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UNDER REVIEW

Independent Healthcare Regulation

Notifications Guidance

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Introduction

Healthcare Improvement Scotland is a national health body created on 1 April 2011. The *National Health Service (Scotland) Act 1978* (the Act) requires Healthcare Improvement Scotland to undertake the regulation of independent healthcare services.

The Act, alongside the *Healthcare Improvement Scotland (Applications and Registrations) Regulations 2011* requires you to notify Healthcare Improvement Scotland of specific events that occur in your premises. This guidance defines the events and circumstances which must be reported.

In addition to the legal requirement to notify certain matters to us as noted below, you must maintain a system to manage risk, review the quality of treatment provided and keep a written record of this. In order to inform this process, providers are encouraged to record all significant incidents, accidents and events as a matter of good practice, and to report significant incidents and changes to us.

Systems for managing notifications

You must submit a notification to Healthcare Improvement Scotland via the Healthcare Improvement Scotland portal Quality Assurance Dashboard (scot.nhs.uk).

If you are unsure of the correct notification form to complete, please contact us for further guidance.

Change of legal entity

If you change the provider of your service, for example moving from an individual provider to a limited company or sell the service to another company, the new provider will be required to submit a new application for registration and pay a registration fee. A change of provider cannot be made as a variation of conditions.

Acknowledgement of notifications

We will acknowledge the notification you make to us within the response timescales noted below. We may ask for further information from you to decide the most appropriate course of action.

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List of notifications

No.	Notification	Timescale for notifying	Response time (within)
1	<p>Absence of a registered service manager</p> <ul style="list-style-type: none"> proposed absence of a registered service manager for more than 28 days (by planned arrangement) an unplanned or emergency absence of a registered service manager of 28 days or more 	<p>At least 14 days before the planned absence</p> <p>Within 5 working days of an unplanned or emergency absence is identified.</p>	5 working days
2	<p>Allegation of misconduct by a:</p> <ul style="list-style-type: none"> provider or any persons employed in the independent healthcare service member of staff dismissed for reasons of gross misconduct member of staff reported to their respective body under fitness to practice rules 	Within 24 hours	1 working day
3	Any formal Civil enforcement action taken (including statutory notice) by any other regulatory body, for example the Health and Safety Executive, Care Inspectorate, fire service or local authority	Within 24 hours	1 working day
4	Application to vary, remove or add conditions of registration	28 days before proposed changes taking place	28 working days
5	Assault on a member of staff	Within 2 working days	5 working days
6	Cancellation of a service	3 months before the date of the proposed cancellation	10 working days
7	Change of address of service or service provider	3 months before proposed changes take place	10 working days
8	Change of name of service or service provider	1 month before proposed changes take place	10 working days
9	Change of name / appointment of new registered service manager	10 working days before proposed changes take place	10 working days

No.	Notification	Timescale for notifying	Response time (within)
10	Change of persons living in the home that the independent healthcare service is provided from	5 working days before proposed changes take place	5 working days
11	Change of relevant individual	1 month before proposed changes take place	28 working days
12	Change of the legal entity of the provider organisation	3 months before proposed changes take place	10 working days
13	Change of staffing levels	1 month before proposed changes take place	10 working days
14	Complication of dermal filler	Within 24 hours	5 working days
15	Concerns regarding public protection, including adult support and protection and child protection: <ul style="list-style-type: none"> in relation to a service user between service users and visitors to the service 	Within 24 hours	1 working day
16	Controlled drug incident	Within 2 working days	5 working days
17	Conviction of an offence (excluding motoring offences) by a: <ul style="list-style-type: none"> registered service manager relevant individual 	Within 2 working days	5 working days
18	Death of a registered service manager or relevant individual	Within 5 working days	5 working days
19	Drug error, including Systemic Anti-Cancer Therapy	Within 2 working days	5 working days
20	Events which threaten a service provider's ability to continue providing an independent healthcare service	Within 2 working days	5 working days
21	Incidents reported to or investigated by the Police	Within 2 working days	5 working days
22	Introduction of controlled drugs within a service	1 month before proposed changes take place	30 working days
23	Mental Welfare Commission (MWC) statutory notifications	Within 24 hours	1 working day

