

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Regulation and Monitoring of Social Care Services

Monitoring notifications handbook

Guidance for registered providers and persons in charge of designated centres for persons (children and adults) with disabilities

Version 3 — October 2024

Safer Better Care

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Section 1: Monitoring notifications

What are monitoring notifications?

The person in charge of a designated centre for persons with disabilities must notify the Office of the Chief Inspector of the occurrence of certain events in the centre. The Office of the Chief Inspector refers to these as **monitoring notifications**.

The duties of the person in charge and the registered provider in relation to these monitoring notifications are set out in the Health Act 2007 (Care and Support of Residents in Designated Centres for Persons (Children and Adults) with Disabilities) Regulations 2013 as amended, specifically in Regulation 31. In this guidance document, whenever we say 'the regulations', we are referring to this set of regulations.

There are three types of monitoring notifications:

- three-day monitoring notifications
- quarterly monitoring notifications, and
- six-monthly nil returns.

Three-day monitoring notifications: The person in charge must notify the Office of the Chief Inspector when any of the 10 types of event set out in Regulation 31(1) occur in the centre. Notifications must be submitted to the Office of the Chief Inspector in writing within **three working days** of the event occurring.

The **10 events** are

- the unexpected death of any resident, including the death of any resident following transfer to hospital from the designated centre
- an outbreak of any notifiable disease as identified and published by the Health Protection Surveillance Centre (HSPC)
- any serious injury to a resident that requires immediate medical or hospital treatment
- any unexplained absence of a resident from the designated centre
- any allegation, suspected or confirmed, of abuse of any resident

- any allegation of misconduct by the registered provider or by staff
- any occasion where the registered provider becomes aware that a member of staff is the subject of review by a professional body
- any fire
- any loss of power, heating or water
- any incident where an unplanned evacuation of the centre took place.

Each event is discussed in detail in Section 2 and is summarised in Table 1 on pages 11– 12. Where an incident is especially urgent or serious, the person in charge may wish to let the Office of the Chief Inspector know of its occurrence immediately by phone on (021) 240 9646 or by email to <u>notify@hiqa.ie</u>, and confirm its occurrence in writing within three working days.

When the person in charge notifies the Office of the Chief Inspector of an unexpected death of a resident, they must provide the cause of death in writing as soon as it has been established. This is required by the regulations. This may not always be possible; however, every effort should be made to seek confirmation of the cause of death.

Quarterly monitoring notifications: The person in charge must notify the Office of the Chief Inspector in writing of the occurrence of the events set out in Regulation 31(3) on a quarterly basis.

The **five** events are:

- any occasion where a restrictive procedure including physical, chemical or environmental restraint was used
- any occasion when the fire alarm equipment was operated other than for the purpose of a fire practice, drill or test of equipment
- any recurring pattern of theft or burglary
- any injury to a resident that did not require notification within three working days (i.e. not 'serious injury')
- any death of a resident, including cause of death, that did not require notification within three working days (that is to say, not `unexpected').

Each event is discussed in detail in Section 3 and is summarised in Table 1.

Notifications of these events are required to be submitted on the following dates:

- quarter 1 on 30 April
- quarter 2 on 31 July
- quarter 3 on 31 October
- quarter 4 on 31 January of the following year.

Six-monthly nil returns: The **provider** must notify the Office of the Chief Inspector in writing on a six-monthly basis where there has been **no occurrence** of the events specified as requiring notification, (a) within three working days, and (b) quarterly notification, in the preceding six months. Submission dates for return of the nil return of quarterly and or the three-day notification form are:

- 31 July (covering the period January to June)
- 31 January (covering the period July to December)

If you have sent the Office of the Chief Inspector any three-day monitoring notifications or quarterly monitoring notifications during the six-month period, the registered provider is not required to make this return.

Submitting monitoring notifications

An online portal has been developed for ease of submitting notifications. Use of the Provider Portal has many benefits, such as:

- easy-to-navigate online forms
- acknowledge of receipt of notifications, including the reference ID
- availability of submitted forms for future reference.

Should you choose not to use the Provider Portal, the forms can be downloaded from the HIQA website. The standard forms request the information required by the

regulations. They also request some additional details that will help the inspector to understand exactly what has happened and how it was responded to. Table 1 lists the form name and form ID for each of the different types of notification events.

How to submit a monitoring notification

Three-day monitoring notifications can be submitted:

- 1. Via the Provider Portal
- 2. By email to notify@hiqa.ie
- 3. By post to **Information Handling Centre**, Health Information and Quality Authority, Dublin Regional Office, George's Court, George's Lane, Smithfield, Dublin 7.

Quarterly monitoring notifications and six-monthly nil returns can be submitted:

- 1. Via the Provider Portal
- 2. By email to <u>dcd@hiqa.ie</u>
- By post to DCD Regulatory Support Team, Health Information and Quality Authority, Dublin Regional Office, George's Court, George's Lane, Smithfield, Dublin 7.

Monitoring notifications submitted by email or post will take longer to process than those submitted via the Provider Portal. The different email and postal addresses for three-day monitoring notifications and quarterly monitoring notifications and nil returns are listed above.

What happens to the submitted monitoring notification?

In general, the inspector will review the information and will risk assess it. The inspector may contact you if you have not provided all the information required by the regulations, or if they need additional information.

After the information has been risk assessed, the inspector will decide on an appropriate response. These regulatory responses may include:

- 1. Closing the notification and retaining it for information.
- 2. Requesting further or follow-up information.
- 3. Requesting a compliance plan update.

- 4. Requesting a provider assurance report.
- 5. Referring the information to an appropriate agency.
- 6. Carrying out an inspection of the service.

