Llywodraeth Cymru
Welsh Government

GUIDANCE

Health service procurement: draft statutory guidance

How the draft Health Services (Provider Selection Regime) (Wales) Regulations 2024 applies to the arrangement of health services under the provider selection regime.

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Executive summary

The Health Services (Provider Selection Regime) (Wales) Regulations 2024

The Health Services (Provider Selection Regime) (Wales) Regulations 2024 are subject to Senedd agreement.

We have published the draft guidance to assist public bodies to prepare for the proposed Provider Selection Regime. The guidance is subject to the regulations becoming law in due course.

We will review and update the guidance once the Senedd approves the regulations.

The **Health Service Procurement (Wales) Act 2024** (“the 2024 act”) provides the ability to introduce a new health service procurement regime in Wales.

The new Provider Selection Regime Wales, which is set out in the Health Services (Provider Selection Regime) (Wales) Regulations 2024 (the “regulations”), replaces the existing procurement regime when procuring independent health services delivered on behalf of the NHS in Wales.

The regulations remove the procurement of certain health services, when procured by relevant authorities, from the scope of the **Procurement Act 2023** (“the 2023 act”). The 2023 act sets the expectation that competitive tendering is used to award contracts.

The regulations have been designed to give the relevant authorities to which it applies more flexibility in selecting providers for health services. Under the regulations, competitive tendering is one tool for relevant authorities to use when

it is of benefit, alongside other routes that may be more proportionate, and which better enable the development of stable partnerships and the delivery of collaborative care. The regime still requires relevant authorities to consider value for money as an important criterion, and to be transparent, fair, and proportionate in their procurement process.

The regulations have been made under section 10A of the **National Health Service (Wales) Act 2006** (“the 2006 act") and section 120A(1) of the 2023 act. This statutory guidance sits alongside the regulations to support organisations to understand and interpret the operational principles.

Why introduce the regulations for the procurement of health services?

In keeping with the intent of the 2024 act, the regulations have been designed to introduce:

- a flexible and proportionate process for selecting providers of health services (so that all decisions can be made with a view to securing the needs of the people who use the services, improving the quality of the services, and improving the efficiency in the provision of the services)
- the capability for greater collaboration across the system, while ensuring that all decisions about how health services are arranged are made transparently
- opportunities to reduce bureaucracy and cost associated with the current regime

The Welsh Government has iteratively co-created the regulations with the NHS in Wales, drawing on the expertise of commissioning and procurement professionals within the NHS and local authorities in Wales. In addition, the Welsh Government has consulted widely on the policy, commanding strong support (from those who responded to the consultation) across Welsh NHS bodies and local government.

How do the regulations work?

This statutory guidance sets out how the regulations should be adopted by the relevant authorities to which it applies. The following relevant authorities must have regard to this guidance when procuring health services on behalf of the NHS in Wales:

- county councils (CC) or county borough councils (CBC)
- local health boards (LHB)
- National Health Service trusts (NHS trusts)
- special health authorities (SHA)

The regulations apply to the arrangement of health services and public health services by relevant authorities. The regulations do not apply to the procurement of goods and non-health services (such as medicines, medical equipment, cleaning, catering, business consultancy services and social care), unless arranged as part of a **mixed procurement**. What constitutes mixed procurement is set out in the regulations and is explained further in this guidance.

Relevant authorities can follow **3 different procurement processes** to award contracts for health services under the regulations:

- direct award processes (direct award process 1 and direct award process 2)
- most suitable provider process
- competitive process

The direct award processes

These involve awarding contracts to providers when there is limited or no reason to seek to change from the existing provider, or to assess providers against one another, because:

- the existing provider is the only provider that can deliver the health services

(direct award process 1)
- the existing provider is satisfying its existing contract, will likely satisfy the new contract to a sufficient standard, and the proposed contracting arrangements are not a considerable change (direct award process 2)

There are 2 potential direct award processes (1 and 2). Further detail is outlined below.

Direct award process 1 must be used when all of the following apply:

- there is an existing provider of the health services to which the proposed contracting arrangements relate
- the relevant authority is satisfied that the health services to which the proposed contracting arrangements relate can only be provided by the existing provider (or group of providers) due to the nature of the health services

Direct award process 1 must not be used to conclude a framework agreement.

Direct award process 2 may be used when all the following apply:

- the relevant authority is not required to follow direct award process 1
- the term of an existing contract is due to expire, and the relevant authority proposes a new contract to replace the existing contract at the end of its term
- the proposed contracting arrangements are not **a considerable change**
- the relevant authority is of the view that the existing provider (or group of providers) is satisfying the existing contract and will likely satisfy the proposed contract to a sufficient standard

Direct award process 2 must not be used to conclude a framework agreement.