No.	Notification	Timescale for notifying	Response time (within)
24	Outbreak of infectious/ communicable disease involving two persons or more	Within 2 working days	5 working days
25	Planned refurbishment of premises used for an independent healthcare service	3 months before proposed changes take place	10 working days
26	Premises extended or additional premises acquired for the independent healthcare service	3 months before proposed changes take place	10 working days
27	Reopening of service after temporary closure	2 days before proposed changes take place	5 working days
28	Serious injury or serious complication to service user	Within 2 working days	5 working days
29	Sequestration, bankruptcy or appointment of a judicial factor of an independent healthcare provider	Next working day	5 working days
30	Trustee or liquidator appointed for bankruptcy purposes	Next working day	5 working days
31	Unexpected death of a service user: <ul style="list-style-type: none"> whilst using an independent healthcare service as a consequence of using an independent healthcare service while detained or liable to be detained under the Mental Health Act 	Within 24 hours	1 working day

Explanation of notifications

1 Absence of a registered service manager either by:

- **a proposed absence of a registered service manager for more than 28 days (by planned arrangement)**

An independent healthcare provider must notify Healthcare Improvement Scotland of a proposed absence of a registered service manager for more than 28 days by planned arrangement. The following details must be provided:

- length or expected length of proposed absence
- the reason for the absence
- the arrangements which have been made for the running of the independent healthcare service during the absence, and
- the name, address and qualifications of the person who will manage the independent healthcare service during the absence.

An independent healthcare provider must notify Healthcare Improvement Scotland of the above absence no later than 14 days before the proposed date of absence commences.

- **an unplanned or emergency absence of a registered service manager of 28 days or more**

An independent healthcare provider must notify Healthcare Improvement Scotland of an unplanned or emergency absence of a registered service manager of 28 days or more. The following details must be provided:

- length or expected length of proposed absence
- the reason for the absence
- the arrangements which have been made for the running of the independent healthcare service during the absence, and
- the name, address and qualifications of the person who will manage the independent healthcare service during the absence.

An independent healthcare provider must notify Healthcare Improvement Scotland within 5 working days of the absence occurring. Where it is not possible for Healthcare Improvement Scotland to be notified within 5 working days of the absence occurring, notification must be made as soon as is practicable.

2 Allegation of misconduct by a:

- **provider or any persons employed in the independent healthcare service**

Misconduct is defined as intentional wrongdoing, deliberate violation of a law or improper behaviour. Healthcare Improvement Scotland regards reportable misconduct to be behaviour which warrants suspension from work pending investigation, dismissal or other disciplinary action and would expect notifications to be made in these circumstances.

The Regulations do not limit this only to acts which are directed at service users.

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This includes, but is not limited to:

- any allegation of misconduct by one member of staff against another
- any allegation of misconduct by one member of staff against a service user
- any allegation of misconduct by one service user against another service user
- any allegation of misconduct by a service user's relative, carer, representative or member of public against a member of staff
- any allegation of misconduct relating to breach of confidentiality, and
- any allegation of misconduct relating to the records held by an establishment.

Any issues of misconduct that relate to **controlled drugs** must be reported as a **Controlled drug incident**.

Healthcare Improvement Scotland recognises that, at times, complaints or issues are raised that, once an investigation takes place, are found not to be considered a matter of misconduct. Nevertheless, these require to be notified to Healthcare Improvement Scotland.

Personal details of the individual concerned are not required at the time of the initial reporting of the allegation.

Where the alleged matter is criminal in nature, Healthcare Improvement Scotland expects that the provider will contact the Police, where appropriate, and that Healthcare Improvement Scotland would be notified of this.

- **member of staff dismissed for reasons of gross misconduct**

Gross misconduct is defined as behaviour, on the part of an employee, which is so bad that it destroys the employer/employee relationship, and merits instant dismissal without notice or pay in lieu of notice.

An independent healthcare provider must notify Healthcare Improvement Scotland of any staff member dismissed for reasons of gross misconduct.

Personal details of the individual concerned are not required at the time of the initial reporting of the allegation.

Where the alleged matter is criminal in nature, Healthcare Improvement Scotland expects that the provider will contact the Police, where appropriate, and that Healthcare Improvement Scotland would be notified of this.

- **member of staff reported to their respective body under fitness to practice rules**

An independent healthcare provider must notify Healthcare Improvement Scotland if a member of staff is reported to their respective professional regulatory body under fitness to practice rules. Examples include:

- General Medical Council
- Nursing and Midwifery Council
- General Dental Council

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- Health Professions Council
- Scottish Social Services Council

Any member of staff that is reported to their professional regulatory body for matters relating to **controlled drugs** must be reported as a **Controlled drug incident**.