The information submitted as part of the notification on the response of the registered provider or person in charge to the specific event should assure the Office of the Chief Inspector that any risk to the quality and safety of care and support has been or is being addressed.

When and how to submit follow-up information?

While follow-up information is normally only required when the inspector specifically requests it, there is one exception to this:

 where there has been an unexpected death of a resident, the regulations require the cause of death to be submitted once it has been established.

A notification submitted using the Provider Portal is assigned a **notification reference number** in the format NOT-XXXXX. You should quote this reference if you need to supply follow-up or additional information. The reference number of past notifications can be found in the section of the Provider Portal labelled 'notification history'.

If a notification is submitted by email or through the post, a reference number may not be issued; however, one is generated internally.

If the **notification reference number** is not known, see the box below for the information to be provided. This will allow the Office of the Chief Inspector to locate the original notification that the information relates to.

Before submitting follow-up information, check that you have included:

• the notification reference number.

If the notification reference number is unknown, please submit the following information:

- your centre ID (also called ORG SERVICE ID)
- your centre name
- the notification type of the original notification (e.g. NF01, NF02, NF09, NF39A)
- the date you first submitted your notification of the event.

Follow-up information and data protection

The Office of the Chief Inspector will not request the name of any resident in notification forms. Therefore, when submitting information or follow-up documents, make sure the name of the person or persons involved in the event are removed. This is to protect their privacy. This is particularly important when sending outcomes of investigations or sensitive or confidential information requested by the inspector.

Maintaining a record of notifications submitted

The regulations¹ require the registered provider to keep a copy of every notification submitted to the Office of the Chief Inspector for a period of not less than **seven years** from the date of notification. Inspector may ask to see these as part of an inspection. Every notification submitted through the Provider Portal is available in the Portal's 'notification history' section. This record fulfills the requirement of the regulation. If the Provider Portal is not used you must have arrangements in place to ensure that you retain a copy of all notifications submitted to Office of the Chief Inspector by email or by post.

A video tutorial on accessing the notification history in the Provider Portal is available on HIQA's website in the resource centre section.

¹ Regulation 21.

Does notification to the Office of the Chief Inspector affect the registered providers or person in charges' obligation to notify other bodies?

Notifications to HIQA have no impact on any obligation the registered provider or person in charge may have (under statute or otherwise) to report the incident to other bodies such as the Coroner, the Health Service Executive (HSE), the Child and Family Agency (Tusla), An Garda Síochána, or, professional bodies such as the Nursing and Midwifery Board of Ireland or CORU, Ireland's multi-profession health regulator.

What are the consequences of failure to notify?

Failure to comply with the regulations will be reported in the compliance plan following an inspection. It may also constitute an offence under the Health Act 2007 as amended.

How to use the Provider Portal?

There are a number of resources on HIQA's website to guide new and existing users of the Provider Portal. They include a user's guide and video tutorials. These can be accessed through the resource centre on HIQA's website.

A designated helpdesk for portal users can be accessed by emailing <u>portalsupport@higa.ie.</u>

Portal users whose accounts are locked should email portalsupport@hiqa.ie.

How to submit a notification by email?

The Provider Portal is the most efficient way to submit a notification. If for any reason the portal is unavailable, notifications can be submitted by email. All notification forms are available in the resource centre.

As the forms are available in editable PDF format, Adobe Acrobat Reader software is required to access them.

Three-day monitoring notifications should be sent to <u>notify@hiqa.ie</u>, while quarterly monitoring notifications and six-monthly nil returns should be sent to <u>dcd@hiqa.ie</u>.

Notification forms may be changed from time to time. The Provider Portal and the resource centre will always have the current version of the notification forms. Please do not use older, obsolete versions of forms.

day monitoring notifications	
Event	Further information
The unexpected death of any resident, including the death of any resident following transfer to hospital from the designated centre	Person responsible for notifying: person in charge of the centre
An outbreak of any notifiable disease as identified and published by the Health Protection Surveillance Centre	Time frame: within three working days of the occurrence of the event
Any serious injury to a resident that requires immediate medical or hospital treatment	Follow-up information: as requested by your inspector,
Any unexplained absence of a resident from the designated centre	except for NF01, where the cause of death must be submitted.
Any allegation, suspected or confirmed, of abuse of any resident	
provider or by staff	
Any occasion where the registered provider becomes aware that a member of staff is the subject of review by a professional body	
Any fire Any loss of power, heating or water Any incident where an unplanned evacuation of the	
form and Daily Update	1
Event	Further information
Suspected or confirmed incidence of Covid-19 in the designated centre	Person responsible for notifying: person in charge of the centre
This form is only to be submitted at the request of the Chief Inspector in relation to the management of COVID-19 in the designated centre	Follow-up information: report to be submitted as specified by the Chief Inspector.
rly monitoring notifications	
Event	Further information
Any occasion where a restrictive procedure including physical, chemical or environmental restraint was used	Person responsible for notifying: person in charge of the centre
Any occasion where the fire alarm equipment was operated other than for the purpose of a fire practice, drill or test of equipment.	Time frame: events that took
Any recurring pattern of theft or burglary.	place in
Any injury to a resident not requiring notification within three working days (i.e. not serious requiring immediate medical or hospital	Q1 should be notified on 30 April Q2 should be notified on 31 July
	Event The unexpected death of any resident, including the death of any resident following transfer to hospital from the designated centre An outbreak of any notifiable disease as identified and published by the Health Protection Surveillance Centre Any serious injury to a resident that requires immediate medical or hospital treatment Any unexplained absence of a resident from the designated centre Any allegation, suspected or confirmed, of abuse of any resident Any cocasion where the registered provider or by staff Any occasion where the registered provider becomes aware that a member of staff is the subject of review by a professional body Any loss of power, heating or water Any loss of power, heating or water Any incident where an unplanned evacuation of the centre took place Form and Daily Update Event Suspected or confirmed incidence of Covid-19 in the designated centre This form is only to be submitted at the request of the Chief Inspector in relation to the management of COVID-19 in the designated centre rly monitoring notifications Event Any occasion where a restrictive procedure including physical, chemical or environmental restraint was used Any occasion where the fire alarm equipment was operated other than for the purpose of a fire practice, drill or test of equipment. Any recurring pattern of theft or burglary.

