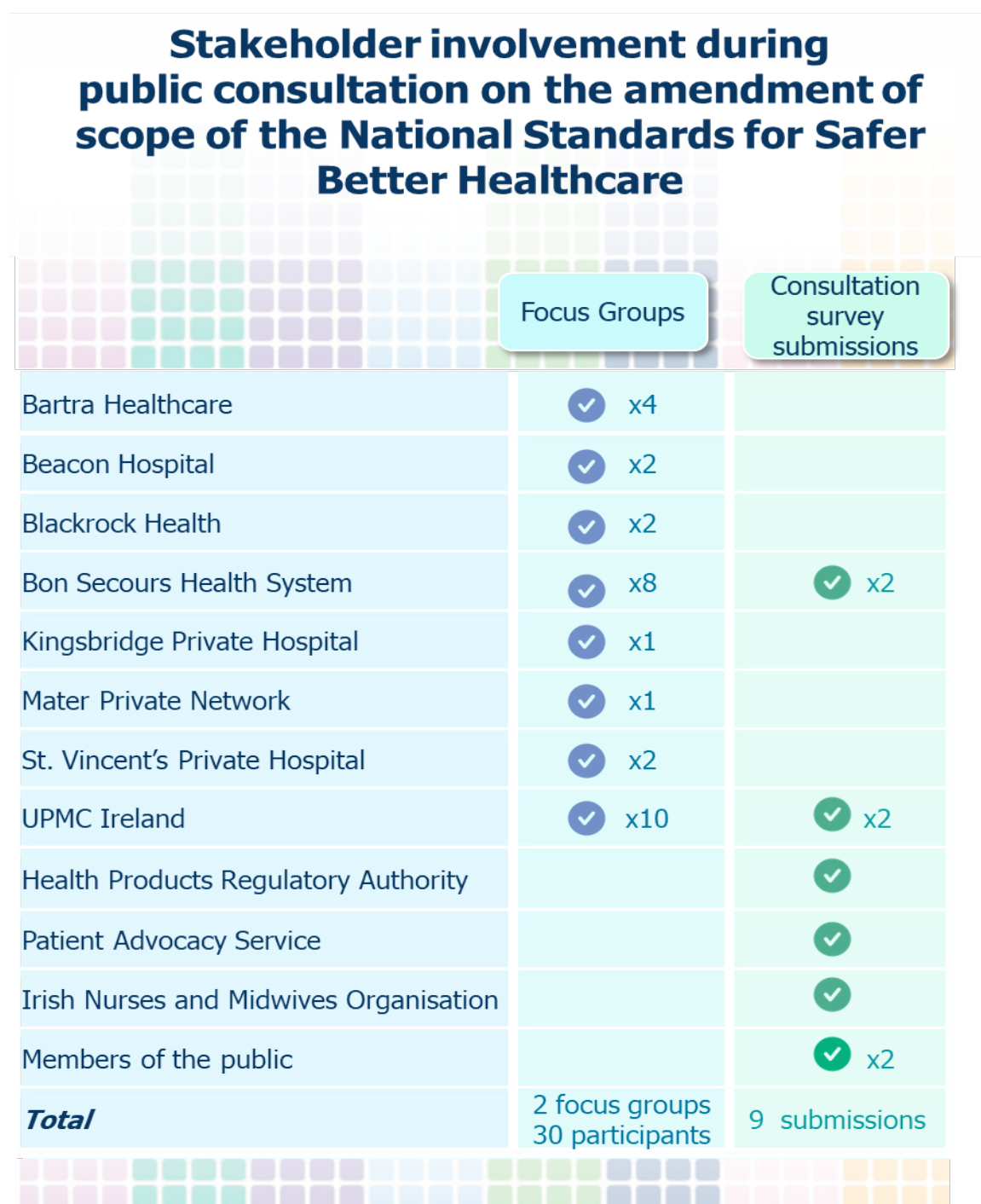
Of the nine written responses, two people responded in a personal capacity and seven were submitted on behalf of an organisation.

