**UNIFIED CONTRACT ASSURANCE FRAMEWORK**
**Guidance for Health Boards and Practices**

## SECTION 1 – PURPOSE AND PRINCIPLES

### Purpose

This document sets out the Unified Contract Assurance Framework for use across NHS Wales and by general medical services (GMS) contractors to provide assurance of delivery of the GMS Unified Contract. The framework has been developed taking account of the context of the new Health and Care Quality Standards for Wales (2023).

### Unified Contract

The new Unified Contract for GMS has been negotiated over 18 months as part of a tripartite approach with Welsh Government, NHS Wales and the General Practitioners Committee (Wales) (GPCW). The NHS (General Medical Services Contracts) (Wales) Regulations 2023 (2023 Regulations) underpinning the Unified Contract came into effect on 1 October 2023.

The Unified Contract will simplify what services all GP practices in Wales must provide and how they evidence assurance of delivery. Key aims are:

- to make it easier for patients and healthcare professionals to understand responsibilities for the provision of services;
- to reduce administrative bureaucracy, freeing up time and resource for service delivery; and
- to enable use of data and technology to help plan resources and delivery of services.

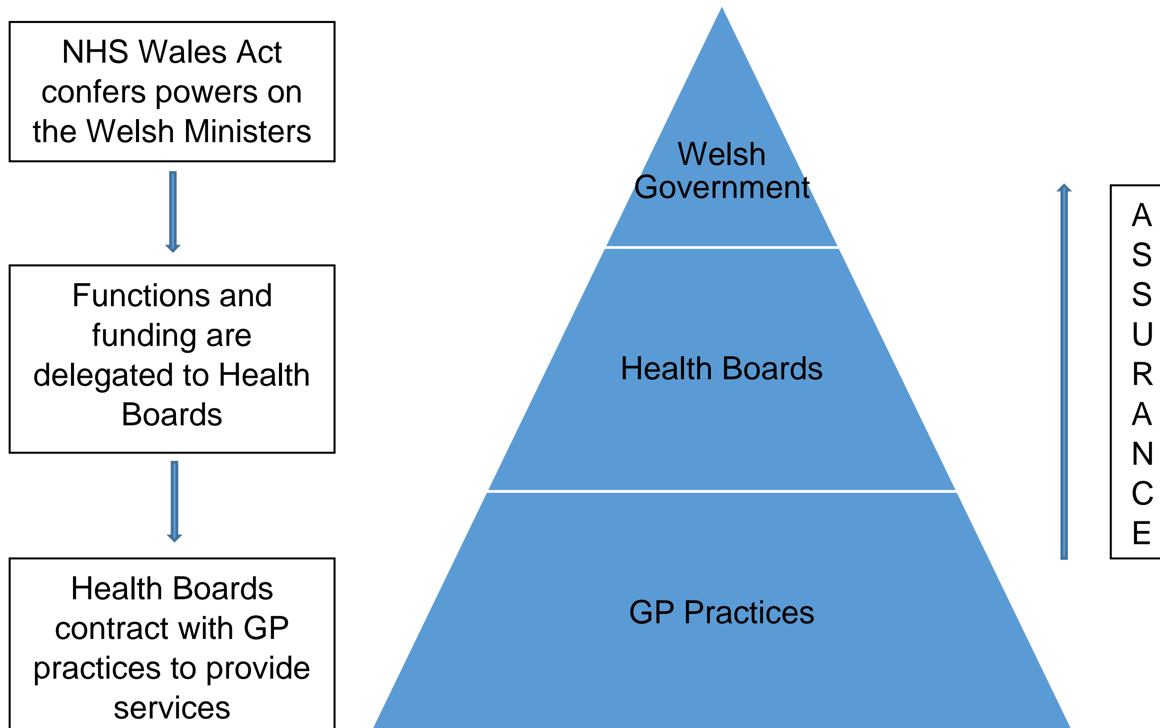
The Unified Contract consists of three parts: Unified Services, Quality Improvement and Supplementary Services.