Table 1: Monitoring notifications — summary details

NF39E		nt, including cause of death, required notification within e. not 'unexpected').	 Q3 should be notified on 31 October Q4 should be notified on 31 January of the next calendar year. Follow-up information: as requested by the inspector.
Six-mo	nthly nil return		
NF40	Six-monthly nil return for events that require notification within three days or on a quarterly basis.	Time frame: where no ever (NF01 – NF09) or notification occurred in the preceding six • 31 July (covering the	otifying: registered provider nt requiring a three-day notification n on a quarterly basis (NF39A-E) (months: e period January to June) a the period July to December).

Section 2. Three-day monitoring notifications

Information common across three-day monitoring notifications

i. Centre details

The start of each form requires the centre details, including the centre name and the Centre ID (OSV). Notifications submitted through the Provider Portal will have the centre name and Centre ID (OSV) pre-populated.

ii. Resident details and the use of unique identifiers

Where the event being notified involves a resident, a unique identifier should be used rather than the resident's name. This is to ensure the resident's privacy is protected and compliance with data protection. The identifier should be a number and it should not be possible to identify the resident from the number used; therefore, do not use the resident's date of birth, admission date, room number or National Intellectual Disability Database personal identification number NIDD.

When a resident is assigned a number, a record of the number and the resident to whom it relates must be kept. **The identifier for a resident should be unique to them and used in all future notifications**. This number should **not** be used for any other resident. A method of validating the unique identifier should be kept securely in the centre and be available to an inspector if requested. This could be as simple as keeping a list of each resident and the unique identifier assigned to them.

iii. Staff member details

Where the event being notified involves a member of staff, the staff member's role and not their name should be used.

iv. Providing additional information applicable to the notification

Many of the forms request 'any additional information applicable to this notification'. As a general rule, when completing the forms, try to provide as much detail as possible. The information should be **factual**, **objective and accurate**.

v. Completing the declaration section

At the end of each form there is a declaration section. Completing this section indicates that the information provided is correct to the best knowledge of the person submitting the notification.

If completing the PDF version of the form, the name of the person submitting the notification should be typed in the signature field.

The person in charge is responsible for notifying the Office of the Chief Inspector of the events set out in the regulations. If someone other than the person in charge completes the notification form, they must do so with the full knowledge and delegation of the person in charge.

vi. Before you submit the completed form — whether using the Provider Portal or email

Before submitting the form check that it is clear from the information contained:

- what exactly has occurred
- what actions were taken or are proposed in response to the incident
- what actions were taken to address any concerns around the safety and wellbeing of the residents arising from the incident.

Please ensure that the names of residents and staff involved in the incident have not been mentioned.

NF01 The unexpected death of any resident

You must notify the Office of the Chief Inspector of the unexpected death of a resident, including the death of a resident following transfer to hospital from the designated centre.

What is an unexpected death?

The regulations do not define an 'unexpected death'. However, the Chief Inspector has offered this definition to assist in making this notification: an unexpected death is one that was not anticipated or occurred earlier than expected.

What if the cause of death is not yet known?

In some cases, the cause of death may not be established at the time the notification is made. It can be several months before the cause of death is established in some cases. The Office of the Chief Inspector acknowledges that this is often outside the control of the person in charge. The regulations require that the Chief Inspector is provided with the cause of death **in writing** when it has been established. This can be done by emailing notify@hiqa.ie. As outlined in Section 1, this email should quote the reference number of the original notification.

Completing the form

The form should be completed in full, and the information provided should be clear and accurate.

Notifiable incidents under the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023

Additionally, there is a requirement under section 28 of the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 (the '2023 Act') to notify the Chief Inspector of certain unintended or unanticipated deaths of residents of designated centres.

Appendix 1 describes the obligations regarding the notification of these incidents and Appendix 1.1 outlines the definition of a health service provider.

NF02 Any outbreak of any notifiable disease

The Office of the Chief Inspector must be notified of the outbreak of any notifiable disease.

What are notifiable diseases?

Notifiable diseases are those diseases identified and published by the Health Protection Surveillance Centre (HSPC) <u>www.hpsc.ie</u> and include COVID-19, *Clostridium Difficile* infection, norovirus infection, Meticillin-Resistant *Staphylococcus aureus* (MRSA), influenza and hepatitis.

What is an outbreak?

The National Clinical Effectiveness Guidelines (NCEG) developed by the National Clinical Effectiveness Committee (NCEC) and published by the Department of Health, states:

An outbreak may be defined as occurrence of more cases of disease than expected in a given area among a specific group of people over a particular period of time. Two or more linked cases of the same illness / colonisation. <u>gov.ie - Infection Prevention and Control (IPC) (www.gov.ie)</u>

What if a diagnosed cause has not yet been determined?

In some situations, the diagnosed cause of the outbreak may not be confirmed at the time of the notification. Where this is the case, state the suspected diagnosis and provide the confirmed diagnosis by email when it becomes available. If a follow-up email with the confirmed diagnosis is required, it should quote the notification reference number to allow the Office of the Chief Inspector to locate the original incident (see Section 1).