3 **Any formal Civil enforcement action taken (including statutory notice) by any other regulatory body, for example the Health and Safety Executive, Care Inspectorate, fire service or local authority**

All formal Civil enforcement action taken (including statutory notice) from any other regulatory body must be notified to Healthcare Improvement Scotland.

4 **Application to vary, remove or add conditions of registration**

Please submit your application form through the notifications system on the forms portal to add, vary or remove a condition of registration.

This application form tells us:

- which condition you wish to add, vary or remove
- the reason you are seeking a variation of your conditions of registration, and
- information in support of your application.

5 **Assault on a member of staff**

Any serious physical assaults on a member of staff should be reported to Healthcare Improvement Scotland. Please include details of:

- the date of the serious assault
- job title of the staff member who was assaulted
- who was involved in the assault (a service user, other member of staff, visitor)
- any injuries sustained
- if an investigation is under way / has been carried out
- any temporary and/or permanent measures put in place, and
- if the injury has been reported to the Health and Safety Executive (if applicable).

A serious assault would usually involve physical harm that would lead to the staff member needing hospital treatment or time off work.

6 **Cancellation of a service**

A formal application to terminate a currently registered service by an independent healthcare provider must be made to Healthcare Improvement Scotland **at least 3 months** before the cancellation is intended to take place.

An independent healthcare provider will require to notify Healthcare Improvement Scotland of its intention to cancel a service if there **is also a change of legal entity of the service provider**,

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as this will result in a new application for registration of an independent healthcare service.

If you fail to cancel your service before the annual continuation fee is due, then it is payable in full. No refunds of the continuation fee are available for services that only operate for part of a year.

7 Change of address of service or service provider

You must notify us of any change to the:

- service provider address
- service address

Healthcare Improvement Scotland currently does not charge a fee for a change of address of either the service provider or service. For a change of service address, a new site visit must take place. The service is not permitted to operate from the new premises until the site visit has been completed and the notification has been approved by Healthcare Improvement Scotland.

Where there is a change of legal entity of the provider organisation in addition to a change of provider organisation address, please use the notification ‘Change of legal entity of the provider organisation’ and ‘Cancellation of a service’. Please see the notification ‘change of legal entity of provider organisation’ for further information.

8 Change of name of service or service provider

You must notify us of any change to the:

- service provider name
- service name (trading name)

Where there is a change of service provider name due to a change in legal entity, please use the notification ‘Change of legal entity of the provider organisation’. Please see the notification ‘Change of legal entity of provider organisation’ for further information.

9 Change of name / Appointment of new registered service manager

An independent healthcare provider must complete and submit an application to change the name / appoint a new manager of an independent healthcare service through the notifications system on the eForms portal.

Guidance to help complete this application form can be found below.

Proposed manager’s details

Please detail the full name, address (including postcode) and telephone number of the new manager.

If the current manager is updating their name only (for example due to marriage or divorce), then only complete this first section.

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Background checks

Please tell us if the proposed manager is an existing member of the Disclosure Scotland Protecting Vulnerable Groups (PVG) Scheme. If they are, please detail the Scheme Record registration number and whether this is for work with protected adults, children or both.

Please notify Healthcare Improvement Scotland immediately if the provider organisation is unable to request a Disclosure Scotland PVG Scheme background check for the proposed manager.

Technical and professional qualifications

Please detail any technical and professional qualifications of the proposed manager.

Employment history

Please tell us about the proposed manager's previous employment and self-employment for the last 15 years. Please explain clearly if there are any gaps in their employment history and state what they were doing at that time. You must also explain clearly if they were dismissed from any previous employment, using the reason for leaving box.

Medical declaration

This declaration must be completed on behalf of the proposed manager. It must include a declaration about whether the proposed manager is physically and mentally fit to provide an independent healthcare service. These declarations should be completed on behalf of the proposed manager.

Previous manger

Please tell us if the previous manager is still working within the service / elsewhere for the provider, or if they have left the company completely. If Healthcare Improvement Scotland carried out a PVG check for the previous manager as part of the registration process, we will contact Disclosure Scotland to withdraw our interest in the previous manager.

10 Change of persons living in the home that the independent healthcare service is provided from

Any changes to the home occupant's details must be notified to Healthcare Improvement Scotland.

