

**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') to complete notifiable events forms. The guidance sets out what events need to be notified and by when; and the process to follow when submitting a notification form.

2. Background

Under the Care Standards Act 2000¹ 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 2011² ("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 or the cancellation of your registration.

3. Events that need to be notified

An overview of the events that need to be notified and the timescales for notification is 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 form.

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

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>

Authorised Individuals

Whilst the Regulations require the registered person to notify HIW; it's appreciated that this may not always be possible and that as the registered person you may want to delegate the notification task to others.

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 us³. Please use the Authorisation Form on [our website](#) to do this. Any notifications or correspondence entered into with these authorised individuals will be taken as if it has been provided with the registered person's knowledge and consent.

If HIW receives a notification from someone who is not on the list of authorised individuals, HIW will contact the registered person to clarify whether or not this individual has been authorised and will request an updated list. The new list should be provided within 2 working days. Correspondence relating to a specific incident will be addressed to the person who notifies HIW until it is informed otherwise.

It's recommended as a matter of good practice that if an authorised person is the subject of an allegation of misconduct that HIW is separately informed. HIW will suspend their access to the portal (see section 7) until the matter has been resolved.

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 entitled to inform us. We actively use the information until it is replaced by information on a new form.

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.

5. Completing the notification forms

Key points

- Always use the current forms published on [HIW's website](#)⁴
- Be concise, clear and enclose any supplementary documentation such as investigation reports you have commissioned

³ The same form can be used on behalf of the registered provider and registered manager; there is no need for both registered persons to submit separate forms.

⁴ These forms may be subject to changes from time to time.

- 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

General Data Protection Regulation 2016

HIW, on behalf of the Welsh Government uses this information to process the notification and will share your information with other regulatory bodies, law enforcement agencies and with others within the Welsh Government if needed.

The information provided on the notifiable event forms enables HIW to assess the conduct of health care establishments and agencies in light of the regulatory requirements imposed by the Regulations and what, if any, action is required from a regulatory perspective to ensure ultimately that patients are being appropriately safeguarded.

The Welsh Government will hold your data for 10 years following closure in line with audit requirements.

You have the right to access the personal data we are processing about you, rectify inaccuracies, in certain circumstances object to processing or erasure of your data and lodge a complaint.

For further details and the full Privacy Notice is available at www.hiw.org.uk

6. What happens after you have reported the event

Once HIW has received a notification we will send an acknowledgement letter/email to the same address it was sent from within two working days. The acknowledgment 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.

Unless there is a need to do so sooner, all notifications will be considered by the HIW within 10 working days of receipt. Following which you may be asked to provide additional information. The information provided on the notifiable event forms enable HIW to assess health care provider's ability to comply with the 2011 Regulations and ultimately that patients are being appropriately safeguarded.

7. How to submit your completed notifiable event form

Completed forms will often contain personal or commercially sensitive information and

deserve adequate protection. Consequently, when submitting completed forms you should only use one of the following methods:

- a) Please return completed forms to Healthcare Inspectorate Wales via Objective Connect or via recorded delivery. If you do not have an Objective Connect account please contact HIW on 0300 062 8163.
- b) In hard copy using **Recorded Delivery**. If you are unable to return the completed form via Objective connect, a hard copy should be sent to HIW via recorded delivery to:

Notifiable Events
Healthcare Inspectorate Wales
Welsh Government
Rhydycar Business Park
Merthyr Tydfil
CF48 1UZ

Notifications should not be sent directly to HIW staff or by FAX.

General Data Protection Regulation 2016

HIW, on behalf of the Welsh Government uses this information to process the notification and will share your information with other regulatory bodies, law enforcement agencies and with others within the Welsh Government if needed.

The information provided on the notifiable event forms enables HIW to assess the conduct of health care establishments and agencies in light of the regulatory requirements imposed by the Regulations and what, if any, action is required from a regulatory perspective to ensure ultimately that patients are being appropriately safeguarded.

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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 www.hiw.org.uk.

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	Without delay	Form NE2a
Death	31	Death of a patient: <ul style="list-style-type: none"> (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. 	<ul style="list-style-type: none"> (i) Establishment (ii) Establishment & Agency (iii) 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.	If in a hospice use Form NE1a; otherwise use Form NE2a

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	Form NE2a
Unauthorised absence	30	<p>Unauthorised absence of a patient who is 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 if the order or direction were made pursuant to the provisions of the 1983 Act. 	Establishment	Without delay	Form NE3a
Serious injuries	31	<p>Whilst HIW acknowledges that 'serious injury' isn't defined by the regulations our interpretation of what requires notification under Regulation 31 is as follows:</p> <p>a) incidents which you would inform the Health & Safety Executive under RIDDOR (http://www.hse.gov.uk/riddor/what-must-i-report.htm);</p> <p>b) any incidents which results in</p>	Establishment & Agency	Within 24 hours beginning with the event in question and, if given verbally, must be confirmed	Form NE4a

		<p>the patient attending a hospital or where such attendance has been so advised, regardless of whether or not the patient attended.</p> <p>c) Any incidents which necessitated treatment by either a physician or qualified nurse</p> <p>d) 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>e) Any incidents where a patient had to be transferred to another independent or NHS hospital due to complications with their treatment / surgery.</p>		in writing within 72 hours of the verbal notification.	
Outbreak of an infectious disease	31	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.	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.	Form NE5a
Allegation of misconduct	31	Any <u>allegation</u> of misconduct resulting in actual or potential harm to a patient by any person employed in or for the purposes of the establishment, or any medical practitioner with practising privileges.	Establishment	Within 24 hours of the allegation being made and, if given verbally, must be confirmed	Form NE6a

				in writing within 72 hours of the verbal notification.	
Deprivation of	31	<ul style="list-style-type: none"> • A request to a supervisory body defined 	Establishment	Within 24	Form NE7a

Liberty		<p>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.</p> <ul style="list-style-type: none"> • Any application made to a court in relation to depriving a patient of their liberty. 	& Agency	<p>hours beginning 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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