What if the situation deteriorates after notifying the Office of the Chief Inspector?

If the situation deteriorates and more people become infected after making the notification, a follow-up email should be sent, quoting the original notification reference number to allow the Office of the Chief Inspector to locate the original incident (see Section 1).

Completing the form

The form should be completed in full, and the information provided should be clear and accurate.

NF02A Suspected or confirmed incidence of Covid-19 in the

designated centre

In specific circumstances, the provider may be required to submit an NF02A form to the Chief Inspector for a suspected or confirmed outbreak of COVID-19. **This notification is only submitted at the request of the Chief Inspector.**

When requested, the form should be completed in full. The information provided should be clear and accurate.

NF03 Any serious injury to a resident that requires immediate medical or hospital treatment

What is a serious injury?

The term 'serious injury' is not defined in the regulations. The Chief Inspector has provided the following guidance:

"any bodily injury that involves a substantial risk of death, unconsciousness, extreme physical pain, protracted and obvious disfigurement, serious impairment of health or <u>serious loss</u> or impairment of the function of any bodily organ e.g. fracture, burn, sprain/strain, vital organ trauma, a cut or bite resulting in an open wound, concussion, etc.".

The term 'serious injury' <u>does not include</u> minor injuries for which first aid is sufficient, or minor injuries reviewed by a general practitioner (GP) which do not require further treatment.

What if the situation deteriorates?

If the resident's condition deteriorates after submitting the notification, a follow-up email should be sent, quoting the reference number of the initial notification (see Section 1). A new NF03 form is not required.

Completing the form

The form should be completed in full, and the information provided should be clear and accurate.

NF05 Any unexplained absence of a resident from the designated centre

What is an unexplained absence?

The regulations do not define the term 'unexplained absence'. The Chief Inspector has given the following guidance:

"an unexplained absence has occurred when a resident has been found to be missing from a centre without the staff's knowledge of his or her whereabouts".

Completing the form

The form should be completed in full, and the information provided should be clear and accurate.

NF06 Any allegation, suspected or confirmed, of abuse of any resident

What is abuse?

The regulations define abuse as follows:

"abuse' means mistreatment of any kind and includes the physical, financial or material, psychological, sexual or discriminatory mistreatment or neglect of a resident".

What if the allegation has not been confirmed?

Any suspected or confirmed allegations of abuse must be notified to the Office of the Chief Inspector.

How does this requirement apply to situations where a resident's wellbeing is impacted by the actions or behaviours of another resident?

The provider's policies and procedures for the centre should guide staff when deciding whether a resident's actions or behaviours constitute abuse of another resident. These policies and procedures should reflect national guidance and best practice.

As a general rule, it is not necessary to notify the Office of the Chief Inspector of residents' behaviour that challenges unless it impacts **to such an extent** on another resident or residents that it **falls clearly** within the (above) definition of abuse.

Notifying allegations of abuse, suspected or confirmed, that occurred in the past

The Office of the Chief Inspector should be notified within three working days of the allegation becoming known. It may not be possible to investigate the allegation; for example, where it relates to a case of historical abuse or in matters of a criminal nature. However, the Office of the Chief Inspector should be notified nonetheless.

If there is an allegation of abuse about a member of staff, should two forms be completed?

Where there is an allegation of abuse of a resident by a member of staff or the registered provider, the Chief Inspector should be notified using the NF06 form. Where there is an allegation of **other misconduct** by a member of staff or the registered provider, the Chief Inspector should be notified using the NF07 form.

Residential services for children with disabilities and mixed residential services for children and adults with disabilities

Where there has been an incident, allegation or suspicion of abuse or neglect in relation to a **child**, the Children First Act 2015 and the revised *Children First: National Guidance for the Protection and Welfare of Children* (2017) apply. The Child and Family Agency (Tusla) has extensive resources available on its website to help you to implement Children First in your service.²

Completing the form

The form should be completed in full, and the information provided should be clear and accurate.

² http://www.tusla.ie/services/child-protection-welfare/children-first-2017 Downloaded 10/11/2017

NF07 Allegation of misconduct by the registered provider or by a member of staff

Who is a registered provider or member of staff?

The registered provider is the person whose name is entered in the register as the person carrying on the business of the designated centre. The regulations define staff as "persons employed by the registered provider", including **"persons placed in employment with the registered provider by an employment agency** used by that registered provider". This does not include "persons who provide professional services to the designated centre and to whom the registered provider pays fees for such services, or volunteers."

What is misconduct?

The regulations do not define misconduct. The Chief Inspector has given the following guidance:

"for professionally registered staff such as nurses and social workers, misconduct is generally considered to be a failure to adhere to proper standards of conduct, performance and ethics (as laid down by the relevant registration body e.g. An Bord Altranais (Nursing and Midwifery Board of Ireland) or CORU)".

Misconduct should be considered in terms of the staff member's job description, the provider's operational policies and procedures for the centre, any code of conduct expected of employees and other professional codes of practice. Any breaches of such codes that require disciplinary action by management should be notified to the Office of the Chief Inspector.

For the registered provider (or provider entity), an example of misconduct may be where the provider (or provider entity) is convicted of an offence or where there is an allegation offinancial misappropriation.

What if the allegation of misconduct has not been confirmed?

The Office of the Chief Inspector should be notified within three working days of an allegation of misconduct.

Are details on residents or staff requested in the form?

The form asks whether the allegation of misconduct relates to the registered provider or to a staff member. Where the allegation relates to a staff member, please indicate the role of the staff member, whether the centre has a Garda vetting report for them and whether they are currently reporting for duty. The name of the staff member is not requested.

