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**Non-Compliance and Enforcement Guidance**

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Note: This guidance supersedes all previous enforcement guidance and remains under review

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**Introduction**

Healthcare Inspectorate Wales (HIW) is the regulator of independent healthcare and private dentistry services in Wales on behalf of the Welsh Ministers who, by virtue of the Government of Wales Act 2006, are designated as the registration authority. This document acts as a guide and HIW reserve the right to deviate when justified.

HIW is responsible for ensuring that all registerable providers of independent healthcare and private dentistry comply with the requirements set out in the Care Standards Act 2000 (“the Act”) and associated regulations and standards.

Compliance with these statutory provisions and adherence to standards helps ensure services provided to patients meet essential safety and quality standards and regulations.

HIW discharges its regulatory responsibilities through its assurance activity, which including the inspection of independent health care and private dentistry services in Wales. In the interest of patients, HIW aims to help services improve and eliminate bad practice. Where registered services fail to meet their legal obligations consideration will be given to taking appropriate enforcement action. This includes:

* Civil regulatory action (1)
* Criminal prosecution (2)

In exceptional circumstances, and as a means of securing patients safety, HIW may consider it appropriate to apply to the court for an injunction.

**Purpose**

This document sets out the process that HIW follows when it looks to take enforcement action against any independent health care or private dentistry service in Wales. It does not supersede any relevant statutory requirements.

**NB: HIW cannot take enforcement action against NHS services. The Service of Concern process for NHS Bodies in Wales** [**document**](https://www.hiw.org.uk/sites/default/files/2021-11/20211115NHSSoCProcessdocumentFinal-EN_0.pdf) **sets out how concerns regarding NHS services are dealt with. NHS services cannot attain a ‘Service of Concern’ designation, but follow a similar service of concern pathway which may result in a ‘Service Requiring Significant Improvement’ designation.**

(1) Civil action can only be taken against services that are registered with HIW and can include varying or imposing conditions, or ultimately cancelling registration.

(2) Criminal action can be taken against registered or unregistered services. A criminal prosecution can only be undertaken following a breach of a regulation or a section of an Act.

**Approach to Regulation**

There are detailed regulations and standards governing the provision of independent health care and private dentistry in Wales, they are:

* [The Independent Health Care (Wales) Regulations 2011](https://www.legislation.gov.uk/wsi/2011/734/body/made)
* [The Registration of Private Dentistry (Wales) Regulations 2017.](https://www.legislation.gov.uk/wsi/2017/201/contents)
* [The Private Dentistry (Wales) Regulations 2017](https://www.legislation.gov.uk/wsi/2017/202/contents/made)
* [The Registration of Social Care and Independent Health Care (Wales) Regulations 2002](https://www.legislation.gov.uk/wsi/2002/919/contents/made)
* [The National Minimum Standards for Independent Health Care in Wales](https://www.gov.wales/national-minimum-standards-independent-health-care-services-wales-2011-no16)
* [The Independent Health Care (Fees) (Wales) Regulations 2011](https://www.legislation.gov.uk/wsi/2011/106/made)

HIW expects that those registered to run services are competent to do so and are capable of complying with legal expectations.

HIW recognises that there are many opportunities to ensure services are run safely and in line with the requirements of the law. These include checks made on initial registration, giving advice at inspections and HIW’s work with other agencies; for example commissioners and other regulators. Securing improvement and compliance is therefore not just limited to HIW exercising its power in relation to civil and criminal proceedings.

HIW focuses its inspections on the experience and outcomes for people using services. When the outcomes for people are poor HIW will act. This might include issuing notices of non-compliance or the urgent imposition of conditions on the registration of a service. HIW’s response to non-compliance is informed by the following key principles:

* **Provider responsibility:** Providers of services are responsible for achieving and ensuring compliance with regulations. Unless urgent action is required, providers will be given opportunities to rectify failings.
* **Proportionality:** When action is taken by HIW, this will be proportionate to the outcomes for people receiving services, the risk to their health and wellbeing and the readiness of the provider to achieve compliance. Our priority is to focus on those areas where there is particular concern or risk.
* **Efficiency and effectiveness:** Action taken by HIW will be clear, consistent, timely, fair and transparent.
* **Progressive action:** Providers who persistently fail to comply with regulations will face escalated enforcement action, including action to cancel their registration.
* **Co-ordinated action:** HIW will work with commissioners and other regulators to ensure that any action is co-ordinated and information and concerns are shared. This is particularly so when there are safeguarding concerns or health and safety issues overseen by other regulators. We also work closely with the Nursing and Midwifery Council (NMC), General Medical Council (GMC), General Dental Council (GDC) and the Health and Safety Executive (HSE) sharing concerns about the professional conduct of staff and managers of services.

Our approach recognises the value of providing advice to providers and the importance of meeting providers when problems with compliance are not easily resolved. It also recognises that whilst most providers are able to comply with regulations, there are a small number who repeatedly fail to do this, do not deliver on commitments and who are unable to sustain the improvements required.

We will ensure that there are systems in place to provide accountability for the action we take and to regularly review the effectiveness of our activity.

**Note on terminology**

In this document, “provider” means the following persons in respect of the relevant service:

* In respect of a registered service,
* the individual(s) registered as the provider of that service, or
* in the case of an organisation registered as the provider of the service, the director(s) and/or person nominated as the responsible individual (‘RI’) for that service.
* In respect of services required by law to have a registered manager, references to “provider” include the manager registered or regulated in respect of that service unless from the context of this document it is clear there is a distinction to be drawn as between their two roles in terms of accountability.

**Flowchart 1: How we respond to non-compliance**



**Flowchart 2: How we handle services of concern**



**Technical or isolated failures**

HIW may identify two types of non-compliance with regulations: technical or isolated failures, and failures relating to poor outcomes or systemic failing.

Technical or isolated failures are those which have no immediate or significant impact on the general outcomes for the people using the service. These failures may, for example, be related to a record, a process or a document being incomplete, a low level concern about the environment or a one off minor shortfall in the provision of care. When brought to the attention of a conscientious provider they should be able to correct it immediately.

When identifying such shortfalls, the inspector will notify the provider of non-compliance in the expectation that they will be addressed. This may be included in the improvement plan attached to the draft report. If they are not remedied during the course of inspection, the inspector will record the notification of non-compliance in the inspection report.

It is expected that the provider will take responsibility for addressing the shortfall, doing what is best to achieve compliance.

Such non-compliance may be followed up at further inspections. If action has not been taken then this will be noted and if necessary the notification repeated. Failure to address such compliance issues is likely to result in a less favourable assessment in the inspection report. This is because a provider’s capability and willingness to respond to non-compliance will be given prominence in the report.

The inspector, in consultation with the Escalation and Enforcement team, may however decide that a repeated failure to address non-compliance merits issuing a notice of non-compliance.

**Poor outcomes and/or systemic failings**

This second type of non-compliance is more serious and relates to poor outcomes and systemic failing. This is where there are poor outcomes for people (adults or children) using the service, increased risk to patient safety and where failures lead to people’s rights being compromised. For example the right to be safe, to have control or be treated with respect. Examples of poor outcomes include people’s physical health suffering due to omissions in care and support, people being depressed and agitated because of a lack of opportunity, people having little choice or being treated disrespectfully and people experiencing serious disruption in their lives as a result of poor quality service from the provider.

Systemic failings are those where the underpinning systems (e.g. policies, procedures, staffing arrangements, and health/safety and maintenance systems) are flawed or are not operating efficiently, or at all. These failings are often related to weak, unsound management or underinvestment. They lead to repeated examples of people having poor care and or being at high risk of poor outcomes.

The normal response to this type of non-compliance will be to inform the provider and issue a non-compliance notice if immediate. Other non-compliance will be recorded in the improvement plan attached to the inspection report.

There will occasionally be circumstances in which the threshold for issuing non-compliance notices needs to change, for example in response to new regulations or emergent issues of national concern. HIW will develop additional guidance in response to such circumstances.