Seven respondents gave details of their roles, which included:

- Director of Nursing
- Director of Oncology
- Director of Professional Services
- Chief Nursing, Quality and Patient Safety Officer
- Chief Operating Officer
- Medical Device and In Vitro Diagnostics (IVD) Advisor
- Communications Officer.

The full list of hospital groups and organisations that made contributions to the public consultation are illustrated in Figure 1.

Figure 1. Stakeholder involvement during the public consultation



2.3 Clarity of amendment to the scope

This question asked respondents 'Is the proposed scope of the standards clear?'

Of the eight responses to this question, seven respondents answered 'yes', indicating that there was consensus that the amendment to the scope of the standards was clear and generally well understood.

One respondent indicated that they were 'unsure' if the proposed scope was clear and noted the need to have a clear definition of the term 'private hospital'. This definition is included in the amendment to the standards and is aligned with the definition set out in the Patient Safety Act. The same respondent also highlighted the need to ensure the scope of the standards fully incorporates community and home care services. The scope of the standards includes all healthcare services (excluding mental health) provided or funded by the HSE including, but not limited to: hospital care, ambulance services, community care, primary care and general practice, and all private hospitals. This scope includes community and home care services.

2.4 Potential challenges of implementing standards in private hospitals

This question asked respondents 'On commencement of the Patient Safety Act, the *National Standards for Safer Better Healthcare* will apply to private hospitals. Do you think there will be challenges implementing the standards in the new settings?'

Those respondents who answered 'yes' were asked to describe these challenges.

There were eight responses to this question, with five respondents answering 'yes', two respondents answering 'no' and one respondent who was 'unsure'. The project team reviewed the challenges that were identified by respondents.

Respondents indicated that the most significant challenge for them in implementing the standards in private hospitals will be the differences between the national standards and international accreditation standards that are currently in place in private hospitals. Respondents also discussed requirements of private health insurers with regard to compliance with accreditation standards by the private hospitals following implementation of the national standards.

Respondents also described the potential challenge and administration burden of implementing both the national standards and international accreditation standards, while maintaining quality of care and safe working conditions. Respondents recommended that there should be some alignment of national standards and international accreditation standards, to avoid duplication and allow both processes to be assessed in tandem. HIQA notes that once the *National Standards for Safer Better Healthcare* are approved by the Minister for Health and the Patient Safety Act is commenced, it will be a statutory requirement for all hospitals, including private hospitals, to comply with the national standards. HIQA notes that the *National Standards for Safer Better Healthcare* describe high-level outcomes required to contribute to quality and safety. The standards were designed to be overarching across all healthcare services, settings and locations and are not designed to be prescriptive in nature. However, there are likely to be common areas between the

two inspection processes, relating to the provision of high-quality services for safer, better healthcare.

It was also suggested that consideration should be given to updating the *National Standards for Safer Better Healthcare* in full. It was noted that the international accreditation standards are reviewed and updated on a regular basis. It is HIQA's intention to conduct a full update of the national standards in the coming years, with the learning from the initial implementation in private hospitals.

The population health orientation of the *National Standards for Safer Better Healthcare* was also described as a challenge to implementing the standards in private hospitals. Specifically, respondents indicated that private hospitals would find it challenging to demonstrate compliance with standards that relate to equitable access to healthcare for all people using services. In addition, respondents indicated that private hospitals may also find it difficult to demonstrate compliance with standards that relate to health promotion activities, which may not fit with the private hospital model. In response, the project team noted that all services can be designed to promote equitable access for people using those services, irrespective of factors such as gender, age or geographical location, based on, for example, needs assessment, best available evidence and relevant eligibility criteria.

Challenges regarding potential General Data Protection Regulation (GDPR) issues and Freedom of Information (FOI) requests were also described. Respondents indicated that issues may arise with the sharing of information during the transfer of care between private and publicly-funded healthcare services. A number of other challenges were also identified by respondents, including the need for additional resources for the regulator to monitor against the national standards in private hospitals.

2.5 Additional information or guidance to support implementation

This question asked respondents 'Is there any additional information or guidance needed to support the implementation of these standards in private hospitals?' There were eight responses to this question, with seven respondents answering 'yes' and one answering 'no'.