The most suitable provider process

This involves awarding a contract to providers without running a competitive

process, because the relevant authority can identify the most suitable provider.

This procurement process may be used when all the following apply:

- the relevant authority is not required to follow direct award process 1
- the relevant authority cannot or does not wish to follow direct award process 2
- the relevant authority is of the view, considering likely providers and all relevant information available to the relevant authority at the time, that it is likely to be able to identify the most suitable provider (without running a competitive process)

The most suitable provider process must not be used to conclude a framework agreement.

The competitive process

This involves running a competitive process to award a contract. This procurement process must be used when all the following apply:

- the relevant authority is not required to follow direct award process 1
- the relevant authority cannot or does not wish to follow direct award process 2 and cannot or does not wish to follow the most suitable provider process

The competitive process must be used if the relevant authority wishes to conclude a framework agreement.

Key criteria

Relevant authorities must consider **5 key criteria** when applying direct award process 2, the most suitable provider process, or the competitive process. These are:

- quality

- value
- collaboration and service sustainability
- improving access and reducing health inequalities
- social responsibility

How do the regulations support fair and transparent procurement processes?

The flexibility in procurement processes given to relevant authorities under the regulations is underpinned by strong transparency requirements. These requirements, which enable proper scrutiny of, and ensure accountability for, decisions, include:

- in all circumstances, relevant authorities are required to keep records of their decisions and publish notices confirming the outcome of their procurement process
- when following the most suitable provider process or the competitive process, relevant authorities must make their intentions to use these processes clear in advance
- when following direct award process 2, the most suitable provider process, or the competitive process, the relevant authority must:
  - maintain a record of decisions on the relative importance of each of the key criteria, and how the assessment of providers against the key criteria was made
  - observe a standstill period during which representations can be made and respond to any representations received before confirming their decision and awarding a contract to the selected provider
- when following direct award process 2, the most suitable provider process, or the competitive process, procurement decisions may be reviewed during the standstill period – including by the procurement feedback service

How do organisations use the regulations?

This statutory guidance provides detail on how organisations are expected to adopt the regulations to make arrangements for the delivery of health services, so that they comply with the regulations. In addition, the Welsh Government has developed implementation products that organisations may use to help them apply the regime.

The regulations place an emphasis on relevant authorities behaving in a transparent, fair, and proportionate way when making their arrangements with providers (across the independent and voluntary sectors). Adopting these behaviours will enable the successful application of the regulations, and in turn deliver the intent of the 2024 act to improve patient outcomes by removing unnecessary bureaucracy from the process of working with independent health providers and encouraging collaboration.

Section 1: introduction

Introduction

The Health Service Procurement (Wales) Act 2024 (“the 2024 act”) amended the Procurement Act 2023 (“the 2023 act”) and the National Health Service (Wales) Act 2006 (“the 2006 act”) to put in place legislative changes to enable the Welsh ministers to disapply provisions of the 2023 act in relation to services provided as part of the health service in Wales. The power inserted by the 2024 act into the 2006 act enables alternative provision to be made in that respect which has a whole system approach that is equitable with health services delivering the same high-quality care, and achievement of more equal health outcomes for everyone in Wales.

As part of these legislative changes, section 116A of the 2023 act provides a power to disapply the procurement regime in relation to NHS procurement in

Wales. Section 10A of the 2006 act enables the Welsh ministers to make specific (alternative) provision about the procurement of services provided as part of the health service in Wales.

The Health Services (Provider Selection Regime) (Wales) Regulations 2024 ("the regulations") made under section 10A of the 2006 act introduces a new regime for arranging the procurement of those health services for relevant authorities – the provider selection regime ("the regime").

Due to a focus on competition, the 2023 act is considered to create barriers on collaboration and result in complex procurement processes. Therefore, the regulations will remove the procurement of relevant health services from the scope of the 2023 act.

The Welsh Government has co-developed the regime iteratively by drawing on the expertise of commissioning and procurement professionals working within relevant authorities. The Welsh Government also **consulted on the operational principles** of the regulations as part of a public consultation in November 2023 and received 34 responses from a range of stakeholders. The responses to the consultation exercise helped inform the development of our policy, the regulations and statutory guidance. Respondents welcomed the clarity that the new regime would provide for commissioners and providers: moving away from competition, having a greater focus on collaboration, and removing bureaucracy, as well as bringing increased flexibility, proportionality and consistency whilst providing clarity of processes and facilitating transparency of procurement processes.

