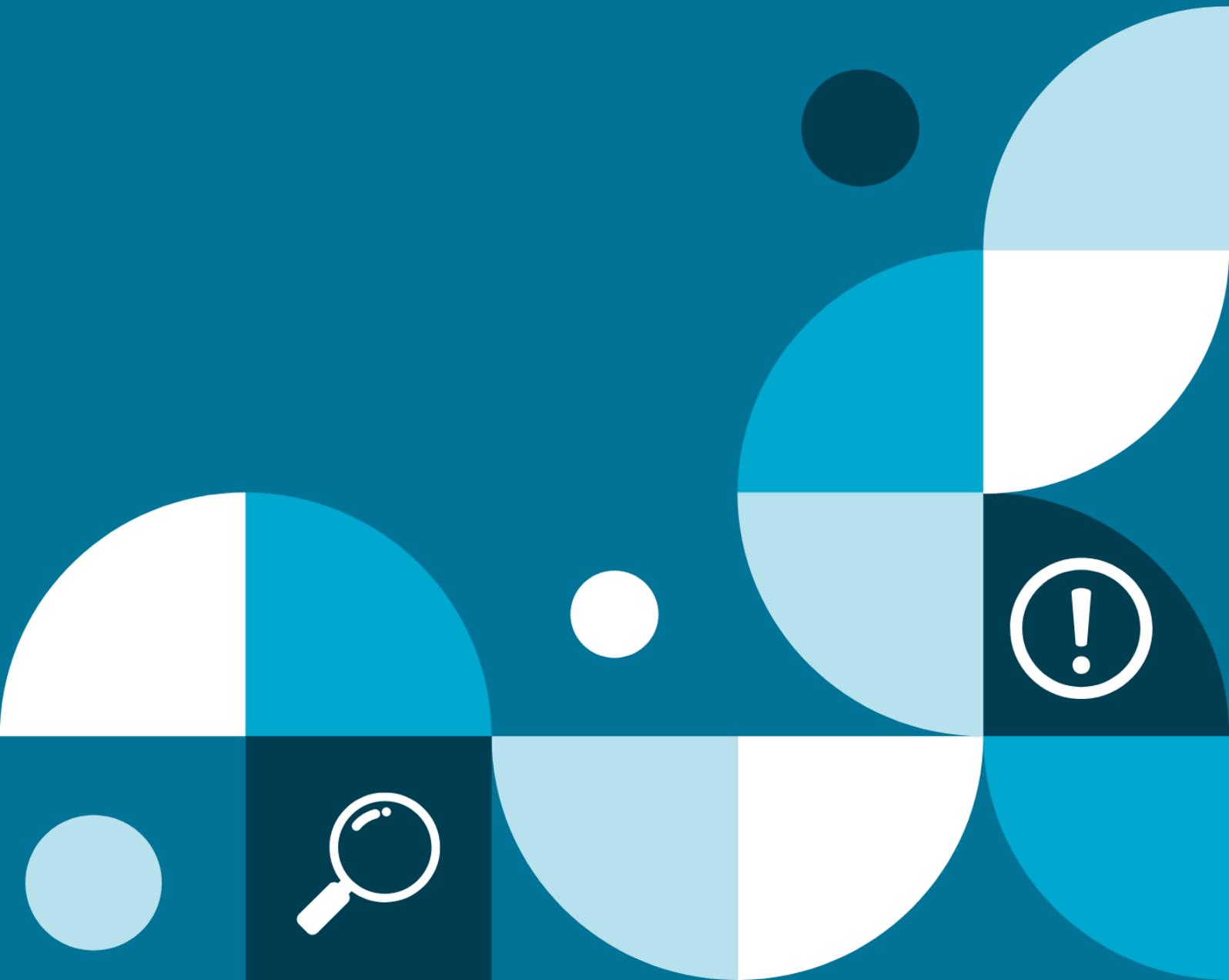


Statutory Notification of Events Under Regulations 30 & 31 of the Independent Health Care (Wales) Regulations 2011

Guidance for Registered Providers and Managers



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1. Introduction

This guidance has been produced to assist providers and managers ('registered persons') of independent health care establishments or agencies registered with Healthcare Inspectorate Wales ('HIW'), on how to complete notifiable events forms. This guidance sets out what type of events need to be notified and the corresponding timescales, and also sets out the process that is to be followed when submitting a notification form.