Completing the form

The form should be completed in full, and the information provided should be clear and accurate.

NF08 Any occasion where the registered provider became aware that a member of staff is the subject of review by a professional body

Who is a member of staff?

The regulations define staff as "persons employed by the registered provider", including "persons placed in employment with the registered provider by an employment agency used by that registered provider". This does not include "persons who provide professional services to the designated centre and to whom the registered provider pays fees for such services, or volunteers."

What is a professional body?

A professional body is an organisation formed to promote the interests of a profession and the public interest. The main professional bodies relevant to staff in designated centres are:

- The Nursing and Midwifery Board of Ireland, and
- Ireland's multi-profession health regulator (CORU).

Should the notification be submitted where the person has left employment before the hearing?

If the person was a member of staff when the provider became aware of the review, the Office of the Chief Inspector should be notified.

Completing the form

The form should be completed in full, and the information provided should be clear and accurate.

NF09 Any fire, any loss of power, heating or water; or any incident where an unplanned evacuation of the designated centre took place

What constitutes a 'loss of power, heating or water' in the designated centre?

A single occurrence of loss of power, heating or water lasting longer than 30 minutes, or two or more instances, each lasting less than 30 minutes occurring in any 24-hour period, constitutes a 'loss of power, heating or water' for the purpose of notification.

The Office of the Chief Inspector should be notified within three working days:

- if there was a fire in the centre
- if there was an unplanned evacuation of the centre in response to the activation of fire alarm equipment
- if there was an unplanned evacuation of the centre for any other reason.

Planned fire alarm activations and planned evacuations for the purpose of fire practice, drill or test of equipment <u>do not require notification</u>. Other occasions where a fire alarm is activated should be notified on a quarterly basis (see Section 3).

Completing the form

 The form should be completed in full, and the information provided should be clear and accurate.

Section 3. Quarterly monitoring notifications (NF39A – NF39E)

Quarterly notification forms

For designated centres for persons with disabilities, there are five types of events that, if they occur, must be notified to the Office of the Chief Inspector at the end of the quarter. A standard form for each type of event has been developed. The form should be completed when one or more events of that type occurred during that quarter. If no event of that type occurred during that quarter, an NF39C form does not have to be submitted. Each standard form allows for the notification of a number of events of that type; for example, if there have been five injuries to residents in the centre during the quarter, they can all be reported using one NF39D form. If a greater number of occurrences need to be reported than the form accommodates, more than one form of that type can be submitted.

The list of standard forms to support quarterly returns are as follows:

- NF39A Any occasion where a restrictive procedure including physical, chemical or environmental restraint was used
- **NF39B** Any occasion where the fire alarm equipment was operated other than for the purpose of a fire practice, drill or test of equipment
- **NF39C** Any recurring pattern of theft or burglary in the designated centre
- NF39D Any injury to a resident that did not require notification within three working days (that is to say, not serious and requiring immediate medical or hospital treatment)
- NF39E Any death of a resident, other than those that required notification within three working days (that is to say, not 'unexpected'). Please also provide the cause of death.

NF39A Any occasion where a restrictive procedure including physical, chemical or environmental restraint was used

What is a restrictive procedure?

The regulations define restrictive procedure as "the intentional restriction of a person's voluntary movement or behaviour". The regulations set out requirements in relation to the use of restrictive procedures and the role of consent where it is used as a therapeutic intervention. Where it is used as a response to challenging behaviour, every effort must be made to identify and alleviate the cause of the challenging behaviour and alternative measures must be considered before it is used. Restrictive procedures should only be used for the shortest duration necessary.

Regulation 7(4) states that "the registered provider shall ensure that, where restrictive procedures including physical, chemical or environmental restraint are used, such procedures are applied in accordance with national policy and evidence based practice".

Are bedrails and lap belts always considered a physical restraint?

The Chief Inspector provides the following clarification on the classification of bedrails and lap belts as restraint: "Where a resident can safely release themselves from a bedrail of their own volition in order to get in or out of bed, or can safely free themselves from a lap belt of their own volition, then the use of a bed rail or lap belt in this context does not need to be reported to the Chief Inspector as an occasion when restraint was used".

What details are requested in the form?

The form allows you to return details on the use of up to eight types of restrictive procedure.

For each type of restrictive procedure used during the quarter, please:

- classify the restrictive procedure from a list of options: environmental restraint (door lock, seclusion, window or other), physical restraint (bed bumpers, bedrails, chair, lap belt or other), chemical restraint or other restrictive procedure
- specify the number of residents that the type of restrictive procedure has been applied to during the quarter
- detail the frequency of use
- provide any other relevant comments.

Depending on the restrictive procedure used, 'any other comments' could be used to provide a description of the procedure, how it was used, how long it was used for, or other details the inspector should be aware of. For example, if during the quarter, three residents in the centre had bedrails in place which they could not easily release, the form could be completed as follows:

Classification of the restrictive procedure: "physical restraint – bed rails"

The number of residents the restrictive procedure was applied to: 3 The frequency of use: daily, or, used in ... circumstances, or used on ... occasions where...

Any other comments: may give more details of occasions where used, or, details of how the restrictive procedure was used.

NF39B Any occasion of fire alarm activation

The Office of the Chief Inspector must be notified at the end of the quarter of any occasion of fire alarm equipment activation (other than for the purpose of fire practice, drill or test of equipment) during the quarter.

Fire practices, drills or test of equipment do not need to be notified to us. However, these records may be reviewed as part of your inspection.

Completing the form

The form allows for details of a **maximum of five occasions** of fire alarm activation.

For each occasion, please :

- specify the date the alarm was activated
- select the reason the alarm was activated from a drop-down list of options
- provide details of the occurrence.

