# RESPONDING TO NON COMPLIANCE

**Non compliance and enforcement process**

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

# Contents Page

[Introduction 1](#_bookmark0)

[Approach to Regulation 2](#_TOC_250000)

[Flowchart 1: How we respond to non-compliance 4](#_bookmark1)

[Flowchart 2: How we handle services of concern 5](#_bookmark2)

[Note 1 – Technical or isolated failures 6](#_bookmark4)

[Note 2 – Poor outcomes and/or systemic failings 6](#_bookmark5)

[Note 3 – Matters requiring urgent action 7](#_bookmark7)

[Note 4 – Non compliance notice 8](#_bookmark9)

[Note 5 – Provider meeting 12](#_bookmark12)

[Note 6 – Service of concern 13](#_bookmark13)

[Appendix 1 19](#_bookmark16)

[Low risk examples – notify in report 19](#_bookmark17)

[High risk examples – may need non compliance notice 19](#_bookmark18)

# Introduction

## Background

Healthcare Inspectorate Wales (HIW) acts as the regulator of healthcare 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.

HIW is responsible for ensuring that all registerable providers of Independent Healthcare 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 has the responsibility for the registration, review and inspection of independent health care services in Wales, which include Independent Hospitals, Independent Clinics and Independent Medical Agencies. In the interest of patients, HIW aims to help services improve and eliminate bad practice. Where service providers fail to meet their legal obligations consideration will be given to taking appropriate enforcement action. This includes:

* **Civil** regulatory action1
* **Criminal** prosecution2

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 adhere to when it looks to take enforcement action against any Independent Health Care Service in Wales. It does not supersede any relevant statutory requirements and in the event of any conflict between the two, the relevant statutory requirements will prevail.

## NB: HIW is unable to take enforcement action against NHS services. The NHS Wales Escalation and Intervention Arrangements document sets out how concerns regarding NHS services are dealt with.

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

2Criminal 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 in Wales, they are:

* the Independent Health Care (Wales) Regulations 2011 (“the 2011 Regulations”);
* the Private Dentistry (Wales) Regulations 2008 (“the Dentistry Regulations”);
* the Registration of Social Care and Independent Health Care (Wales) Regulations 2002 (“the Registration Regulations”);
* The National Minimum Standards for Independent Health Care in Wales (“the NMS”).
* The Independent Health Care (Fees) (Wales) Regulations 2011 (“the Fees Regulations”).

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

We recognise 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.

We focus our inspections on the experience and outcomes for people using services. When the outcomes for people are poor we will take action which might include issuing notices of non compliance or the urgent imposition of conditions on the registration of a service. Our response to non compliance is informed by the following key principles:

1. **Provider responsibility**: Providers of services are responsible for achieving compliance with regulations. Unless urgent action is required, providers will be given opportunities to rectify failings.
2. **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.
3. **Efficiency and effectiveness**: Action taken by HIW will be clear, consistent, timely, fair and transparent.
4. **Progressive action**: Providers who persistently fail to comply with regulations will face escalated enforcement action, including action to cancel their registration.
5. **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, General Medical

Council, General Dental Council and the Health and Safety Executive 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:

* 1. 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.
	2. In respect of services required by law to have a 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

Non-compliance remains outstanding but HIW opts for no further action at this point. Letter to provider\*. **Remains**

**“live” and is recorded at next inspection**.

Inspector/Regulation Officer **not fully** satisfied that compliance has been achieved, issues letter to provider\* and carries out further inspection visit.

Inspector **fully** satisfied compliance achieved, issues letter to provider\*. **Close**.

Inform the provider and issue Non-Compliance Notice\* as normal response. Refer to this in the Inspection Report (see [**Note 4**](#_bookmark10))

Follow up at future inspection, then **close or escalate.**

Matter requiring urgent action (see [**Note 3**](#_bookmark8))

Poor outcomes and/or systemic failing [(**Note 2**](#_bookmark6))

An area of non-compliance or potential non-compliance is identified

Notify provider and record in inspection report

Technical or isolated failure (see [**Note 1**](#_bookmark3))

Provider meeting ([**Note 5**](#_bookmark11))

Non-compliance remains outstanding and judged in need of further action. Inspector schedules provider meeting, issues letter to provider\*, commences chronology sheet.