Unified services form the majority of the contract as the key services all GP practices must provide. This includes all GMS ‘core services’ under the 2004 contract, as well as some services previously classed as additional or directed enhanced, where it has been determined that it is a service every GP practice can reasonably be expected to undertake. Elements of the Quality Assurance and Improvement Framework have also transferred into Unified Services.

Delivery of this contract will be assured through a strengthened, holistic and consistent assurance mechanism. A new **Assurance Framework** has been developed via a tripartite task and finish group. A key goal of the Assurance Framework is to reduce unnecessary bureaucracy via a system of checks that are robust and proportionate.

**Overview of Assurance Framework**

The need for an assurance process comes from the differing roles and responsibilities for the provision of general medical services to the citizens of Wales.




The GMS Assurance Framework is a governance process for the evaluation of assurance on services delivered through the Unified Contract, in the context of the Duty of Quality legislation, and has three components:

- A nationally agreed **data set for quality, safety, governance and contract management.** This comprises of a national set of indicators, a practice assurance return, CGPSAT and IG toolkit.
- A nationally agreed **process for assessing contractors' compliance** against contractual requirements.
- A nationally agreed **escalation ladder** for managing concerns, including an appeals procedure.

The key purpose of the nationally agreed data set is to standardise the information the Health Board Primary Care Management Teams consider through the Assurance Framework. This will give a fair and equitable basis for application of a consistent process in assessment of prioritisation of the level of review a contractor will receive across Wales**.**

## Principles of Assurance

Key principles were agreed with GP representatives in tripartite discussions to inform the development of the Assurance Framework. It was agreed that the Unified Contract assurance process should:

- be open and transparent in process;
- be proportionate and not bureaucratic in execution;
- make use of existing sources of data;
- include data analysed at a national level and provided to practices and Health Boards;
- use national standards and measures;
- be consistently applied across Wales;
- set out processes that are formative and supportive where possible; and
- provide a clearly articulated stepped approach to escalation if concerns exist.

## Health Care Quality Standards

The duty of quality, as part of the Health and Social Care (Quality and Engagement) (Wales) Act 2020, came into force on 1 April 2023. The new duty of quality requires the Welsh Ministers and NHS bodies to think and act differently by applying the concept of "quality" across all functions within the context of the health service and health needs of their populations. It requires quality-driven decision making and planning, to ultimately deliver better outcomes for all people who require health services.

The Health and Care Quality Standards (2023) provide a structure on which to implement the duty of quality. To support Health Boards in discharging their duties, the Assurance Framework indicators have been mapped to the 6 domains of quality and 6 quality enablers set out in the Quality Standards.

## 6 Domains

These quality dimensions (so-called STEEEP) provide a framework to assess quality and guide improvement:

1. Safe
2. Timely
3. Effective
4. Efficient
5. Equitable
6. Person-centred

## 6 Enablers

Quality enablers have been identified which underpin and influence a blueprint to ensure a system-wide approach to improving quality:

1. Leadership
2. Workforce
3. Culture
4. Information
5. Learning, improvement and research
6. Whole-systems perspective

**Review and Development process for the Assurance Framework**

The Assurance Framework is intended to be iterative, with the information available to Health Boards and practices being both expanded and refined as data develops. The Assurance Framework indicators and data sources will be reviewed and refreshed annually to ensure they are fit for purpose.

A newly-formed National GMS Quality Committee with tripartite membership drawn from Welsh Government, NHS Wales and GPC Wales will conduct the annual review and recommend that existing indicators or data sources are either maintained, modified, or removed, and whether new ones are introduced. The committee will report any recommendations into the GMS Contract Reform Group, and these will be used to inform GMS Contract negotiations.

To allow for appropriate digital development, the committee will deliberate and aim to make recommendations before the end of July each year, for indicators to be included at the start of the following financial year.