NF39C Any recurring pattern of theft or burglary

What is a recurring pattern of theft or burglary?

For the purpose of this notification, 'recurring' is defined as **two or more** occasions of theft or burglary in the quarter.

Completing the form

The form allows for details of a **maximum of seven occasions** of theft or burglary.

For each occasion, please:

- specify the date the theft or burglary was discovered
- select the type of injured party from a drop-down list of options
- select the type of item stolen from a drop-down list of options
- provide details of the occurrence
- provide details of the actions taken in response to the occurrence.

NF39D Any injury to a resident not requiring notification within three working days

What injuries must be notified?

Any injury to a resident that took place during the quarter that has not already been notified to the Office of the Chief Inspector within three working days (under the NF03 process for 'serious injury' – detailed in Section 2).

Completing the form

The form allows for details of a **maximum of 10 injuries** during the quarter.

For each injury, please:

- provide the resident's unique identifier
- specify the type of injury
- specify the date of injury
- provide any other relevant details.

NF39E Any death of a resident that did not require notification within three working days

What deaths must be notified?

Any death of a resident that took place during the quarter that has not already been notified to the Office of the Chief Inspector within three working days of the death (under the NF01 process for 'unexpected death' – detailed in Section 2).

Completing the form

The form allows for details of a **maximum of 10 deaths** during the quarter.

For each death, please:

- provide the deceased resident's unique identifier
- specify the cause of death
- specify the date of death
- provide any other relevant details.

Section 4. Six-monthly nil return

The **provider** must notify the Office of the Chief Inspector in writing on a sixmonthly basis where:

- 1. There has been **no occurrence** of any events specified as requiring notification within three working days, and
- 2. There has been **no occurrence** of any events specified as requiring notification on a quarterly basis.³

The two submission dates for six-monthly nil returns are:

- **31 July** (covering the period January to June)
- **31 January** (covering the period July to December).

There is a standard form to support making this return. It is the **NF40** Six-monthly nil return for events that require notification within three working days or on a quarterly basis.

If you have notified the Office of the Chief Inspector of the occurrence of any event that required three-day notification or any event that required quarterly notification during the six-month period, the provider does not need to send the Office of the Chief Inspector a six-monthly nil return.

³ 31(4) The Health Act 2007 (Care and Support of Residents in Designated Centres for Persons (Children and Adults) with Disabilities) Regulations 2013 as amended

Appendix 1 — Obligations to notify the Chief Inspector under the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023

Section 28 of the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 (the '2023 Act') requires providers to notify the Chief Inspector of certain unintended or unanticipated deaths of residents of designated centres ('notifiable incidents'). The notifiable incidents are described in Part 1 of Schedule 1 of the 2023 Act and are set out in Table 2 below.

Who does the notification requirement apply to?

The new notification requirement applies to a "*health services provider*" as defined in section 3 of the 2023 Act⁴ who carries on the business of a designated centre. In summary, where a registered provider of a designated centre also provides "health services" to residents, then that registered provider is potentially a "health services provider". In this context, "health service" means:

the provision, by or under the direction of a health services provider, of clinical care or any ancillary service to a patient for—

- a) the screening (other than screening carried out by a cancer screening service), preservation or improvement of the health of the patient,
- b) the prevention, diagnosis, treatment or care of an illness, injury or health condition of the patient,
- c) the performance or surgery, or a surgical intervention, in respect of aesthetic purposes, or other non-medical purposes, that involves instruments or equipment being inserted into the body of the patient, or
- d) without prejudice to *paragraph (a)*, a cancer screening service;

What is the notification requirement?

Section 28 of the 2023 Act provides that where a health services provider carries on the business of the designated centre and it is satisfied that a notifiable incident has occurred in the course of the provision by it of a health service to a patient (a resident), that provider shall notify the Chief Inspector of that notifiable incident as soon as

⁴ The definition of a Health Services Provider is contained in Appendix 1.1 of this handbook.

practical, and in any event, not later than seven days from the date on which the provider was satisfied the incident had occurred.

When does the notification have to be made?

The register provider is obliged to notify the Chief Inspector of the notifiable incident:

(a) as soon as practicable, and

(b) in any event, not later than **seven days** from the day on which the provider was satisfied the incident had occurred.

What information should be contained in the notification?

A notification to the Chief Inspector shall specify the following information:

(a) the name of the health services provider;

(b) identification of the type of notifiable incident, (specified in Part 1 of Schedule 1 of the 2023 Act) (or, as the case may be, specified in regulations made by the Minister under section 8 of the 2023 Act⁵), into which the notifiable incident concerned falls;

(c) the date the notifiable incident occurred if, having regard to section 5(2) of the 2023 Act, the date is known at the time the notification under this section is made;

(d) the date the notifiable incident came to the notice of the health services provider;

(e) having regard to the notifiable incident and the causes of the notifiable incident insofar as they are known at the time of the notification is made under this section—

(i) the action the health services provider has taken in response to that incident, or proposes to take, to prevent reoccurrence, or mitigate the consequences of any similar such incident should there be a reoccurrence, and

⁵ Note: As of the date of the publication of this guidance, the Minister has not made any regulations under section 8 of the 2023 Act.

(ii) a statement of any action taken, or proposed to be taken, for the purpose of sharing what has been learnt, and knowledge obtained, from the occurrence of the notifiable incident.

How does the register provider make the notification?

The registered provider is obliged by section 30 of the 2023 Act to make the notification by means of the National Treasury Management Agency's National Incident Management System (NIMS). HIQA has provided guidance on using NIMS for health services providers (which includes health services providers who carry on the business of a designated centre). For more information, go to the HIQA website Notification of incidents under the Patient Safety 2023 Act page <u>here</u>. In summary, the registered provider is required to register on the NIMS system and complete the online notification form with the required information.