HIW may consider taking enforcement action should a registered manager not be appointed, or has been appointed and after being in post for three months or more has not taken the necessary steps to apply for registration. If an application has not been submitted within three months after the date HIW were notified, or became aware that, the registered manager had left or is absent, HIW may consider taking further action which may include a focused inspection.

**Matters requiring urgent action**

When HIW discovers very poor outcomes and/or a serious risk of harm to the health and wellbeing of people, whether from an inspection or other area of HIW (e.g. notifications, concerns, intelligence), urgent action may be required. In these circumstances inspectors or the relevant HIW teams will make contact with the relevant Head of Branch/Escalation and Enforcement team for advice and direction. An initial service of concern meeting will convene. If urgent action is required the service may be designated a ‘Service of Concern’ at this stage.

Whilst non-compliance may be evident, issuing an urgent non-compliance notice does not offer an immediate legal remedy to address all concerns. There may be situations where a non-compliance notice needs to be issued immediately (see page 10 for information on an immediate non-compliance notice).

This pathway may also take into account the following additional factors which apply when considering whether to convene a service of concern meeting:

* There has been a history of non-compliance and although the service has become compliant, there is doubt about the ability or commitment of the provider to sustain compliance.
* There is evidence to question the fitness of the provider.
* Other agencies such as GMC, GDC, NMC, the relevant Health Board etc have raised serious concerns about the performance of the service.

**Options for action may include (not exhaustive):**

* **Immediate imposition (variation or removal) of conditions or immediate suspension**

When faced with a situation that necessitates one of these options, HIW will advise the provider or (where the provider is not immediately contactable) the most senior member of staff available, that a statutory notice will be served. Even if the provider agrees to voluntarily comply, offering to comply by agreement, the notice should still be issued and any condition(s) affecting registration put in place. A non-urgent notice of proposal may be considered in this instance. Should a provider not comply with the condition(s) they are directly guilty of an offence and may be liable to prosecution. The notice explains the provider’s right to appeal to the First-Tier Tribunal (Health, Education and Social Care Chamber).

* **Application for urgent cancellation of registration**

Every effort will be made to talk to the provider beforehand and explore possible alternatives. Contingency planning for people using the service is vital and it is therefore important that there is discussion with commissioners for the people concerned. Should urgent action be deemed necessary, the non-compliance processes can be collapsed and a “service of concern” meeting held directly after or even during the inspection or when the information is made known (from concerns, notifications, intelligence etc). HIW will not accept an offer from a provider to voluntarily cancel their registration once a Notice of Proposal to cancel registration has been issued unless there are compelling reasons to do so.

**Immediate Non-compliance notice**

The issuing of an immediate non-compliance notice is a serious matter and is the first step in a process which may lead to civil or criminal proceedings. It indicates that there are significant concerns about people using the service. In reaching a decision as to whether a non-compliance notice is justified HIW may take account of the history of compliance of the service and previous judgements about quality.

Non-compliance notices are documents in their own right, independent of inspection reports. They can be issued in response to both routine inspections and arising from concerns being raised. They can be issued before an inspection report has been completed, and may also be issued without an inspection visit taking place.

The evidence recorded in a notice will be detailed and specific, illustrating why HIW has concluded that there has been non-compliance. However, notices will not contain data sensitive information. Any references to specific people or details of comments made, will be captured in the inspector’s inspection record.

For each area of identified non-compliance, the non-compliance notice will state:

* Action to be taken: i.e. what the provider must do in relation to the specific regulation (but without prescribing a specific solution)
* Timescale for completion: dd/mm/yy
* Regulation number: HIW will use their judgement to identify which regulations are the most appropriate to refer to.

It is quite possible for HIW to both “notify” a provider of some areas of non-compliance at the same time as issuing a notice of non-compliance in respect of other areas. However, where services have multiple areas of non-compliance, inspectors are strongly advised to concentrate on those core, critical areas which are having the greatest impact, or provide the highest risk to people using the service.

Following receipt of a non-compliance notice it may be possible for the provider to submit evidence that they have taken appropriate action and have achieved compliance within the timescale (e.g. records of training, audits of care plans or repairs to buildings for example).