2. Background

Under the Care Standards Act 2000 **(1)** those providing or managing independent hospitals, independent clinics and independent medical agencies must register with the registration authority. In Wales, HIW exercise this function on behalf of the Welsh Ministers.

Regulations 30 and 31 of the Independent Health Care (Wales) Regulations 2011 **(2)** ("the Regulations") require the registered person to notify HIW about prescribed events (they can be found at Appendix A). The events in question relate to patient safety, and whilst there is a legal requirement to notify HIW of their occurrence, it is also expected that the registered person has the necessary policies and procedures in place to reduce the risks of their occurring in the first instance; appropriately manage the situation if and when it occurs; and ensure the occurrence of the identified risk is appropriately managed so as to avoid future occurrences.

Failing to notify HIW of a notifiable event within the timescales stated in the legislation can result in HIW taking enforcement action; this in turn could lead to a criminal prosecution and/ or the cancellation of your registration.

(1) *The Act can be viewed*
on <http://www.legislation.gov.uk/ukpga/2000/14/contents>

(2) *These Regulations can be viewed*
on <http://www.legislation.gov.uk/wsi/2011/734/contents/made>

3. Events that need to be notified

An overview of the events that need to be notified and the timescales for notification are set out in **Appendix A**.

If there is any doubt as to whether an event is reportable or not, guidance should be sought by contacting HIW. Our contact details can be found at the end of this document.

4. How to report a notifiable event

Use the standard notification forms

When notifying HIW of a notifiable event you should use the relevant form which is published on [HIW's website](#) as this will ensure that you are using the most appropriate and up to date version of the form.

Completing each section of the form comprehensively will also reduce the need for HIW to seek further clarification/assurances.

Authorised Individuals

Whilst the Regulations require the registered person to notify HIW; it is recognised that this may not always be possible. Therefore, the registered person may need to delegate the notification task to authorised individuals.

Before we are able to accept a notification which has been sent on your behalf, you will need to provide HIW with a list of individuals (and their e-mail addresses) who you have authorised to contact us **(3)**. HIW allows each registered establishment to nominate up to six authorised individuals, in addition to the Registered Manager and the Responsible Individual, to be permitted access to submit notifications via the secure system.

Any notifications or associated correspondence received from these authorised individuals, will be taken as if it has been provided with the registered person's knowledge and consent.

It is the responsibility of the relevant establishment to update HIW anytime the list of authorised individuals needs to be updated, for example, if an individual leaves the establishment.

If HIW receives a notification from an individual who is not on the list of authorised individuals for the relevant establishment, the notification form will not be accepted and HIW will contact the registered person to clarify.

Correspondence relating to a specific incident will be addressed to the person who notifies HIW until it is informed otherwise.

If an authorised person is the subject of an allegation of misconduct, HIW should be separately informed, to ensure actions are taken to restrict access to the relevant workspace and the documents being shared.

Privacy notice

The event notification forms and the list of authorised individuals ask for personal information about you and your staff.

We use the list of authorised individuals to verify that the information we receive is from your establishment and someone who is authorised to inform us.

We use the names and email addresses on the notifiable event forms to send an acknowledgement and, occasionally, to ask further questions about the event. We keep old forms for no more than ten years before destroying them securely in line with Welsh Government record-keeping guidelines.

We will use Objective Connect, the Welsh Government's preferred secure portal for sharing information.