**Letter to provider** summarising actions and timescale agreed. Hold additional meetings if required (in exceptional circumstances).

(as needed)

Convene service of concern meeting (**see Flowchart 2**)

Inspector **not fully** satisfied that compliance has been achieved. Schedule service of concern meeting.

Inspector **fully** satisfied compliance achieved. Issue letter to provider\* and close **on electronic record** .

**Note: the inspection report, non compliance notice and letter templates are generated via electronic record. Other templates are saved on iShare**

# Flowchart 2: How we handle services of concern

An urgent need for enforcement action has been identified (see [**Note 3**](#_bookmark8))

Service operating without being registered, or managed by someone who is not registered.

A service remains non- compliant after a provider meeting

Possible outcomes of service of concern meeting may include:

* Placing service on list of services of concern (recorded within Enforcement Record)
* Civil action including Enforcement Notice Criminal proceedings: investigation under Police and Criminal Evidence Act (PACE) potentially leading to Simple Caution, or prosecution.
* Serious Warning letter

A service of concern meeting is held with participation of Legal Services (where feasible), enforcement support staff and minute-taker (see [**Note 6**](#_bookmark14))

Products of service of concern meeting include, as necessary:

* HIW Action plan
* Monitoring plan
* Contingency plan
* Communication plan

These will be recorded on the Meeting to Determine a Service of Concern form.

Ongoing oversight: HIW will hold quarterly meetings to review all services of concern in addition to quarterly (at least) management meetings on each individual service of concern, recording relevant information on the Service of Concern Review form. The position for each such service to be reviewed every twelve months after it was identified as a service of concern. (see [**Note 7**](#_bookmark15))

\* Where a provider operates three or more ‘services of concern’, or there is a possible organisational and systemic failure, they will be regarded as a ‘provider of concern and the guidance on page 13 followed.

**Notes on flow charts**

## Note 1 – 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.

For examples see Appendix 1.

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. It is the sort of thing that when brought to the attention of a conscientious provider can be put right quickly.

When identifying such shortfalls, the inspector will notify the provider of non compliance in the expectation that they will be addressed. 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 will 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 Regulation Team, or the Regulation Team itself may however decide that a repeated failure to address non compliance merits issuing a formal notice of non compliance (see below).

## Note 2 – 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, 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 for example) are flawed or are not operating properly. 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.

In reaching a judgement as to whether there is non compliance, the Regulation Team will primarily consider those who are the most vulnerable and whose needs are greatest, even though they may be only a small minority of those being supported. This is because they are at the greatest risk and need the greatest safeguards.

The normal response to this type of non compliance will be to inform the provider and issue a **non compliance notice**. The fact a notice has been issued will be recorded within 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.

There may be times when there are changes to the position of registered manager, or a registered manager is absent. Please refer to ‘**Guidance for Dealing with Absent and Vacant Managers’** which explains the different circumstances where this may arise, sets out principles of HIWs approach and required action which could include increased monitoring.

HIW may consider taking enforcement action should a 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 should consider whether a focussed inspection should take place to assess the impact for people using the service.

## Note 3 – Matters requiring urgent action

Where inspectors find very poor outcomes and a serious risk to the health and wellbeing of people urgent action may be required. In these circumstances inspectors will where possible make immediate contact with the Regulation team for advice and direction if needed, and where appropriate convene a service of concern meeting.

Whilst non compliance may be evident, issuing urgent non compliance notices does not offer an immediate legal remedy to address the concerns. However there may be situations where a non compliance notice needs to be issued immediately (see Note 4 for information on immediate non compliance notice).

This pathway may also take into account the following additional factors that may apply when considering whether to convene a service of concern meeting and draw up an enforcement action plan:

1. 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.
2. There is evidence to question the fitness of the provider.
3. Other agencies such as GMC, GDC, NMC, the relevant Health Board or Health and Safety Executive have raised serious concerns about the performance of the service and have invoked protocols eg.. Escalating Concerns, a placement embargo.

Options for action include:

## 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, and offers to comply by agreement, the notice should be issued and any condition(s) affecting registration put in place. 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:

This is a more complex matter. 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.

In any event, 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.

As a general rule we 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. Where this is the case the agreement of the Head of Department is needed.