**Data Sources**

Future Data sources will be identified and agreed by the GMS Quality Committee. Previously presented data sources, which in principle are already available to Health Boards, include:

1. Audit+
2. Welsh Immunisations System
3. DATIX RL and other local processes for incident reporting to Health Boards
    a. Serious incidents
    b. Safeguarding
    c. Complaints/compliments
    d. Coroners reports
    e. Medical Examiner referrals
    f. Ombudsman referrals
4. Post Payment Verification reports
5. NHS Wales Shared Services Partnership Primary Contractor Services claims
6. Enhanced Service audits/reports
7. Clinical Governance Practitioner Self Assessment Toolkit
8. Information Governance Toolkit
9. Prescribing data
10. PHW vaccination data

11. Referrals/diagnostics rates
12. Admissions/ED/GP Out of Hours data
13. Welsh Index of Multiple Deprivation
14. European Standardised Populations

This list is not exhaustive and is expected to be modified as learning occurs.

Where possible, data should be standardised before analysis to remove the impact of factors that are outside of contractors' control.

**Managed Practices**

For the purposes of assurance of quality, safety and contract assurance, practices that are managed by Health Boards will be included in this framework in the same way as GMS practices. This includes all requirements for provision, analysis and publication of data on the Primary Care Information Portal, and the subsequent governance reviews, as for GMS practices. Health Boards will ensure adequate separation between management teams in the managed practice and teams leading the assurance processes.

**Indicators**

An indicator is a measure that has been agreed by the National GMS Quality Committee to be used by a Health Board to seek assurance that the contractor is delivering the services expected in GMS Unified Contract to an acceptable quality. A single indicator in itself does not prove failure to deliver the contract or that services are poor quality.

- Indicators will be weighted by national agreement.
- Indicators will be mapped against ONE of the 6 domains of quality or the 6 quality enablers in the Duty of Quality – Health and Care Quality Standards for Wales (2023).
- Data relating to each contractor for each indicator will be or can be made available.
- Data is ideally available at national level where analysis should occur.
- Sensitive data will be collected and analysed locally, but not published on PCIP.

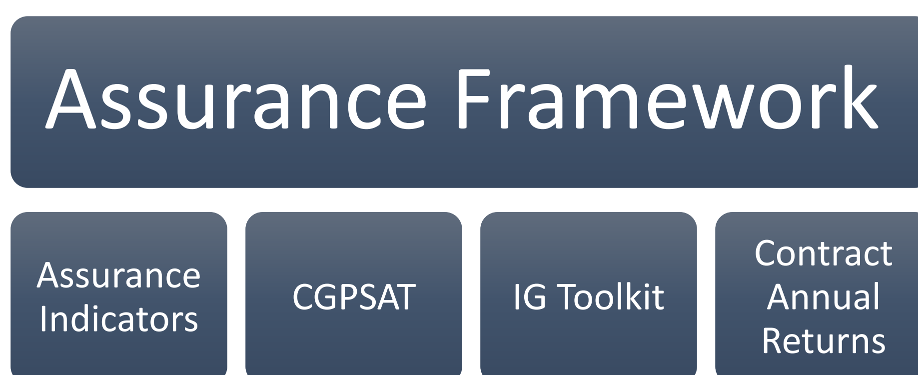
## SECTION 2 – ASSURANCE FRAMEWORK PROCESS

The aim of this section is to set out detail of how the Framework is applied across NHS Wales, based on the principles in section 1.

### Stage One – Nationally agreed data set for quality, safety, governance and contract management

The Health Board will make an assessment of practice assurance using a nationally agreed set of indicators (see Annex A) and information from a number of other sources which are contractual requirements for practices to complete:

GMS Assurance Information




a. Indicators covering the full spread of activity and domains of quality based around the GMS contract are agreed nationally – Annex A sets out the indicators that will be used at April 2024. Weightings will be agreed by the National GMS Quality Committee.
b. Data analysed and benchmarked at a national level and provided to Health Boards – data will be presented on the Primary Care Information Portal (PCIP), where possible and appropriate ("sensitive data" will not be displayed).
c. Clinical data from the former QAIF – this will be available in the primary care portal, development of a rolling view available throughout the year will be explored, as well as a year-end view.
d. CGPSAT and IG Toolkit to be completed by 31 March 2024.
e. Annual Contract Assurance Return – this will consist of two parts, with a national template on the primary care portal and a second part for local priorities (this will supplement the national template and not duplicate information available or asked for elsewhere). The Health Board must agree local information requirements in the second part with the Local Medical Committee.