11 Change of relevant individual

'Relevant individuals' are persons who act as:

- a director, manager or secretary of the body corporate
- a member of the firm (where the applicant is a limited liability partnership)
- a member of the firm (where the applicant is a limited partnership)
- a partner in the firm (where the applicant is a partnership), or who are
- concerned in the management or control of the association (where the applicant is an unincorporated association other than a firm).

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An application form should be completed and submitted through the notifications system in the eForms portal where there are changes to relevant individuals in the organisation, for example a new director is appointed to the provider organisation or a previous director has left the provider organisation. This also applies to charitable organisations where new trustees are appointed. Guidance on how to complete this application form can be found on our website.

Details of new relevant individual

Please complete a separate application form detailing the full name, address (including postcode) and telephone number of the relevant individual that has changed.

Services that members of the organisation have previously provided

This declaration must be made by the relevant individual.

Bankruptcy and sequestration

This declaration must be made by the relevant individual.

If you are unable to make the declaration, you have the opportunity to explain why. We will take account of the explanations and details when considering your application.

Declarations about convictions and prosecutions

This declaration must be made by the relevant individual.

The *Rehabilitation of Offenders Act 1974 (Exclusions and Exemptions) (Scotland) Order 2003* requires that anyone applying to provide an independent healthcare service must declare all convictions, whether 'spent' or not. Any failure to disclose convictions may result in refusal of the application to register the proposed independent healthcare service with Healthcare Improvement Scotland. Any information provided will be confidential. The disclosure of conviction(s) in relation to a relevant individual does not necessarily exclude an applicant from becoming registered. Full consideration will be given and the nature of the offence(s) will be taken into account.

Background checks

Healthcare Improvement Scotland will complete a Disclosure Scotland Protecting Vulnerable Groups (PVG) background check for selected relevant individuals (key relevant individual). Please identify if the new relevant individual is the nominated key relevant individual for your provider.

Further information about these checks can be found on our website.

References

Please provide the full names and contact details of two people for the relevant individual. Healthcare Improvement Scotland will complete reference checks for the new relevant individual if the provider does not hold on file completed references for that person.

Referees must:

- **not** be a relative
- be your employer, where you have been employed by one employer for at least 3 months in the last 15 years.

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Statement about the applicant's previous involvement in registered services

Any relevant individual completing this form should complete this question on behalf of the applicant.

Details of relevant individual who has left

Please complete a separate application form detailing the full name, address (including postcode) and telephone number of each relevant individual that has changed/left the provider. If a new relevant individual has been appointed, but no other relevant individuals have left, please leave this section blank.

12 Change of the legal entity of the provider organisation

Any changes to the legal entity of the provider organisation must be notified to Healthcare Improvement Scotland.

Examples of this may be:

- changing the legal entity of the provider organisation from sole trader to a limited company.
- selling the company and the provider organisation will change.
- dissolving a partnership and a new partnership or company will be formed.
- dissolving the company and a new company will be formed.

A change of legal entity of the provider organisation will require a new application for registration of the independent healthcare service with Healthcare Improvement Scotland. This will mean that payment of a new registration fee is required when a new application for registration is submitted.

13 Change of staffing levels

You must notify us of changes to your staffing levels that will impact on your continuation fee:

- Change from single-handed practitioner service to a service with staff (including employed staff, admin, practitioners who work under practicing privileges and prescribers).
- Change from staffed service to single-handed practitioner service.

The date of the change must be included in the notification.

Please note that you must ensure that all staff (including practitioners who work under practicing privileges and prescribers) possess the appropriate skills, training and experience to ensure the safety and welfare of all service users. All relevant staffing checks are completed and recorded.

14 Complication of dermal filler

Service providers must notify Healthcare Improvement Scotland of each incidence of complication of dermal filler when they occur as a consequence of using an independent health

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care service. This includes complications that may result in a person returning to the service for further treatment, attending another IHC service or NHS hospital for treatment. Examples include, but are not restricted to, vascular occlusion, necrosis, nodules and infection.

This does not include incidents involving service users who did not receive the original dermal filler treatment from the independent health care service.

15 Concerns regarding public protection, including adult support and protection and child protection:

- **in relation to a service user**

Services must have clear and consistent guidance in place for public protection. This guidance must be in line with local and national child protection and adult support and protection legislation and guidance in Scotland.

An independent healthcare provider must notify Healthcare Improvement Scotland of any public protection concerns for a service user while using the independent healthcare service. This includes concerns about the actual or potential abuse of a child, young person or vulnerable adult.