## Note 4 – Non compliance notice

The issuing of a 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 the wellbeing of 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 inspections 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 (e.g. where there is a repeated failure to undertake an annual self assessment).

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 contemporaneous record of the inspection.

References to areas of non compliance in the inspection report will indicate the findings of the inspector in more general terms, with less specific details.

For each area of identified non compliance, the non compliance notice will first 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:** The Regulation Team 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 on the wellbeing and risks 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).

However, HIW will need to be fully satisfied that compliance has been achieved. If there is **any** doubt the Regulation Team will issue a letter to the provider and undertake a further visit to check compliance has been achieved. In most circumstances, 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.

Once HIWis 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, following a non compliance notice and further visit, HIW is still not satisfied that compliance has been achieved in the required time frame, then further action will normally be taken as set out in Note 5 below. There may however be occasions when it is decided that further action would be inappropriate or counter-productive, in which case the original notice will remain “live” with the original date for compliance. HIW will not issue a further non compliance notice. The fact that a non compliance notice is outstanding will be recorded in the inspection report.

HIW has systems in place to monitor which services have been issued with non compliance notices, which are overdue and for how long these have been outstanding. This enables us to target services which fail to achieve timely compliance.

## Immediate non compliance notice

It may occasionally 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. However, it is anticipated that this would only be necessary in a minority of cases and consideration should be given instead to a) notifying the provider verbally and referring to this in the inspection report, with the report and non compliance notice issued at the earliest possible date, or b) immediate imposition of conditions (as described in Note 3 above), 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.

Examples of Non-Compliance Notices can be found on page 11.

### Example 1

*The service is not compliant with regulation 20(1)(a) of the Independent Health Care (Wales) Regulations 2011 regarding staffing–*

*This is because the number of staff on duty at night was not in sufficient numbers to ensure the health and welfare of the patients.*

### Evidence

*An inspection was carried out on [date] and the following documents were examined:*

* *staff rotas*
* *patient care plans*

*These documents indicated:*

* *There was not enough staff on duty to adequately supervise the number of patients*
* *The Hospital was at full capacity (24 patients) with a number of these patients on increased observations, this meant that there was an insufficient amount of staff present at the hospital to ensure the health and safety of patients resident at the hospital.*

*The impact on people using the service is that they are being placed at significant risk of not having their care needs met adequately.*

### Example 2

*The service is not compliant with regulation 6(1) & (3) – Statement of Purpose*

*There is an exclusion criteria within the Statement of Purpose which states that people with a Learning Disability should not be admitted, however a patient is currently being accommodated with that diagnosis.*

### Evidence

*An unannounced inspection was carried out on [date]. The following were examined:*

* *Patient care plans*
* *The most recent Statement of Purpose*
* *Admission checklists*

*These indicated:*

* *That a patient should not be accommodated if they have a diagnosis of Learning Disability.*
* *Within patient XX’s care plan is states that they have a diagnosis of Learning Disability*

*The impact on the patient is that they are not appropriately placed therefore are not necessarily going to receive the most appropriate care. There is also an impact on the other patients resident in the service.*

## Note 5 – Provider meeting

We anticipate that only a small proportion will remain non-compliant after a non compliance notice has been issued.

Where a service remains non-compliant HIW will commence a chronology sheet and ask the provider to attend a **provider meeting3**. Apart from urgent action under Note 3, this marks the beginning of our formal enforcement process. The registered manager for the service will also be expected to attend.

We believe 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 why they remain non compliant, what action they have taken or are taking. The meeting may result in a number of outcomes.

* Resolution of the non compliance
* Agreement that HIW will not escalate enforcement action at this stage
* The provider gives written agreement
* The service is identified as a potential **service of concern** (see below).

Provider meetings are very important. They are a significant 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 our enforcement pathway and make arrangements to convene a service of concern meeting to decide what action we will be taking in respect of the continued failings. The date for the Service of Concern meeting should be arranged after the date of any proposed Provider Meeting.

We will not amend the original timescale set for achieving compliance. It is the provider’s responsibility to ensure that action is taken and that compliance is achieved. The original timescale will have reflected the best interests of people using the service and allowed reasonable time for the provider to resolve non compliance.