It is important for the registered provider to choose "Chief Inspector of Social Services" as the recipient of the notification on the NIMS system in order to ensure that a valid notification is made by the registered provider. The NIMS system will automatically forward the notification made by the registered provider to the Chief Inspector.

How does this affect existing regulatory notifications?

Registered providers are already obliged to make a number of notifications pursuant to regulations made under the Health Act 2007 as amended. In particular, registered providers are obliged to notify the Chief Inspector of the death of a resident using a Form NF01. The new notification obligation under the 2023 Act does not affect or replace the existing obligations on registered providers to submit a Form NF01 within three days of the death occurring. The new notification obligation under the 2023 Act a submit a Form NF01 within an additional obligation.

Does this mean a provider might have to send two notifications?

Yes. In some circumstances, a registered provider might be obliged to notify the Chief Inspector of the death of a resident twice, first using a Form NF01 within three working days and second via the NIMS system within seven calendar days. It is important that the registered provider submits both notifications as both are required by law and the information returned in each notification is different.

What happens if I do not make the new notification?

Section 77 of the 2023 Act provides that a person who fails to comply with their obligations to make the notification as required shall be guilty of an offence and shall be liable on summary conviction to a class A fine.⁶

What should I do if I am uncertain whether the new notification applies to me?

The definitions and provisions contained in the 2023 Act are quite detailed. If you are uncertain whether the notification obligations in section 28 of the 2023 Act apply to your circumstances, you may wish to seek your own legal advice. Given the seven-day time period for making a notification, the Chief Inspector recommends that if you are in doubt, you should consider making the section 28 notification via the NIMS system to ensure that you have complied with your legal obligations.

⁶ Note: at the date of this handbook, a class A fine is a fine within the meaning of the Fines Act 2010 as amended (that is to say, a fine not exceeding \in 5,000).

Table 2. Notifiable incidents as set out in Part 1 of Schedule 1 of the 2023 Act

Type of Notifiable Incident (Short Text)	Full Text Of Notification
1.1 Surgery performed on the wrong patient — unintended and unanticipated death	1.1 Surgery performed on the wrong patient resulting in unintended and unanticipated death which did not arise from, or was a consequence of, an illness, or an underlying condition, of the patient, or having regard to any such illness or underlying condition, was not wholly attributable to that illness.
1.2 Surgery performed on the wrong site — unintended and unanticipated death	1.2 Surgery performed on the wrong site resulting in unintended and unanticipated death which did not arise from, or was a consequence of, an illness, or an underlying condition, of the patient, or having regard to any such illness or underlying condition, was not wholly attributable to that illness.
1.3 Wrong surgical procedure performed on patient — unintended unanticipated death	1.3 Wrong surgical procedure performed on a patient resulting in an unintended and unanticipated death which did not arise from, or was a consequence of, an illness, or an underlying condition, of the patient, or having regard to any such illness or underlying condition, was not wholly attributable to that illness.
1.4 Unintended retention of a foreign object in a patient — unanticipated death	1.4 Unintended retention of a foreign object in a patient after surgery resulting in an unanticipated death which did not arise from, or was a consequence of, an illness, or an underlying condition, of the patient, or having regard to any such illness or underlying condition, was not wholly attributable to that illness.
 1.5 Healthy patient undergoing elective surgery unintended, unanticipated death 	1.5 Any unintended and unanticipated death occurring in an otherwise healthy patient undergoing elective surgery in any place or premises in which a health services provider provides a health service where the death is directly related to a surgical operation or anaesthesia (including recovery from the effects of anaesthesia) and the death did not arise from, or was a consequence of (or wholly attributable to) the illness of the patient or an underlying condition of the patient.

1.6 Unintended, unanticipated death directly related to any medical treatment	1.6 Any unintended and unanticipated death occurring in any place or premises in which a health services provider provides a health service that is directly related to any medical treatment and the death did not arise from, or was a consequence of (or wholly attributable to) the illness of the patient or an underlying condition of the patient.
1.7 Patient death due to transfusion of ABO incompatible blood or blood components	1.7 Patient death due to transfusion of ABO incompatible blood or blood components and the death was unintended and unanticipated and which did not arise from, or was a consequence of (or wholly attributable to) the illness of the patient or an underlying condition of the patient.
1.8 Patient death associated with a medication error	1.8 Patient death associated with a medication error and the death was unintended and unanticipated as it did not arise from, or was a consequence of (or wholly attributable to) the illness of the patient or an underlying condition of the patient.
1.9 Unanticipated death while pregnant or within 42 days of the end of pregnancy	1.9 An unanticipated death of a woman while pregnant or within 42 days of the end of the pregnancy from any cause related to, or aggravated by, the management of the pregnancy, and which did not arise from, or was a consequence of (or wholly attributable to) the illness of the patient or an underlying condition of the patient.
1.10 An unanticipated and unintended stillborn child	1.10 An unanticipated and unintended stillborn child where the child was born without a fatal foetal abnormality and with a prescribed birthweight or has achieved a prescribed gestational age and who shows no sign of life at birth, from any cause related to or aggravated by the management of the pregnancy, and the death did not arise from, or was a consequence of (or wholly attributable to) the illness of the patient or an underlying condition of the child.
1.11 An unanticipated and unintended perinatal death	1.11 An unanticipated and unintended perinatal death where a child born with, or having achieved, a prescribed gestational age and a prescribed birthweight who was alive at the onset of care in labour, from any cause related to, or aggravated by, the management of the pregnancy, and the death did not arise from, or was a consequence of (or wholly attributable to) the illness of the child or an underlying condition of the child.