The information and guidance specified by respondents as needed to support the implementation of the standards in private hospitals mainly related to the inspection process. Respondents indicated that making information available that sets out how inspections will be conducted and how hospitals can demonstrate compliance with the standards will help support the implementation of the standards. Further detail

on this is provided in section 4, which summarises areas raised during stakeholder engagement that were outside the scope of this project.

Respondents also indicated that the implementation of the standards could be supported by providing information for patients and members of the public to outline what the standards mean for them in private hospitals. Respondents described the importance of individual private hospitals ensuring that their internal policies and procedures are up to date and that all staff are aware of their obligations under the Patient Safety Act.

3. Focus group discussions during public consultation

This section describes the process of collating and analysing the responses from focus group participants to inform the amendment to the scope of the *National Standards for Safer Better Healthcare*.

3.1 Overview of the focus group process

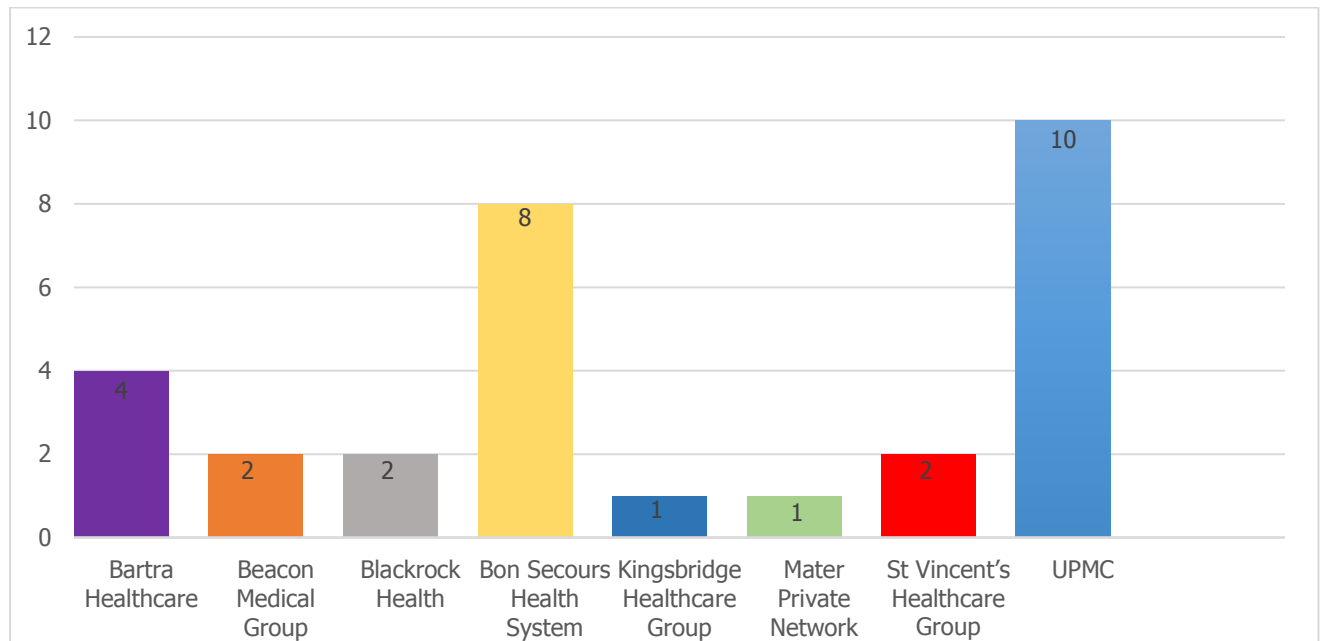
Two targeted focus groups were conducted during the six-week public consultation with senior representatives from private hospitals. These targeted focus groups provided an opportunity to engage directly with those who will have a role in implementing the standards in private hospitals following amendment to their scope. Stakeholders in private hospitals were notified about the public consultation and invited to nominate relevant senior representatives to take part in a focus group.

A total of 30 participants from private hospitals took part in the two focus groups. These focus groups were hosted online via Microsoft Teams. Each focus group was facilitated by a member of the project team and an additional team member took notes on the discussion. Another member of the project team acted as the Microsoft Teams host to ensure that there were no technical difficulties during the focus groups. These roles were shared across the team.