Following the provider meeting, the Chair of the meeting 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

3 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.

opportunity to advise of any factual inaccuracies or corrections they wish to be considered. These should be received within 10 working days.

We 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.

## Note 6 – Service of concern

HIW maintains a record of **services of concern**. These are services which provide poor outcomes for people or place people at unacceptable risk and fail to address shortfalls and achieve compliance with regulations.

Each service of concern will be the subject of a HIW enforcement action plan and these plans will be kept under constant review. The fact that a service is regarded by HIW as a “service of concern” will be recorded in inspection reports.

When services of concern do not achieve the required improvements HIW will ensure that consideration will be given to 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 will be given to cancelling the service’s registration.

## Provider of Concern

Where a provider [possibly operating with different registration identities] is operating three or more services of concern across Wales, or there is evidence to suggest possible organisational or systemic failure e.g. financial viability, the Head of Division holding the primary level of concern should convene a ‘Provider of Concern’ meeting.

When a service remains non compliant following the provider meeting, or is otherwise deemed potentially to be a service of concern, a HIW internal **service of concern meeting** will be convened.

The provider will not be invited but will be informed that a meeting is taking place. The purpose of the meeting is to agree a HIW enforcement action plan in response to the non compliance.

Similarly, where enquiries have established reasonable cause to believe a person is not registered in respect of a service, and is therefore operating illegally, a service of concern meeting will be convened.

**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.

Possible outcomes of the meeting are described below.

## Placing or not placing the service on the service of concern list

If there are outstanding concerns about poor outcomes and no prospect of early compliance then the service will be placed on the service of concern list.

## No civil or criminal action at this stage

At the meeting HIW **must** give active consideration to applying its regulatory powers and have good reason not to. A decision not to take further regulatory action may be because the service has recently become compliant, decided to close or has been sold.

## 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 an 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 PACE. Legal Services should be involved in the investigation from the outset.

NB: 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 (eg the police and social services) and consider the need for a written agreement.

Further service of concern meetings can be held to review the progress of the investigation.

A recommendation to proceed with prosecution is made to Welsh Government Legal Services Department 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 registered with HIW. The same civil or criminal enforcement options are not therefore available.

Under sections 72, 73, 74 and 75 of the Health and Social Care (Community Health and Standards) Act 2003 HIW has the following powers:

* + to inspect, take copies of and remove from the premises any documents or records (including personal records)
	+ Inspect any other item and remove it from the premises;
	+ To interview in private any person working at the premises or any person receiving health care there who consents to be interviewed;
	+ To make any other examination into the state and management of the premises and treatment of persons receiving health care there;
	+ To be able to require any person holding or accountable for documents or records kept on the premises to produce them;
	+ In relation to records kept on computer, the power to require the records to be produced in a form in which they are legible and can be taken away.
	+ To check the operation of any computer and any associated apparatus or material which is or has been in use in connection with the records in question.

HIW also has the power to require any person4 to provide it with any information, documents, records (including personal records) or other items which relate to the provision of health care by or for a Welsh NHS body, to the discharge of any of the functions of a Welsh NHS body and which it considers necessary or expedient to have for the purposes of sections 72, 73, 74 and 75.

Within the Health and Social Care (Community Health and Standards) Act 2003 (Healthcare Inspections) (Wales) Regulations 2005 HIW also has the following powers:

* + Can require the persons named below to provide an explanation, in person or in writing, of any documents, records or items inspected, copied or provided under the Act:
		- A Welsh NHS Body;

4 The Welsh NHS body, any person providing health care for, or exercising functions of, the Welsh NHS body or a local authority in Wales.

* + - A Chairman, member, director, employee, member of a committee or sub-committee of a Welsh NHS Body;
		- A service provider;
		- A Chairman, Director or employee of a service provider;
		- A person, other than the ones named above, who is assisting a service provider in the provision of health care for a Welsh NHS Body;
		- A person, other than the ones named above, who is assisting, has assisted or is to assist a Welsh NHS body in the exercise of its functions.

HIW holds regular meetings with Welsh Government and the Wales Audit Office regarding escalating any concerns that it has found. If any urgent issues arise, a meeting can be called at short notice. Welsh Government are responsible for performance managing the NHS and would be responsible for any intervention (following advice from HIW and WAO).