1.12 An unintended death of a patient where the cause is believed to be suicide	1.12 An unintended death where the cause is believed to be the suicide of a patient while being cared for in or at a place or premises in which a health services provider provides a health service whether or not the death was anticipated or arose from, or was wholly or partially attributable to, the illness or underlying condition of the patient.
2.1 (a) A baby who is	2.1 (a) in the clinical judgment of the treating health practitioner
referred for therapeutic	requires, or is referred for, therapeutic hypothermia, or
hypothermia	
2.1 (b) A baby who did not	2.1 (b) A baby who has been considered for, but did not undergo
undergo therapeutic	therapeutic hypothermia as, in the clinical judgment of the health
hypothermia —	practitioner, such therapy was contraindicated due to the severity of
contraindicated	the presenting condition.

Appendix 1.1 — Definition of 'Health Services Provider' as set out in section 3 of the 2023 Act

Definition of "Health Services Provider" Section 3 of the 2023 Act

3. (1) In this Act, "health services provider" means—

(a) a person, other than a health practitioner, who provides one or more health services and for that purpose—

(i) employs a health practitioner for the provision (whether for, or on behalf of, that person) by that practitioner, of a health service,

(ii) enters into a contract for services with a health practitioner for the provision (whether for, or on behalf of, that person) by that health practitioner of a health service,

(iii) enters into an agency contract for the assignment, by an employment agency, of an agency health practitioner to provide a health service for, or on behalf of, that person,

(iv) enters into an arrangement with a health practitioner—

(I) for the provision by that health practitioner of a health service (whether for, or on behalf of, that person, or through or in connection with that person),

(II) for the provision by that health practitioner of a health service on his or her own behalf (whether through or in connection with, or by or on behalf of, that person or otherwise), or

(III) without prejudice to the generality of clause (II), to provide that health practitioner with privileges commonly known as practising privileges (whether such privileges are to operate through or in connection with, or by or on behalf of, the person or otherwise),

or

(v) insofar as it relates to the carrying on of the business of providing a health service—

(I) employs one or more persons,

(II) enters into a contract for services with one or more persons,

(III) enters into an agency contract for the assignment of an agency worker, or

(IV) enters into an arrangement with one or more persons,

in respect of the carrying on of that business,

(b) a health practitioner who provides a health service and does not provide that health service for, or on behalf of, or through or in connection with (whether by reason of employment or otherwise), a person referred to in paragraph (a) and includes a health practitioner who—

(i) employs another health practitioner for the provision (whether for, or on behalf of, the first-mentioned health practitioner) by that other health practitioner of a health service,

(ii) enters into a contract for services with another health practitioner for the provision (whether for, or on behalf of, the first-mentioned health practitioner) by that other health practitioner, of a health service,

(iii) enters into an agency contract for the assignment, by an employment agency, of an agency health practitioner to provide a health service for, or on behalf of, the first-mentioned health practitioner, or

(iv) insofar as it relates to the carrying on of the business of providing a health service—

(I) employs one or more persons,

(II) enters into a contract for services with one or more persons,

(III) enters into an agency contract for the assignment of an agency worker, or

(IV) enters into an arrangement with one or more persons,

in respect of the carrying on of that business,

(c) a partnership of 2 or more health practitioners who provide a health service in common which does not provide that health service for, or on behalf of, or through or in connection with (whether by reason of employment or otherwise), a person referred to in paragraph (a) and includes a partnership which—

(i) employs another health practitioner for the provision (whether by or on behalf of, the partnership) by that other health practitioner of a health service,

(ii) enters into a contract for services with another health practitioner for the provision (whether for, or on behalf of, the partnership) by that other health practitioner of a health service,

(iii) enters into an agency contract for the assignment, by an employment agency, of an agency health practitioner to provide a health service for, or on behalf of, the partnership, or

(iv) insofar as it relates to the carrying on of the business of providing a health service—

(I) employs one or more persons,

(II) enters into a contract for services with one or more persons,

(III) enters into an agency contract for the assignment of an agency worker, or

(IV) enters into an arrangement with one or more persons,

in respect of the carrying on of that business, or

(d) in the case of a cancer screening service, the Executive or, in respect of the cancer screening service referred to in paragraph (b) of the definition of "cancer screening service", a provider referred to in paragraph (b) or (c).

(2) For the purposes of paragraphs (b) and (c) of the definition of "health services provider", references in each such paragraph to "through or in connection with" do not include the use by a health services provider referred to in each such paragraph of a health service (or processes related to a health service) provided—

(a) by a health services provider referred to in paragraph (a) of that definition, and

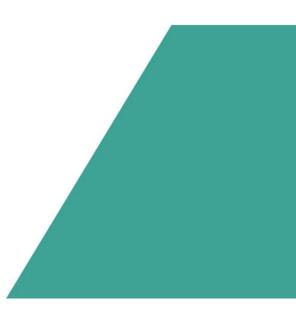
(b) for the purpose of the provision, by a health services provider—

(i) referred to in paragraph (b) of that definition, of a health service on its own behalf, or

(ii) referred to in paragraph (c) of that definition, of a health service on behalf of a partnership.

Appendix 2 — Revision History

Revision date	Summary of changes	
October 2024	Version 3	
	 new information on the requirement for notifiable incidents to be submitted as set out under the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 	
	 updated definition for an outbreak of any notifiable disease and guidelines on submitting a NF02A 	
	 various style and grammar amendments throughout. 	
December 2018	Version 2 updates to HIQA contact details	
February 2018	Version 1 Publication of monitoring notifications handbook.	



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