HIW will need to be fully satisfied that compliance has been achieved. If there is any doubt, the Inspection team will issue a letter to the provider seeking further information. Once HIW is satisfied that a provider has achieved compliance a letter will be sent to confirm this. This may relate to only one element of a non-compliance notice and other elements may remain outstanding.

If the response to non-compliance is not accepted, the appropriate Head of Branch and Escalation and Enforcement team will be consulted. At this stage, this will not be to gather evidence as a criminal investigation and therefore the provisions of the Police and Criminal Evidence Act 1984 (PACE) and the relevant Codes of Practice will not apply.

It may be necessary to issue a non-compliance notice before the inspection report is ready, for example when the inspector identifies an area of non-compliance that requires immediate action. A non-compliance notice may also be issued by the HIW Inspection team, Investigation team, Clinical Team or Escalation and Enforcement Team where required. Consideration should be given to;

a) notifying the provider verbally and referring to this in an inspection report (if applicable), with the report and non-compliance notice issued at the earliest possible date, or

b) immediate imposition of conditions, for example where HIW believes there is an immediate risk to the health and well-being of service users.

There may also be situations where a non-compliance notice needs to be issued without an inspection taking place, for instance, when evidence indicates that a provider has not adhered to the legal requirement to notify HIW of a [reportable event.](https://www.hiw.org.uk/notify-us-event)

Additional non-compliance may be recorded in the improvement plan attached to a draft report.

**Provider meeting**

HIW can arrange a provider meeting at any time when a concern has been raised.

In the instance of a non-compliance notice being issued, HIW would anticipate that only a small proportion will remain non-compliant. Where a service remains non-compliant HIW will ask the provider to attend a provider meeting. The registered manager for the service will also be expected to attend along with the responsible individual.

HIW believes that registered providers should be able and competent to attend Provider Meetings without the need for external or legal support. However in exceptional circumstances, the provider may request the opportunity to bring a person to the meeting, subject to the agreement of the Chair.

The provider will be asked to explain the non-compliance, what action they have taken or are taking. The meeting may result in a number of outcomes; (list not exhaustive)

* Resolution of the non-compliance
* Agreement that HIW will not escalate enforcement action at this stage
* The provider produces a written agreement
* The service is identified as a service of concern (if not already designated)
* HIW set out actions it expects the provider to complete within a prescribed timescale

Provider meetings offer an opportunity for the provider to demonstrate their commitment and capability for achieving compliance. Responsible providers understand this and seek to work constructively with HIW and attend meetings when requested to do so. Where a provider declines to attend a Provider Meeting HIW will pursue the enforcement pathway. It is the provider’s responsibility to ensure they take action to achieve compliance.

Following the provider meeting, HIW will write to the provider summarising the discussion, identifying outstanding concerns and the action agreed by each party, along with agreed timescale for those actions. This letter will serve as a minute of the meeting. The provider will have the opportunity to advise of any factual inaccuracies or corrections they wish to be considered. These should be received within 10 working days.

HIW believe meetings with providers are an effective means of highlighting serious concerns and securing the necessary commitment to address areas of non-compliance. In exceptional circumstances it may be appropriate to arrange additional meetings to review progress or to respond to extenuating circumstances, e.g. ill health of the provider.

In the case of organisations, the responsible individual (RI) will ordinarily be expected to attend the provider meeting. There may be circumstances where other personnel with responsibility for the provision of the relevant service would be expected to attend the meeting, in addition to, or instead of, the RI. This might be, for instance, where the RI is not also a director of the company, or where the non-compliance issues under consideration are attributable to the conduct of the RI, in which case the director(s) may be asked to attend.

**Service of concern**

When designated a service of concern, HIW will add the setting to a list to be monitored and will be held to higher scrutiny. A service of concern meeting can take place at any time when concerns have been received. A service will not automatically be designated a service of concern during these meetings. The panel will discuss the necessity of the designation as part of the escalation process.