- Personal details of the individual concerned are not required at the time of the initial reporting of the allegation.
- Healthcare Improvement Scotland expects that the provider will follow all local child protection and adult support and protection procedures set by the respective local authority for notifying their local child protection and adult support and protection committees of any allegations of abuse in relation to a service user, and will follow all appropriate advice and guidance given.
- Where the alleged matter is criminal in nature, Healthcare Improvement Scotland expects that the provider will contact the Police where appropriate, and that Healthcare Improvement Scotland would be notified of this.
- Abuse in relation to a service user, means:
 - Types of child abuse
 - physical abuse
 - sexual abuse
 - neglect
 - emotional abuse
 - Types of adult abuse
 - physical abuse
 - sexual abuse
 - neglect
 - psychological abuse
 - financial abuse
 - institutional harm or abuse

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- medication harm or abuse
 - discriminatory
 - **between service users and visitors to the service**
- Services must have clear and consistent guidance in place for public protection. This guidance must be in line with local and national child protection and adult support and protection legislation and guidance in Scotland.

An independent healthcare provider must notify Healthcare Improvement Scotland of any:

- public protection concerns between a service user and visitor to the service.

This includes concerns about the actual or potential abuse of a child, young person or vulnerable adult.

- Personal details of the individual concerned are not required at the time of the initial reporting of the allegation.
- Healthcare Improvement Scotland expects that the provider will follow all local child protection and adult support and protection procedures set by the respective local authority for notifying their local child protection and adult protection committees of any allegations of abuse in relation to a service user and will follow all appropriate advice and guidance given.
- Where the alleged matter is criminal in nature, Healthcare Improvement Scotland expects that the provider will contact the Police, where appropriate, and that Healthcare Improvement Scotland would be notified of this.
- Abuse in relation to a service user, means:
 - Types of child abuse
 - physical abuse
 - sexual abuse
 - neglect
 - emotional abuse
 - Types of adult abuse
 - physical abuse
 - sexual abuse
 - neglect
 - psychological abuse
 - financial abuse
 - institutional harm or abuse
 - medication harm or abuse
 - discriminatory

16 Controlled Drug incident

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All adverse events, significant adverse events, near misses and concerns involving a Controlled Drug must be notified to Healthcare Improvement Scotland when they occur while the service user is receiving healthcare from the independent healthcare provider.

This does not include incidents involving service users who have been formally and permanently discharged from the registered healthcare service.

This guidance applies to Schedules 2, 3, 4 and 5 Controlled Drugs (see table below). It does not apply to Schedule 1 Drugs (CD Lic) which are not recognised as having any medicinal use or to illicit drugs.

Examples of Controlled Drugs include:	
Schedule 2	alfentanil, diamorphine, fentanyl, ketamine, methylphenidate, morphine, oxycodone, methadone, cannabis based medicinal products
Schedule 3	buprenorphine, diethylpropion, midazolam, phentermine, temazepam, tramadol, gabapentin, pregabalin
Schedule 4	benzodiazepines, zolpidem, zopiclone
Schedule 5	co-codamol, codeine linctus, dihydrocodeine (oral)

NB Safe custody requirements apply for controlled drugs in Schedule 2, and buprenorphine, diethylpropion and temazepam in Schedule 3.

Purpose of notification

The purpose of the notification is to provide a summary of the event and subsequent action taken to Healthcare Improvement Scotland. It is not designed to provide a report of the review or investigation of the incident to Healthcare Improvement Scotland.

The notification process does not replace the need to report incidents through services' local reporting systems in order to manage and respond to the incident.

If you have serious concerns about an incident, please contact your NHS Controlled Drug Accountable Officer directly to discuss these.

The notification should include the following information:

- name of the NHS board area in which the registered service is situated
- date, time and location of the event
- category of event (I, II or III)
- type of event
- summary of event

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- name of the controlled drug and route of administration
- impact or likely impact on the health and wellbeing of the service user
- whether an investigation is being/will be carried out
- the outcome of investigation, if known, and if external agencies are involved (police; regulatory body, Health Board, CDAO etc).

Categories of Adverse Events

- Category I - Events that may have contributed to or resulted in permanent harm (for example unexpected death, intervention required to sustain life, severe financial loss (£>1m), ongoing national adverse publicity).
- Category II - Events that may have contributed to or resulted in temporary harm (for example initial or prolonged treatment, intervention or monitoring required, temporary loss of service, significant financial loss, adverse local publicity).
- Category III – Events that had the potential to cause harm but no harm occurred (for example near miss events (by either chance or intervention) or low impact events where an error occurred but no harm resulted).