5. Completing the notification forms

Key points

- Always use the current forms published on [HIW's website](#) (*Any out of date notification forms submitted to HIW, will not be accepted and will be returned to sender*)

- Be concise, clear and enclose any supplementary documentation such as investigation reports you have commissioned
- All sections of the relevant form should be completed (where relevant information isn't available at the time of completion, please state this and indicate when you expect to send it to HIW)
- Avoid using any jargon, acronyms and abbreviations
- Ensure that both Part A and Part B forms are submitted for each notification. Please ensure that all sections of the form are filled out entirely. If a particular section is not applicable to the incident, indicate this by adding 'N/A'
- Ensure that the Part A form clearly outlines what has occurred and the immediate actions taken by the establishment to safeguard the patient(s)
- Ensure that the Part B form provides additional details on the actions taken by the establishment to mitigate against the risk of similar incidents occurring again in the future
- If there are any additional investigations ongoing, please include further details within the Part B form on the additional activity, as well as estimate timescales for completion.

6. How to submit your completed notifiable event form

When submitting completed notification forms to HIW, you should only use one of the following methods:

- a) Please send completed electronic forms to HIW via Objective Connect (OC). Should you have any queries or issues accessing the OC account please contact HIW Notifiable Events mailbox - hiwnotifiableevents@gov.wales.
- b) If any issues arise resulting in the inability to submit electronic notification forms to HIW, please submit a completed paper copy of the notification form to HIW using recorded delivery. **Please ensure you notify HIW in advance of sending any notification documents via post. Please notify HIW via HIW Notifiable Events mailbox.**

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A hard copy should be sent to HIW via recorded delivery to:

Investigation Team, Healthcare Inspectorate Wales, Welsh Government, Rhydycar Business Park, Merthyr Tydfil, CF48 1UZ

Please note, notifications should not be sent directly to HIW staff or by FAX.

7. What happens after you have reported the event

Once HIW has received a notification we will send an acknowledgement email to the authorised individual who submitted the form within two working days. The acknowledgment email will include a HIW reference number for use on all follow up correspondence related to the event. If having notified HIW of an event you don't receive an acknowledgement within two working days, you should contact HIW immediately. The acknowledgement email will include the deadline date to return the Part B notification form.

Following receipt, all notifications will be reviewed and triaged within three working days. Following review, you may be asked to provide HIW with additional information/assurances on the incident and subsequent actions taken, in advance of the Part B.

Please ensure that Part B notification forms are submitted to HIW within the specified timescale outlined in the HIW acknowledgement email. Part B forms should detail any additional actions taken by the establishment, including measures to investigate the incident and mitigate the risk of similar incidents in the future. If the investigation is not completed by the Part B deadline, please submit the form with an update on progress and estimated timescales for completion/submission to HIW. Subsequently, send the investigation report to HIW when complete.

For notifications related to patient deaths, if the certified cause of death has not been confirmed within the Part B deadline period, please submit the Part B with this information. Please ensure HIW are provided with an update once the certified cause of death has been confirmed.

Upon receipt of Part B forms and any associated investigation report, HIW will review the documents to ascertain whether sufficient assurances have been

provided. If the assurances are deemed sufficient, HIW will close the notification. However, if additional clarity or assurances are required, HIW will contact the establishment to request further information.

HIW will follow up on any outstanding Part B or investigation reports through the HIW Chaser Letter Process. Letters will be sent to the establishment Registered Manager to detail any information which is yet to be submitted to HIW, related to active notifications. Please note, any failure to respond to the HIW chaser letter, within the given timescale, may result in a non-compliance notice being issued.

General Data Protection Regulation 2016

Healthcare Inspectorate Wales (HIW), on behalf of the Welsh Government, processes this information in accordance with UK GDPR and the Data Protection Act 2018. We may share your information with other regulatory bodies, law enforcement agencies, and others within Welsh Government where necessary.

The information provided on the notifiable event forms enables HIW to assess the conduct of healthcare establishments and agencies in light of regulatory requirements and determine what, if any, action is required to ensure patients are appropriately safeguarded.

Your data will be stored securely and handled in accordance with Welsh Government security standards. The Welsh Government will hold your data for 10 years following closure, in line with audit requirements.

Your Rights

You have the right to:

- Access the personal data we process about you
- Rectify inaccuracies
- In certain circumstances, object to processing or request erasure of your data
- Lodge a complaint with the Information Commissioner's Office

For further details, or to exercise your rights, please contact the Data Protection Officer at: dataprotectionofficer@gov.wales or visit our full [HIW Privacy Notice](#).