### Stage two – Prioritisation by Health Boards

a. Data will as far as possible be made available via PCIP.
b. "Sensitive data" as defined in Annex A will be in the possession of Health Boards and will not be placed on PCIP.

c. Health Boards will determine the level of assurance they can conclude using the data for the weighted indicators in Annex A. Health Boards will then prioritise practice assessments and the depth required, taking into account the degree of assurance obtained.
d. Data is shared with practices, including a high-level summary of any “sensitive data”.

**Stage three – nationally agreed process for assessing compliance against contractual requirements**

a. Health Boards may visit practices that are prioritised for further assessment on up to three occasions with visits planned to take place throughout the year. Visits may focus on specific themes.
b. Standard letter templates will be created for the purpose of notifying practices of selection for a practice visit and the themes to be covered.
c. Standard practice visit agenda will be devised.
d. A national training schedule will be devised for Health Board Primary Care Management Teams to ensure consistency of approach to practice visits.
e. A national training schedule will also be devised for practice managers, to explain what can be expected to happen during a practice visit, practice visit reports and the development of practice governance framework response plans.
f. Practices will be expected to demonstrate any action plans for addressing any concerns raised, including good practice examples.

**Stage four – Output of Visit (Contract and Governance Visit Report)**

a. Verbal feedback of any immediate concerns or “No Assurance” to be given to the contractor on the day and to be followed up in writing by the Health Board within 5 working days.
b. Written feedback **(Contract and Governance Visit Report**) from the Health Board to be shared with the contractor within 20 working days of visit. A template will be developed and made available to Health Boards, the feedback will be based on the following assurance levels:

    **Substantial Assurance**
    Few matters require attention and are compliance or advisory in nature. Low impact on residual risk exposure.

    **Reasonable Assurance**
    Some matters require management attention in control design or compliance.
    **Low to moderate impact** on residual risk exposure until resolved.

    **Limited Assurance**
    More significant matters require management attention.
    **Moderate impact** on residual risk exposure until resolved.

    **No Assurance**
    Action is required to address the whole control framework in this area.
    **High impact** on residual risk exposure until resolved.

**Assurance not applicable**
Given to reviews and support provided to management which form part of the internal audit plan, to which the assurance definitions are not appropriate. These reviews are still relevant to the evidence base upon which the overall opinion is formed.

c. A written action plan (**Practice Contract and Governance Framework Response Plan - PCGFRP)** is required from the contractor to be agreed by the Health Board and monitored for compliance. A template will be developed and made available to practices.
d. Date of next review to be agreed.

**Stage five – nationally agreed escalation ladder for managing concerns including an appeals procedure**

The Escalation Ladder stages and process are set out in Annex B and are intended for use in scenarios where a breach or remedial notice may ultimately be issued by the Health Board. The Escalation Ladder does not apply in more serious scenarios where the Health Board may need to take other action under the contractor's contract.

Use of the Escalation Ladder:

a. If a contractor receives a Governance Visit Report with **substantial** or **reasonable** assurance, the escalation ladder is **NOT** invoked.
b. If a contractor receives a Governance Visit Report with **limited** or **no assurance AND** the Practice Contract and Governance Framework Response Plan (PCGFRP) is either not accepted or monitoring shows non-compliance, the escalation ladder is invoked.
c. Failure to engage fully with the process or complete the PCGFRP within agreed timescales with result in progress up the escalation ladder.