Notifications must be made for the following types of events

Type of incident	Examples
Prescribing incident	Wrong medication or wrong dose of medication prescribed.
Administration incident	Person given wrong medication, wrong dose of medication, wrong route, or not given medication.
Dispensing/supply incident	Wrong medication or wrong dose of medication dispensed by pharmacy, or supply not available.
Missing Controlled Drugs	Unexplained losses of any Controlled Drug.
Security issues	Any concerns about safe and secure storage of Controlled Drugs, for example loss of Controlled Drug Register (CDR) or other relevant controlled stationery, or loss of controlled drug locker keys.
Discrepancy in CD register against actual stock	Discrepancy identified, but reasonable explanation or unexplained overage. Note that liquid CD discrepancies within the organisation's agreed tolerances do not need to be reported unless concerns exist.

Record keeping	Any concern about general record keeping related to controlled drugs, for example failure to record in CDR.
Suspected or Actual Criminality of Fraud	Attempts to obtain controlled drugs by deception (patients, staff, members of public). Suspected falsification of CDR entries. Lost or stolen prescription forms. Attempts to fraudulently produce prescriptions.
Other	Controlled drug related complaints from patients, carers or service users, all concerns and adverse events involving controlled drug destruction.

Medication details

Below is a list of the drugs currently controlled under the misuse of drugs legislation:

<https://www.gov.uk/government/publications/controlled-drugs-list--2>

On a quarterly basis the information provided within this notification will be shared by HIS with the relevant NHS board Controlled Drugs Accountable Officer for the purposes of identifying issues that may have local or national implications and to support learning and improvement. Information may also be shared within Controlled Drugs Local Intelligence Networks in accordance with information sharing protocols.

Wherever possible, person identifiable information should not be included.

17 Conviction of an offence (excluding motoring offences) by a:

- registered service manager
- relevant individual

An independent healthcare provider must notify Healthcare Improvement Scotland if the registered service manager or a relevant individual is convicted of an offence, excluding motor offences.

18 Death of a registered service manager or relevant individual

An independent healthcare provider must notify Healthcare Improvement Scotland if there is a death of a registered person, relevant individual or service manager either in the provider organisation or independent healthcare service.

19 Drug error, including Systemic Anti-Cancer Therapy

Notification of a drug error should be made to Healthcare Improvement Scotland when the error occurs while the service user is receiving a service from the independent healthcare provider.

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This would not include service users who have been formally and permanently discharged from the registered healthcare service.

Healthcare Improvement Scotland must be notified of drug errors when the following criteria apply:

- a drug error/near miss involving Systemic Anti-Cancer Therapy
- a drug error that results in a medical practitioner intervention
- a drug error that results in hospital admission or re-admission, or
- a drug error that is reportable under Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR).

Healthcare Improvement Scotland requires that an independent healthcare provider must notify of any suspected or actual drug error to include:

- date, time and location of the drug administration error
- name of the drug administered
- impact or likely impact on the health and wellbeing of the service user, and
- action taken by the independent healthcare provider.

Further guidance about Systemic Anti-Cancer Therapy can be found below:

http://www.healthcareimprovementscotland.org/our_work/cancer_care_improvement/programme_resources/systemic_anti-cancer_therapy.aspx

20 **Events which threaten a service provider's ability to continue providing an independent healthcare service**

Notifications of events which prevent, or appear to the independent healthcare service provider to be likely to threaten to prevent, the service provider's ability to continue to provide the independent healthcare service must be reported to Healthcare Improvement Scotland. These include:

- an insufficient number of suitably qualified, skilled and experienced persons being employed for the purpose of providing the independent healthcare service.
- an interruption to the supply of gas, water or electricity to the independent healthcare premises owned or used by the service provider, where that interruption has lasted for longer than a continuous period of 24 hours.
- a fault, break or blockage to the waste water or sewerage system that results in the backflow of sewerage or waste water into the independent healthcare premises.
- physical damage to the independent healthcare premises owned or used by the service provider for the purposes of providing the independent healthcare service which has, or is likely to have, a detrimental effect on the treatment or care provided to service users.
- a reduction in the number of beds or treatment areas available for use by service users due to either planned, unplanned or unforeseen circumstances.