8. Queries and further information

If you would like help to complete the forms or need any further information about the process outlined in this guidance, please contact HIW on 0300 062 8163 or email us at hiwnotifiableevents@gov.wales

Appendix A - Overview of Events to be notified under the Independent health care (Wales) regulations 2011

The Registered Person must notify HIW of the following events:

Category of event	Regulation	Event Details	Who needs to notify	Timescale for notification	Form to be completed
Death	30	Death of a patient who is liable to be detained by the registered person: <ul style="list-style-type: none"> • under the Mental Health Act 1983 (–the 1983 Act); or • pursuant to an order or direction made under another enactment (which applies in relation to Wales), where that detention takes effect as if the order or direction were made pursuant to the provisions of the 1983 Act. 	Establishment	Within 24 hours beginning with the event in question and, if given verbally, must be confirmed in writing within 72 hours of the verbal notification.	NE2a

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		<p>Information required by HIW</p> <p>Please ensure that the initial notification includes circumstances leading to the patient death, including care and treatment provided. HIW will subsequently require the certified cause of death for the patient, as well as outcomes of any internal and external investigation completed, prior to closing the notification.</p>			
Unauthorised absence	30	<p>Unauthorised absence of a patient who is detained or liable to be detained by the registered person:</p> <ul style="list-style-type: none"> • under the Mental Health Act 1983 (–the 1983 Act); or • pursuant to an order or direction made under another enactment (which applies in relation to Wales), where that detention takes effect as 	Establishment	Within 24 hours	NE3a

		<p>if the order or direction were made pursuant to the provisions of the 1983 Act.</p> <p>Information required by HIW</p> <p>Please ensure the initial notification outlines circumstances leading to the unauthorised absence and the immediate actions taken by the establishment. Within the initial notification, confirm whether the patient has since returned to the establishment, as well as initial actions to prevent similar issue occurring.</p> <p>Within the Part B, please ensure details are included outlining actions implemented to mitigate any further unauthorised absence for the relevant patient.</p>			
Death	31	Death of a patient:	(i) Establishment	Within 24 hours beginning	If in a hospice use Form

	<p>(i) in an establishment (ii) during treatment provided in or for the purposes of an establishment or for the purposes of an agency, or (iii) as a consequence of treatment provided in or for the purposes of an establishment or for the purpose of an agency.</p> <p>Information required by HIW</p> <p>Please ensure that the initial notification includes circumstances leading to patient death, including care and treatment provided. HIW will subsequently require the certified cause of death for the patient, as well as outcomes of any internal and external investigations completed, prior to closing the notification. If a Coroner's inquest is undertaken, it is the responsibility of the relevant establishment</p>	<p>(ii) Establishment & Agency (iii) Establishment & Agency</p>	<p>with the event in question and, if given verbally, must be confirmed in writing within 72 hours of the verbal notification.</p>	<p>NE1a; otherwise use Form NE2a</p>
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		to provide an update on the certified cause of death once available.			
Death	31	<p>Death associated with a termination of a pregnancy in the last 12 months.</p> <p>If the registered person receives information concerning the death of a patient who has undergone termination of a pregnancy in an independent hospital during the period of 12 months ending on the date on which the information is received; and has reason to believe that the patient's death may be associated with the termination, the registered person must give notice in writing to HIW of that information, within the period of 14 days beginning on the day on which the information is received.</p>	Establishment	14 days beginning on the day on which the information is received	NE2a
Serious injuries	31	Whilst HIW acknowledges that 'serious injury' isn't defined by the regulations our	Establishment & Agency	Within 24 hours beginning	Form NE4a