## 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 (eg General Medical Council, General Dental Council, Nursing and Midwifery Council).

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.

## 7. Monitoring plan/Service of Concern reviews

The service of concern meeting will agree a monitoring plan, including the frequency and focus of further inspections and liaison with other agencies which may have active oversight of the service.

HIW will hold ongoing service of concern meetings on a quarterly basis to review progress. There will be at least quarterly management meetings for each service of concern.

The decision that a service is no longer a service of concern is made at one of these meetings. The provider and other interested parties will be informed of this in writing afterwards.

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 is they remain a service of concern for a long period.

Once a service has been removed from the service of concern monitoring plan HIW will consider whether an inspection should take place, if it is agreed then the inspection should take place within six months of 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. Our expectation is that there will normally be a meeting with the provider following service of concern meetings/reviews to explain the outcome and the implications. If a criminal investigation is underway then the provider (and registered manager) may need to be cautioned under PACE.

At this stage in the process (i.e. when services are identified as services of concern), we recognise that the provider may benefit from having independent support or advocacy at meetings. However we would wish to be advised in advance of who may be attending.

## Contingency plan

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 local authority and NHS commissioners will always 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 achieve a registered manager or concerns about who in effect is “running the business”).

In such cases service of concern meetings can capture both these aspects in order to ensure that any action is co-ordinated.

## Action regarding unregistered services

Where there is reasonable cause for concern that a person 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, and the need to inform the person of their need to complete an application form and where to obtain one.

Where HIW has reasonable cause to believe a person 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 an enforcement notice will need to have regard to the provisions of the relevant Codes of Practice under PACE.

## Providers operating a number of services of concern

There may be an instance where a provider who runs a number of services which cause concern. Such providers will often switch resources between services (e.g. managers, staff) to provide temporary improvements to one service to the detriment of another. As a result any improvement is not sustained. It is important to ensure action by HIW is co-ordinated and takes account of the wider business activity and that engagement with the provider addresses their operation of the whole business not just individual services.

.Where a provider [possibly operating with different registration identities] is operating three or more services of concern across HIW will convene a

‘Provider of Concern’ meeting.

The purpose of the meeting is to determine whether the enforcement action in relation to each setting is sufficient or whether there is a fundamental concern about the fitness and operation of the provider which merits formally co- ordinated action in addition to that being taken against individual services.

The fact that a provider is regarded by HIW as a “provider of concern” will be recorded in any related inspection reports.

# Appendix 1

## Low risk examples – notify in report

1. Care workers from a Mental Health/Learning Disability Hospital have all had training relating to safeguarding people and were able to explain how to report an allegation of abuse. The policy has been updated to include the new telephone number of social services, but this new version has not been circulated to all staff. Staff said this could have delayed their ability to make an immediate referral to the local safeguarding team. The manager has said that she will circulate the latest policy straight away. She will also implement a regular review process.
2. An inspector visiting an Acute Hospitals, with overnight beds, noticed that some of the floor tiles were damaged and presented a hazard. The staff took immediate remedial action to tape down the damaged tiles and make arrangements for a more permanent repair to be undertaken the following week.
3. On the day of visiting a Hospice for 8 people we find that there are two fewer staff on duty than on the rota. The manager says that there has been a stomach bug going around and that three staff had called in sick. They have found cover for one member but not the others yet. They have clear procedures for accessing agency staff and their staff record shows they are very rarely down in staff numbers. On the day in question, some of the activities had been rearranged so that all residents had adequate support.

## High risk examples – may need non compliance notice

1. The window in a resident’s room in a MH/LD Hospital does not shut properly and the radiator does not work. The resident tried to raise the issue with staff in the hospital telling them he is constantly cold. They told him to stop complaining and put another jumper on. After becoming ill and being admitted to hospital with a chest infection, his family raised the issue with staff, but they still did not acknowledge this as a complaint.
2. A patient is detained within a Low Secure MH/LD Hospital and is currently on 4 to 1 observations. The patient has carried out various assaults on fellow patients and members of staff, because of this they have been held in seclusion for the past 2 weeks. The Manager has expressed concerns that the needs of the patient cannot be met by the Hospital.
3. During an inspection to an Independent Clinic, an inspector has noticed that some re-usable tools have not been decontaminated and have been used by practitioners.