A briefing document outlining details on the commencement of the Patient Safety Act and the expansion of HIQA's standards setting and monitoring functions to private hospitals was shared with participants in advance of the focus groups. The briefing document also outlined the purpose of the session, key questions for consideration, how feedback would be used, and provided assurance that feedback would not be attributable to any individual. Participants were also provided with a copy of the draft standards with the amended scope in advance of the focus groups. All of the feedback gathered during the focus groups was reviewed and considered by the project team to inform the amendment to the scope of the standards.

A breakdown of the participants by hospital group who participated in the focus groups is included in Figure 2.

Figure 2: Breakdown of focus group participants by hospital group (n=30)



The 30 focus group participants were all senior personnel from the various private hospital groups. Examples of the roles held by the focus group participants included Managing Director, Chief Executive Officer, Quality and Risk Manager, Chief Risk Officer, Director of Governance and Compliance, Director of Quality, Patient Safety and Risk, Deputy Director of Nursing, and Director of Oncology.

The project team also attended a number of targeted individual stakeholder consultation sessions with private hospitals. These sessions were facilitated by HIQA's Healthcare Regulation Team and provided stakeholders from private hospitals with an update on relevant requirements under the Patient Safety Act, HIQA's monitoring role against the *National Standards for Safer Better Healthcare* and the public consultation on the amendment to the standards.

3.2 Feedback from focus groups

The project team analysed all feedback received from the focus groups. The findings were collated using the same questions that were asked during the public consultation survey. These questions are:

- Is the proposed scope of the standards clear?
- On commencement of the Patient Safety Act, the *National Standards for Safer Better Healthcare* will apply to private hospitals. Do you think there will be challenges implementing the standards in the new settings?

- Is there any additional information or guidance needed to support the implementation of these standards in private hospitals?

Overall, the findings from the focus groups were aligned to the findings from the written submissions to the public consultation survey. These findings are set below.

Question 1: Is the proposed scope of the standards clear?

There was consensus among focus group participants that the amendment to the scope of the standards to include private hospitals is clear. In particular, participants noted that the wording used in the amendment was easy to follow and understand.

While noting that the amendment to the scope of the standards is clear, there was a suggestion from one participant to update the wording throughout the main standards document to reflect the changes made to the scope of the standards. The project team noted that the standards statements and features that are set out in *National Standards for Safer Better Healthcare* are outside the scope of this project and will remain unchanged at this time. However, it was noted that it is HIQA's intention that a review of all national standards, including the *National Standards for Safer Better Healthcare* will be conducted in the coming years to ensure alignment with the Patient Safety Act. In addition, footnotes will be added to the introductory text to the standards to reference the relevant changes made by the amendment.

Question 2: Do you think there will be challenges implementing the standards in the new settings?

Focus group participants discussed a number of challenges to implementing the *National Standards for Safer Better Healthcare* in private hospitals. These challenges are set out in this section within a number of sub-themes.

Alignment with existing accreditation

Participants discussed concerns regarding the alignment of the national standards with international accreditation standards currently used in private hospitals. Participants felt that there are differences between the national quality standards and the international accreditation standards, as the accreditation standards are more prescriptive in nature, whereas the *National Standards for Safer Better Healthcare* are high-level and focused on outcomes for people using services. Participants felt that having two separate audit and inspection processes in place in private hospitals may lead to a resource and administrative burden for these hospitals. HIQA notes that once the *National Standards for Safer Better Healthcare* are approved by the Minister for Health and the Patient Safety Act is commenced, it will be a statutory requirement for all hospitals to comply with the national

standards. However, it was recognised that there are likely to be common areas between the two processes, relating to the provision of high-quality services for safer, better healthcare.

Participants felt that an incremental lead-in approach to the implementation of the *National Standards for Safer Better Healthcare* in private hospitals would help to ease any confusion and apprehension among staff.

Concerns regarding the age of the *National Standards for Safer Better Healthcare* were also discussed. It was noted that the accreditation standards are updated every three years. HIQA notes that the *National Standards for Safer Better Healthcare* describe high-level outcomes required to contribute to quality and safety. The standards were designed to be overarching across all healthcare services, settings and locations and are not designed to be prescriptive in nature.