Each service designated a ‘Service of Concern’ will be monitored by the HIW Escalation and Enforcement team. The services will be subject to regular reviews dependant on risk. The fact that a service is regarded by HIW as a ‘Service of Concern’ will be recorded in inspection reports if non-compliance during inspection was discovered, and may be recorded on the HIW website or via other media sources. HIW may also notify interested parties.

When a Service of Concern does not achieve the required improvements, HIW will ensure that consideration will be given to varying the registration to add conditions or cancelling the service’s registration.

Where a service remains non-complaint for a period of more than 12 months, despite every effort by HIW to bring about compliance, active consideration may be given to cancelling the service’s registration.

**Decisions and considerations at a service of concern meeting:**

There are a number of possible outcomes of the meeting and a number of matters which require consideration. More than one approach to taking enforcement action may be agreed which may take place in parallel. In reaching decisions, the impact on people using the service should be taken into account, although short term inconvenience and distress should not prevent action which will result in improved outcomes in the longer term. This list is not exhaustive.

Possible outcomes of the meeting are described below;

* **Designating the service as a service of concern**

If there are outstanding concerns about poor outcomes and no prospect of early compliance then the service will be designated a service of concern. A service which has been designated may be recorded on the HIW website, and other parties with an interest in the service will be notified. The service will also be notified in writing of the designation.

* **Civil and/or criminal action at this stage**

At the meeting HIW will give active consideration to applying its regulatory powers if necessary. It will be noted if civil/criminal action is not being progressed if it was considered during the meeting. If civil and criminal actions are required, HIW will appoint separate individuals to lead each aspect.

* **Civil action**

HIW can undertake a number of actions in relation to its civil powers. These primarily relate to the registration of the persons responsible for carrying on and managing a service. In circumstances requiring urgent action, HIW may decide to use its urgent powers to impose, remove or vary conditions of registration, suspend a person’s registration, or seek urgent cancellation of their registration.

In non-urgent situations HIW may decide to issue a notice of proposal to vary, remove or impose conditions on a person’s registration, or suspend or cancel a person’s registration. In these circumstances the registered person has the right to make written representations to HIW.

* **Criminal investigation / proceedings**

HIW may decide that there is reasonable cause to believe that a criminal offence is being, or has been committed either under the relevant Act, or the relevant regulations. If the meeting agrees that it is proportionate to consider criminal proceedings, a decision will be made to undertake an investigation having regard to the provisions of the relevant Codes of Practice under the Police and Criminal Evidence Act 1984 (PACE). Welsh Government Legal Services will be involved in the investigation from the outset.

If this is decided, it will be important to have regard to the provisions of the relevant Codes of Practice under PACE in conducting any further inspections and meetings as a part of the evidence gathering exercise. Where a criminal investigation is being pursued as a result of an adult protection referral under the All Wales Adult Safeguarding procedures it may be necessary to plan that investigation with other interested parties (e.g. the police and social services) and consider the need for a written agreement.

Further service of concern meetings will be held to review the progress of the investigation when required.

A recommendation to proceed with prosecution is made to Welsh Government Legal Services who will make the final decision as to whether to issue proceedings in accordance with Welsh Government’s Prosecution Code.

The outcome may be to issue a simple caution or to proceed with prosecution. Alternatively the outcome may be not to pursue criminal proceedings and that consideration needs to be given to a different approach.

* **Options for services not registered with HIW**

NHS services are inspected by HIW but are not regulated or registered with HIW. The same civil or criminal enforcement options are not therefore available. More information on how HIW inspect NHS services can be found in the ‘Service of Concern process for NHS Bodies in Wales’ [document](https://www.hiw.org.uk/sites/default/files/2021-11/20211115NHSSoCProcessdocumentFinal-EN_0.pdf).

* **Other action**

Situations vary considerably and can sometimes be very complex. The meeting may determine that further enquires are required before any decision can be made.

There may also be other options beyond or in addition to criminal or civil proceedings. Examples of other action could include issuing a “serious warning letter”, seeking a written agreement from the provider, informing other regulators or professional bodies of the actions taken.

A “serious warning letter” will be a specific action designed to bring an issue to a close where it is considered disproportionate to take further progressive action. It could be used for an isolated serious failure in a service which is otherwise generally compliant.