## SECTION 3 - ASSURANCE FRAMEWORK TIMELINE FOR HEALTH BOARDS AND PRACTICES

| Date | Assurance Framework development/implementation | Key points for Health Boards and practices |
|---|---|---|
| 1st October 2023 | | Regulations underpinning the Unified Contract come into effect |
| October 2023 – February 2024 | Implementation period – HB training, training and information to practices, digital platform finalised, Contract Annual Return agreed. | |
| 21st October 2023 | | Q2 reporting for access standards deadline for submission via PCIP tile |
| 31st December 2023 | | End of Q3 |
| 21st January 2024 | | Q3 reporting for access standards deadline for submission via PCIP tile |
| 31st March 2024 | | End of Q4 and financial year |
| 30th April 2024 | | Deadline for year-end data submission via PCIP on access standards and annual return. Collection of data on former QAIF indicators, CGPSAT and IG Toolkit. |
| May/June 2024 | | HB teams lead desktop reviews and prioritise assessments. |
| 30th June 2024 | | End of Q1 |
| 21st July 2024 | | Q1 reporting for access standards deadline for submission via PCIP tile |
| July 2024 onwards | | Practice visits by Health Boards commence |
| July 2024 | Review point: GMS Quality Committee meets to consider any changes/development recommendations for year 2. | |

## Annex A: National Indicators for April 2024

Note to users:

Triggers in themselves are not absolute indicators of poor care or deficiencies but are used to highlight potential reasons why a targeted visit is indicated. Where triggers and practice processes have been previously assured this should be taken into account when assessing triggers for targeted visits.

| **GMS Assurance Framework**<br>Version 1 22/06/2023 | | **Evidence for assurance of…** | |
|---|---|---|---|
| **Domain of Quality and Indicator** | **What triggers further scrutiny?** | **Quality & Safety?** | **Contract?** |
| 1. Safe | | | |
| **1.1 CGPSAT** | Response not submitted to any single question, a section or whole toolkit; or a deterioration in score. [YES/NO] | Yes | Yes |
| **1.2 Compliance with national patient safety alerts that apply to Primary Care** | Failure to provide reassurance to Health Board Primary Care Management team that mandated actions in Drug and Safety Alerts from CMO have been undertaken. [YES/NO] | Yes | No |
| **1.3 Prescribing Safety Module (Audit Plus and PCIP)** | Being in the top 10% of all practices in Wales for an AWMSG measure (higher is worse). [OUTLIER] | Yes | No |
| **1.4 Significant Local Safety Concerns** | Health Board awareness of significant adverse reports or findings from a statutory body, or a HB serious incident investigation, within the last 12 months [YES/NO]<br>e.g.<br>• Coroners Court<br>• Ombudsman<br>• HIW<br>• HB national reportable incident | Yes | Yes |
| **2.** Timely | | | |
| **2.1 Contract Access Standards – PHASE 1** | Phase 1 Evidence not submitted. [YES/NO] (Self-declaration) | Yes | Yes |
| **2.2 Contract Access Standards – PHASE 2** | Phase 2 Evidence not submitted. [YES/NO] (Quarterly data not submitted on PCIP with 2 weeks grace) | Yes | Yes |
| **2.3 Timely Monitoring of High Risk Medication (Audit Plus and PCIP)** | Being in the top 10% of all practices in Wales for a time-bound AWMSG measure (higher is worse) [OUTLIER]<br>e.g. Lithium, Warfarin, Amiodarone, Azathioprine and Methotrexate | Yes | Yes (if Shared care/ supplementary service) |