Participants felt that consideration should be given to a full update of the national standards. Participants were reassured of HIQA's intention to conduct a full update of the national standards in the coming years, with the learning from the initial implementation in private hospitals.

Orientation of National Standards for Safer Better Healthcare

Participants discussed the potential challenges of demonstrating compliance with the *National Standards for Safer Better Healthcare*, given that some of the standards have a focus on population health. It was noted that, in preparation for the legislative commencement of the Patient Safety Act, a number of private hospitals have conducted their own gap analyses to assess the applicability of each of the standards to their settings. Participants noted that while the majority of standards are applicable to private hospitals, these analyses highlighted that private hospitals may face inherent challenges in demonstrating compliance with the standards that relate to equity of access to services and population health promotion. In response, the project team noted that all services can be designed to promote equitable access for people using services, irrespective of factors such as gender, age or geographical location based on, for example, needs assessment, best available evidence and relevant eligibility criteria.

Some participants discussed their concerns regarding what may be published in inspection reports. Participants recommended that commercially-sensitive information, such as contracts with health insurers would not be published. Respondents queried whether patient feedback would be included in inspection reports. It was noted that as part of the inspection process, HIQA inspectors speak with people who use services to find out their views on and experiences of the service.

Question 3: Is there any additional information or guidance needed to support the implementation of these standards in private hospitals?

Focus group participants noted that information will be needed to support staff working in private hospitals to feel prepared for the commencement of inspections. Participants discussed the possibility of a lead-in period prior to the commencement of inspections and some participants indicated their interest in taking part in pilot inspections.

Linked to the discussion on alignment between international accreditation and the national standards, participants discussed the importance of ensuring that there is clarity with regard to the requirements of private health insurers in the future. Participants recommended that health insurers should provide clarity with regard to the statutory requirements that will apply to private hospitals under the Patient Safety Act.

4. Feedback that was out of scope of the project

A number of additional areas that are outside the scope of this project were noted in the responses to the public consultation survey and the focus group discussions. Specific challenges relating to monitoring, inspection and reporting of notifiable incidents were raised by participants. For example, it was suggested that the current Assessment Judgement Framework and the guidance document for the inspection process should also be updated to reflect the amended scope of the standards. It was also suggested that the development of a self-assessment tool would further support organisations and staff to prepare for the inspection process and to understand what compliance with the standards should look like in everyday practice. In addition, it was suggested by respondents that there should be ongoing engagement and support provided by HIQA for any queries on the inspection process which are not covered in the supporting guidance or information. The need for clarity for hospitals on the process for reporting notifiable incidents was also raised by respondents. This feedback was shared with HIQA's Healthcare Regulation team for their consideration, as part of the review of the Guide to the Assessment Judgement Framework and associated guidance documents. This feedback will be considered in any future update of the *National Standards for Safer Better Healthcare* or any other relevant standards.

5. Conclusion and next steps

Both the public consultation survey submissions and the focus group feedback were reviewed and considered and the scope of the *National Standards for Safer Better Healthcare* was revised. The revised standards with amendment to scope were approved by the HIQA Board on 22 May 2024 and submitted to the Minister for Health for approval on 29 May 2024.

The amended *National Standards for Safer Better Healthcare* were approved by the Minister for Health on the 27 August 2024. A notice of the approval of the standards was also published in *Iris Oifigiúil*, specifying the date from which the standards come into operation, which is 26 September 2024.

HIQA would like to thank all those who contributed to the amendment of these standards through attendance at focus groups and written submissions to the public consultation. The feedback received through this engagement has helped to inform the amendment to the scope of the standards and will also be used to inform the full update of the standards, as appropriate. This will help contribute to the provision of consistent, quality care to all patients in both public and private hospitals.

The current amendment to the scope of the standards is an interim measure in preparation for commencement of the Patient Safety Act and there is a plan to conduct a full update of the *National Standards for Safer Better Healthcare* in the coming years. This will involve a full evidence review, convening an Advisory Group and extensive consultation with a wide range of stakeholders.



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