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- the failure or malfunctioning of fire alarms or other safety devices in independent healthcare premises owned or used by the service provider for the purposes of providing the independent healthcare service, where that failure or malfunctioning has lasted longer than a continuous period of 24 hours.
- the failure or malfunctioning of essential equipment needed to maintain the health and welfare of service users for the purposes of providing the independent healthcare service where that failure or malfunction has lasted longer than a continuous period of 24 hours or where no alternative equipment of a similar standard is available for use by service users.
- physical, chemical or biological contamination of the water supply servicing or used by the independent healthcare service.

21 Incidents reported to or investigated by the Police

When there has been an incident reported to or investigated by the Police, this must be notified to Healthcare Improvement Scotland.

22 Introduction of controlled drugs within a service

If a service wishes to introduce controlled drugs, Healthcare Improvement Scotland must be notified to ensure procedures are in place which meet the legislative requirements for safe and secure handling of controlled drugs. This notification relates to all controlled drugs in schedule 2-5 (see page 15/16 for examples) and in relation to:

- prescribing controlled drugs for a patient to obtain a supply at community pharmacy such as ADHD treatment or painkillers.
- ordering controlled drugs from a wholesaler/pharmaceutical supplier and storing on site, either to use on site (such as alfentanil in surgery) or to provide a supply for patient to take home (such as diethylpropion in slimming clinics or co-codamol analgesia post -surgery).

The following information should be included (if applicable):

- If a private prescriber code has been awarded or requested from the relevant NHS board (if prescribing schedule 2/3 controlled drugs on a private prescription to be dispensed from a community pharmacy).
- If holding stock and a Home Office license is required. Provide evidence from the Home Office if exempt from requiring a license.
- Details of the Controlled Drugs Accountable Officer (a requirement for hospitals and hospices with more than 10 members of staff). Independent healthcare clinics are exempt from appointing a CDAO but these services should still identify a controlled drugs lead i.e. an individual who has responsibility for ensuring the safe and secure handling of CDs within the service.
- Details of storage arrangements. If storing controlled drugs on the premises, legislation must be adhered to for the ordering, storage, recording, prescription and destruction. Please provide information about the arrangements in place to meet the requirements of the legislation and good practice guidelines.

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23 Mental Welfare Commission (MWC) statutory notifications

The following incidents must be notified to Healthcare Improvement Scotland and the Mental Welfare Commission (MWC).

<https://www.mwcscot.org.uk/>

- All cases in which there is evidence of, or allegation made of, ill treatment, neglect or cruelty towards a person with a mental disorder.
- Incidents where a person with a mental disorder suffers a serious injury or adverse physical effects in circumstances where it is possible that there has been a deficiency in care or treatment or where the injury has been caused deliberately by another person.
- All deaths (including suicide) of a service user subject to compulsory treatment of guardianship orders.
- Where it is likely that a Fatal Accident Inquiry will be held.
- Where it appears that any person with a mental disorder is being improperly detained in hospital or in any other setting.
- Where a patient is detained in hospital and it appears that there is some impropriety in relation to that detention.
- Where a person with a mental disorder is living alone or without care and is unable to look after him or herself or his or her property or financial affairs and no intervention is taking place to remedy the situation.
- Incidents or circumstances in which a deficiency in care has led to a person's property suffering loss or damage or be at risk of loss of damage.

The following information must be included in the notification to the Mental Welfare Commission.

- A brief account of the circumstances of the incident or situation, its antecedents and any other relevant information.
- Information on the diagnosis, treatment and the mental state of the person.
- Information on any other person involved.
- What further action is being taken or considered, including any changes in procedure, policy or the physical environment.
- An indication of any further investigation, enquiry or review that is being carried out or considered, and a copy of the outcome of these when available.

24 Outbreak of infectious/communicable disease involving two persons or more

An independent healthcare provider must notify Healthcare Improvement Scotland of any suspected and/or confirmed outbreak of infectious or communicable disease involving two persons or more with similar symptoms.

A notification relating to an outbreak of infection/communicable disease should include the following information:

- the cause of the outbreak if possible
- the dates when the illness first started and how many service users/staff members are affected

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- the Public Health team of the local NHS board has been notified of the outbreak and if an outbreak management team has been formed
- the infection prevention and control precautions in place including, where appropriate, isolation, barrier nursing, education and restricting visiting by relatives and friends.

25 Planned refurbishment of premises used for an independent healthcare service

An independent healthcare provider must notify Healthcare Improvement Scotland of any intention to make operational changes to an already established independent healthcare service at least 3 months before the planned change is to take place. The following information must be provided:

- the date the intended change is planned to commence
- the expected length of time that the change process shall take
- a description of the operational change that is planned, and
- the impact that the change will have on the existing independent healthcare services provided.