| 3. Effective | | | |
|---|---|---|---|
| **3.1 Clinical Data extracted using Audit+ and published on PCIP – 'Atrial Fibrillation/'Stop a Stroke'** | Practice percentage for *"NO Rx but Risk >=2"*, is in top 10% of all practices in Wales (high is worse). [OUTLIER] | Yes | Yes (DSS) |
| **3.2 Clinical Data extracted using Audit+ and published on PCIP - National Diabetes Audit (Practice Support Module) Processes** | Practice percentage for *"PRO1 – 8 measures recorded"* is in bottom 10% of all practices in Wales (low is worse). [OUTLIER] | Yes | Yes |
| **3.3 Clinical Data extracted using Audit+ and published on PCIP - National Diabetes Audit (Practice Support Module) Outcomes** | Practice percentage for *"TT07-All Treatment Targets met" is in bottom* 10% of all practices in Wales (low is worse). [OUTLIER] | Yes | Yes |
| **3.4 Prescribing Data from National Prescribing Indicators – Opioid Burden** | Practice Percentage for "*Opioid Burden User Defined Group Average Daily Quantity*" is in top 10% of all practices in Wales (high is worse). [OUTLIER] | Yes | No |
| **3.5 Prescribing Data from National Prescribing Indicators** | Practice Percentage for *"Gabapentin and Pregabalin DDDs per 1000 patients"* is in top 10% of all practices in Wales (high is worse). [OUTLIER] | Yes | No |
| **3.6 Prescribing Data from National Prescribing Indicators – Antimicrobial Stewardship (Total Antibacterial Items)** | Practice Percentage for *"Antibacterial items per 1,000 STAR-PUs"* is in top 10% of all practices in Wales (high is worse). [OUTLIER] | Yes | No |
| **3.7 Prescribing Data from National Prescribing Indicators – Antimicrobial Stewardship (4Cs)** | Practice Percentage for *"4C Antibacterial Items per 1,000 patients*" is in top 10% of all practices in Wales (high is worse). [OUTLIER] | Yes | No |
| 4. Efficient | | | |
| **4.1 Adverse PPV reports** | Significant Reclaims – defined as PPV team issuing a report where all claims for a specific service had to be reviewed and errors in claims were identified resulting in reclaim. [YES/NO] | Yes | Yes |
| **4.2 Prescribing Data from National Prescribing Indicators – Low Value for Prescribing** | Practice Percentage for *"Low Value for prescribing UDG spend for 1000 patients"* is in top 10% of all practices in Wales (high is worse). [OUTLIER] | Yes | Yes |

| 5. Equitable | | | |
|---|---|---|---|
| **5.1 Disease Prevalence Rates – e.g.**<br>• **Asthma**<br>• **Atrial Fibrillation**<br>• **COPD**<br>• **Type 2 Diabetes**<br>• **Heart Failure**<br>• **Coronary Heart Disease (Secondary Prevention)**<br>• **Stroke**<br>• **Hypertension**<br>• **Dementia**<br>• **Obesity**<br>• **Epilepsy**<br>• **LD**<br>• **Severe Mental Health**<br>• **Rheumatoid Arthritis**<br>• **Palliative Care** | Practice Percentage for specific long-term conditions is in bottom 10% of all practices in Wales (low is worse) after standardisation of practice population. [OUTLIER] | Yes | No |
| **5.2 Cervical Screening Rates (5-year coverage)** | Practice Percentage for Cervical Screening Rates (5-year coverage) is in bottom 10% of all practices in Wales (low is worse) after standardisation of practice population [OUTLIER] | Yes | Yes |
| **5.3 Childhood Immunisation - Uptake of scheduled childhood vaccinations at age 4** | Practice Percentage for Children who are up to date with immunisations by age 4 years – Diphtheria, Tetanus, Pertussis, & Polio – is in bottom 10% of all practices in Wales (low is worse) after standardisation of practice population. [OUTLIER] | Yes | Yes |
| **5.4 Childhood Immunisation - Uptake of the 6 in 1 vaccination for babies at one year** | Practice Percentage for Babies who are up to date with immunisations by one year – Diphtheria, Tetanus, Pertussis, Polio, Hib disease (Haemophilus influenza type b) and Hepatitis B is in bottom 10% of all practices in Wales (low is worse) after standardisation of practice population. [OUTLIER] | Yes | Yes |
| **6. Person-centred** | | | |
| **6.1 Not providing a service considered to be in the unified contract**<br>e.g. 6-8 week check, child surveillance, former additional services, pre-employment checks, opening hours | Practice admits it does not provide a service otherwise accepted as being in the Unified Contract. Allegations must have already been investigated and found proven. Non-compliance with Unified Contract. [YES/NO] | Yes | Yes |
| **6.2 Significant Complaints about quality of care** | Within the last 12 months, Health Board intervention was required regarding a significant complaint. Any investigation has been completed. [YES/NO] | Yes | Yes |