		<p>interpretation of what requires notification under Regulation 31 is as follows:</p> <p>a) any incidents which results in the patient attending a hospital or where such attendance has been so advised, regardless of whether or not the patient attended.</p> <p>b) Any incidents which necessitated patient treatment by either a physician or qualified nurse</p> <p>c) All ‘Never Events’. Never Events are serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented.</p> <p>d) Any incidents where a patient had to be transferred to another independent or NHS hospital due to complications with their treatment / surgery.</p>		<p>with the event in question and, if given verbally, must be confirmed in writing within 72 hours of the verbal notification.</p>	
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		<p>e) Any incidents relating to injuries suffered by staff members following actions of patients, which require medical assessment and / or treatment by either a physician or qualified nurse.</p> <p>Information required by HIW</p> <p>Incidents that are reportable to HIW in line with the details above also include:</p> <ul style="list-style-type: none"> • Any patient ligature attempts requiring any form of staff intervention • Any intentional or accidental choking incidents involving patients relating to ingestion or attempted ingestion of items, that require any form of staff intervention 			
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		<ul style="list-style-type: none"> • Any medication errors which require further assessment or treatment from physician or qualified nurse • Patient pressure sores <ul style="list-style-type: none"> - If patient acquires pressure damage (grade 2 or above) whilst in the care of the establishment - If patient is admitted into the establishment with pressure damage at grade 2 or above - If patient is admitted to establishment with any pressure damage which worsens, regardless of grade - If patient acquires any pressure damage as a result of poor practice, neglect or abuse. 			
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<p>Outbreak of an infectious disease</p>	<p>31</p>	<p>The outbreak in an establishment of any infectious disease, which in the opinion of any medical practitioner employed in the establishment is sufficiently serious to be so notified.</p> <p>The establishment should refer to current Public Health Wales guidance for establishing whether an outbreak has occurred, to determine whether a HIW notification is required.</p> <p>Information required by HIW</p> <p>Please ensure the initial notification provides details regarding the infectious disease and number of individuals affected, both patients and staff. The initial notification should include information on the immediate actions taken to prevent further transmission.</p> <p>The follow-up notification should update HIW on the outbreak and outline current</p>	<p>Establishment</p>	<p>Within 24 hours beginning with the event in question and, if given verbally, must be confirmed in writing within 72 hours of the verbal notification.</p>	<p>Form NE5a</p>
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		and planned measures to prevent future occurrences.			
Allegation of misconduct	31	<p>Any allegation of misconduct resulting in actual or potential harm / abuse to a patient by any person employed in or for the purposes of the establishment.</p> <p>Information required by HIW</p> <p>Types of allegations may encompass various categories, including but not limited to:</p> <ul style="list-style-type: none"> • Patient physical, sexual, verbal or financial abuse from any staff member • Any neglect suffered by patient from staff member 	Establishment	<p>Within 24 hours of the allegation being made and, if given verbally, must be confirmed in writing within 72 hours of the verbal notification.</p>	Form NE6a

		<ul style="list-style-type: none"> • Staff not following prescribed care plans / risk assessments in place relating to patients • Medication errors which occur • Please note HIW must also be notified if allegations raised relate to any agency or locum staff working at the establishment. <p>The initial notification should outline the incident that has occurred, resulting in actual or potential harm to the patient(s).</p> <p>It should include immediate actions taken to safeguard the patient, as well as details of any actions taken against the staff member or measures implemented. The follow-up notification should provide the results of any internal or external investigations conducted and steps taken to</p>			
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		mitigate the risk of similar incidents in the future.			
Deprivation of Liberty	31	<ul style="list-style-type: none"> • A request to a supervisory body defined within the Mental Capacity Act 2005 made by the registered provider or registered manager for a standard authorisation under the Deprivation of Liberty safeguards, including the result of such a request. • Any application made to a court in relation to depriving a patient of their liberty. <p>Information required by HIW</p> <p>Provide clear details on the rationale for the requests or applications. An additional update needs to be provided to HIW on progress or outcome of any requests or applications made by the establishment for</p>	Establishment & Agency	Within 24 hours beginning with the event in question and, if given verbally, must be confirmed in writing within 72 hours of the verbal notification.	Form NE7a

		<p>patients. If the DoLs application/request exceeds 28-days, please provide HIW with an update on the arrangements in place to provide ongoing care and treatment to the patient.</p>			
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