**Continued Monitoring**

Service of concern meetings will take place regularly when HIW require assurance from a service. This may take place regardless of the service receiving the ‘Service of Concern’ designation. HIW may also liaise with other organisations which may have active oversight or relevant involvement with the service.

HIW will hold ongoing service of concern meetings to review progress. These meeting will take place every three months at a minimum, or more frequently if required. This will be decided on a case by case basis dependant on the non-compliance discovered and level of risk identified. Meeting discussions are recorded and saved. HIW will liaise with the provider to monitor improvements.

A service that has been designated a service of concern will be monitored at a higher level commensurate with the non-compliance findings. This may include regular reporting, requests for information, provider meetings and assessment of policies, although this list is not exhaustive.

The decision that a service is no longer a service of concern is made at a service of concern meeting. The provider and other interested parties will be informed of this in writing afterwards. The service may remain in an enhanced monitoring period following de-escalation to ensure non-compliance is not repeated.

Any service of concern will be reviewed on a regular basis, active consideration must be given to the appropriateness of the ongoing registration of the service if they remain a service of concern for a prolonged period.

Once a service has been removed from the service of concern designation, HIW will consider whether an inspection should take place. If agreed, the inspection should take place within an appropriate timescale from the date of removal. The inspection will be used to provide an assurance that remedial actions have been undertaken and maintained.

**Engagement with the Provider**

It is important that the provider remains actively and directly engaged with HIW. HIWs expectation is that there may be a meeting with the provider following service of concern meetings/reviews to explain the outcome and the implications.

Where there is high risk to people in the service or the service is “unstable” (e.g. financially vulnerable) a contingency plan may be put in place. This is particularly the case if it is likely HIW may be required to take urgent action. This enables HIW to be prepared and commissioners and providers to be forewarned and prepared.

**Communication**

Services of concern are often in the public eye and are often the cause for concern for commissioners. The service of concern meeting may need to consider:

* Whether HIW has a direct role in keeping people using services or their relatives/advocates informed of action being taken.
* Whether a ministerial briefing is required and who will do this.
* Whether the media need to be informed or a line to take prepared.

The meeting will also need to consider how it communicates with other interested parties.

It is important to note that when applicable, the local authority and NHS commissioners will be notified when services of concern are identified. Any inspection reports produced during this time will make specific reference to the fact that the service is viewed as being of concern.

**Link to registration**

HIW’s approach to non-compliance is closely linked with its registration processes. Complex failing services often have parallel problems of non-compliance and concerns about registration, such as failure to retain a registered manager or concerns about who is managing the business. In such cases, a service of concern meeting can capture both these aspects in order to ensure that any action is co-ordinated.

**Statutory notifications and concerns**

The HIW Investigation team capture and monitor notifications submitted to HIW as required under regulation 30 and 31 of The Independent Health Care (Wales) Regulations 2011, and regulation 25 of The Private Dentistry (Wales) Regulations 2017. The Investigation team also monitor concerns regarding services registered and inspected by HIW. When necessary, these will be shared with the Escalation and Enforcement team which may trigger an initial service of concern meeting.

**Action regarding unregistered services**

Where there is reasonable cause for concern that a service is illegally operating or managing a service without being registered in respect of it, a service of concern meeting will be convened by HIW.

The initial service of concern meeting is likely to focus on evidence gathering and planning the investigation. The meeting may or may not result in a decision to list the service as a service of concern at this stage depending on the perceived risk to people accessing the service. The meeting will also consider whether a service falls within the relevant definition to be registered, the need to inform the person concerned that they risk prosecution if they continue to operate/manage without being registered unless already completed, and the need to inform the person of their need to complete an application form and where to obtain one if not already completed.

Where HIW has reasonable cause to believe a service is acting in contravention of an enforcement notice the matter will be brought back to a service of concern meeting. The meeting will consider the action to be taken as described above. An investigation in respect of a person contravening the regulations or legislation will need to have regard to the provisions of the relevant Codes of Practice under PACE.