| | | | |
|---|---|---|---|
| **Enablers** | | | |
| **7. Leadership** | | | |
| **7.1 Attendance at collaborative meetings** | Practice fails to attend GMS collaborative meeting(s) without HB agreement [YES/NO] A single unauthorised absence is a trigger. | No | Yes |
| **7.2 Absence of key roles in an effective governance system** | Practices fails to provide names of individuals in key leadership roles e.g. Clinical Governance lead, Caldicott Guardian. [YES/NO] | Yes | Yes |
| **8. Workforce** | | | |
| **8.1 WNWRS** | Practice fails to complete WNWRS returns [YES/NO] | No | Yes |
| **9. Culture** | | | |
| **9.1 Declaration on applying directed contractual pay increases to all staff** | Practice fails to return declaration that it has applied directed contractual pay increases to all staff or declares that it has not applied the increase [YES/NO] | No | Yes |
| **10. Information** | | | |
| **10.1 Information Governance Toolkit** | Response not submitted to any single question, section or whole platform. [YES/NO] | Yes | Yes |
| **11. Learning, improvement and research** | | | |
| **11.1 Contractual QI projects** | Practice fails to undertake or complete a contractually required QI project [YES/NO] | Yes | Yes |
| **12. Whole-systems perspective** | | | |
| **12.1 GMS Escalation tools** | Practice fails to update the PCIP GMS Escalation tool within contractually specified timeframes [YES/NO] | No | Yes |

**Annex B: Escalation Ladder**

1. ***Practice Contract and Governance Framework Response Plan (PCGFRP)***

   a. **If the actions in the contractor's PCGFRP are completed fully and accepted by the Health Board, with no further issues, then escalation stops**.
   b. If no plan agreed proceed to next level.
   c. If plan not completed, proceed to next level.
   d. If the action not completed, then the Health Board may move straight to level 4 to issue a breach / remedial notice, whilst also progressing to level 2 (sustainability framework).

2. ***Sustainability Framework***

   a. Completion of application required, with or without sharing of accounts, for Health Board to have holistic and supportive review of contractor's situation, including population demographics, premises and workforce issues.
   b. LMC and Llais (all-Wales citizen body for health and social care, replacing former community health councils) involvement in process.
   c. Supportive discussions between contractor and Health Board.
   d. Action plan agreed between Health Board and contractor.
   e. If no accounts shared, then financial support cannot be considered for a contractor and may limit consideration of any other support.
   f. If no plan agreed proceed to next level.

3. ***Unified and Supplementary Service Review***

   If the Health Board is unable to seek assurance at earlier levels of the ladder, it may seek to use NWSSP to review compliance with the Unified Contract, and consider contractual remedies and implications for continuation of any supplementary services:

   a. PPV in depth review of all supplementary services.
   b. PPV review of unified services.
   c. Health Board to review PPV findings and consider:
      i. Whether a breach or remedial notice is to be issued;
      ii. Whether, in the event that a breach or remedial notice is served, payments should be withheld or deducted in respect of obligations which are the subject of the default; and
      iii. Whether to terminate any or all supplementary service contracts, to allow contractor to focus on delivery of unified services.

4. ***Remedial/Breach Notice issued***

   In the case of a remedial notice**, corrective action must be taken by the contractor within 28 days** (unless a shorter period is necessary to protect the safety of the contractor's patients or protect the Health Board from material financial loss) and, where relevant, withholding / deduction of sums otherwise payable in respect of obligations which are the subject of the default.

The contractor should be aware that if it fails to take the corrective action following a remedial notice or, following a breach or remedial notice, the contractor repeats the same breach or otherwise breaches the contract resulting in a further breach or remedial notice, the Health Board may need to take more serious action under the contract.

**Note:** The Escalation Ladder is intended for use in scenarios where a breach or remedial notice may ultimately be issued by the Health Board. The Escalation Ladder does not apply in more serious scenarios where the Health Board may need to take other action under the contractor's contract.