Please note that some notified proposed operational changes may require the submission of a notification to Healthcare Improvement Scotland to add, vary or remove conditions of registration.

26 Premises extended or additional premises acquired for the independent healthcare service

An independent healthcare provider must notify Healthcare Improvement Scotland of any intention to make operational changes to an already established independent healthcare service at least 3 months before the planned change is to take place. The following information must be provided:

- the date the intended change is planned to commence
- the expected length of time that the change process shall take
- a description of the operational change that is planned, and
- the impact that the change will have on the existing independent healthcare services provided.

Please note that some notified proposed operational changes may require the submission of a notification to Healthcare Improvement Scotland to add, vary or remove conditions of registration.

27 Reopening of service after temporary closure

An independent healthcare provider must notify Healthcare Improvement Scotland of their intention to reopen an independent healthcare service a minimum of 2 days before the reopening. This notification should follow the previous notification of 'Events which threaten a service provider's ability to continue providing an independent healthcare service'. This notification cannot be used to reregister a service that has previously cancelled registration.

The following information must be provided:

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- the date the service will reopen
- how the reopening will be managed, and
- any extra precautions/changes to the service as a result of the temporary closure.

28 Serious injury or serious complication to service user

An independent healthcare provider must notify Healthcare Improvement Scotland of any serious injury, self-injury or serious complication to a service user. The following information must be provided:

- the nature of the injury and the impact that this has had/is likely to have on the health and wellbeing of the service user(s).
- the cause/likely cause of the injury.
- a full investigation has been carried out or is under way and that the outcomes from the investigation will be appropriately recorded.
- appropriate safeguards or measures, which might be temporary or permanent, are in place to stop a similar injury recurring either by the same or another service user.
- where applicable, that the injury has been reported to the Health and Safety Executive (HSE).
- risk assessments have been/will be reviewed and any appropriate action taken to prevent recurrence either by the same or another service user.

A serious injury or complication may result in a person attending hospital or returning to the service for emergency treatment. Examples include (but are not limited to):

- fractures
- concussions
- internal injuries
- crushing
- burns (excluding friction burns)
- severe cuts
- severe general shock (requiring medical treatment even if not resulting in a stay as an in-patient)
- disfigurement
- anaphylaxis
- necrosis

29 Sequestration, bankruptcy or appointment of a judicial factor of an independent healthcare provider

An independent healthcare provider must notify Healthcare Improvement Scotland of any sequestration, bankruptcy or the appointment of a judicial factor. The following information must be provided:

- date of court order granting sequestration and the identity of the trustee appointed
- date of court order adjudging the provider bankrupt and the identity of the trustee appointed
- date of court order appointing judicial factor and the identity of the person appointed, and

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- date of grant of trust deed and the identity of the trustee.

30 **Trustee or liquidator appointed for bankruptcy purposes**

An independent healthcare provider must notify Healthcare Improvement Scotland if a liquidator, receiver or other person is appointed. The following information must be provided:

- the date of appointment of liquidator/administrator or trustee, and
- the identity of that person.

31 **Unexpected death of a service user:**

- **whilst using an independent healthcare service**

Notification of the unexpected death of a service user must be made to Healthcare Improvement Scotland when the death is not attributed to end-of-life care or associated with the condition for which they are receiving care. This would not include service users who have been formally and permanently discharged from the registered healthcare service.

Healthcare Improvement Scotland requires that the provider notifies a description of the circumstances of the death.

- **as a consequence of using an independent healthcare service**

Notification of the death (including suicide) of a service user must be made to Healthcare Improvement Scotland in all circumstances when the death occurs as a consequence of the service user receiving a service from the independent healthcare provider. This would include service users who have been formally and permanently discharged from the registered healthcare service.

Healthcare Improvement Scotland requires that the provider notifies a description of the circumstances of the death.

- **while detained or liable to be detained under the Mental Health Act**

An independent healthcare provider must notify Healthcare Improvement Scotland of the death (including suicide) of a service user who is detained or liable to be detained under the *Mental Health (Care and Treatment) (Scotland) Act 2003*.

Healthcare Improvement Scotland requires that the provider notifies a description of the circumstances of the death.

In addition, notification must also be made to the Mental Welfare Commission. See notification 22: Mental Welfare Commission (MWC) statutory notifications, for further information.

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