Under the regime, relevant authorities are expected to:

- act in the interest of patients and individuals who use the services, improving the quality of the services, and improving the efficiency in the provision of the services
- ensure decisions about which organisations provide health services are robust and defensible, with conflicts of interest appropriately managed
- adopt a transparent, fair, and proportionate process when following the

regulations

The regime makes it possible to continue with existing arrangements for service provision where those arrangements are working well and there is no value for people who use the service in seeking an alternative provider. Where there is a need to consider changing arrangements for service provision, it provides a fair, transparent, and proportionate process for procurement processes, which includes the option of using competitive tendering.

This guidance is published under section 10A(6) of the 2006 act, which requires the Welsh Ministers to publish guidance about compliance with the regulations.

This guidance sets out how the regulations must be followed by the relevant authorities to which it applies:

- a county council (CC)
- a county borough council (CBC)
- a local health board (LHB)
- a National Health Service trust (NHS trust)
- a special health authority (SHA)

It also details the scope of the regulations and how relevant authorities must apply it while considering key criteria and transparency requirements. The guidance also outlines how relevant authorities are expected to manage conflicts of interest.

Relevant authorities must apply the regulations, must have regard to this guidance, and are expected to read it alongside its annexes, which give further detail on the regulations and the transitional arrangements in place for when the regulations come into force.

The Welsh Government has developed a toolkit to accompany this guidance, which organisations may use in applying the regime to arrange the provision of health services.

When exercising functions to comply with the regulations, relevant authorities

must continue to comply with other legal obligations, where applicable.

This guidance does not specify how to comply with other legal obligations.

Any reference made within this statutory guidance to legislation, or a legislative provision is a reference to it as amended, extended, or re-enacted from time to time. Relevant authorities are advised to also be aware of other requirements and duties not set out in legislation. For example, relevant authorities are expected to adhere to Welsh Government's **net zero emissions requirements and carbon budget**, **A healthier Wales**, **Welsh procurement policy notes** and the **Welsh procurement policy statement** requirements in the procurement of NHS goods and services (this list is not exhaustive).

Section 2: scope of regulations

> The scope is set out in regulation 3(1) of the Health Services (Provider Selection Regime) (Wales) Act 2024.
>
> Relevant authorities are defined in section 10A(9) of the 2006 act.
>
> The health service is defined in section 206(1) of the 2006 act. Health services are defined in section 10A(1)(a) of the 2006 act. The common procurement vocabulary codes for use under the regulations are defined in schedule 1.

Which organisations does this guidance apply to?

This guidance applies to the following relevant authorities in Wales, which, under section 10A of the 2006 act, are required to comply with the regulations:

- county councils or county borough councils in Wales
- local health boards
- NHS trusts
- special health authorities

When does the regime apply?

The regulations specify that the regime applies when relevant authorities procure relevant health services for the purposes of the health service in Wales (subject to provisions on **mixed procurements**).

The "health service" is defined in section 206(1) of the 2006 act as the health service, continued under section 1(1) of the 2006 act and under section 1(1) of the National Health Service Act 2006. Section 1(1) of the 2006 act refers to:

> “ […] the promotion in Wales of a comprehensive health service designed to secure improvement—
> (a) in the physical and mental health of the people of Wales, and
> (b) in the prevention, diagnosis and treatment of illness. ”

This definition encompasses NHS health services and the comprehensive health service that is provided in the delivery of the public health functions of the Welsh ministers under the 2006 act.

As such, the health services subject to this regime only includes those services (whether treatment, diagnosis, or prevention of physical or mental health conditions) provided to individuals (that is patients or service users) or groups of individuals (such as where treatment is delivered to a group such as in the form of group therapy).

The regulations only cover relevant health services, defined by the CPV codes set out in schedule 1 (listed in **annex A**).

In summary, a service is in scope when a relevant authority is commissioning or subcontracting a service that:

- is provided as part of the health service, whether NHS or public health in Wales
- consists of the provision of health services to individuals or groups of individuals
- falls within one or more of the specified CPV codes

In-scope health services include services provided by providers within the Voluntary, Community, and Social Enterprise (VCSE) and independent sectors. In broad terms, these are services arranged by the relevant authority such as hospital, community, mental health, primary care services, palliative care, ambulance, and patient transport services for which the provider requires Healthcare Inspectorate Wales (HIW) or Care Inspectorate Wales (CIW) registration, as well as services arranged by relevant authorities focused on substance misuse, sexual and reproductive health, and health visits.

This definition purposefully excludes "non-health" or "health-adjacent" services from being arranged under the regime. This means, for example, that business consultancy, catering, administrative services, patient transport services that do not require HIW or CIW registration, or other services that may support health service infrastructure, but do not provide health services directly to people, must not be arranged under the regime (other than when legitimately part of a **mixed procurement**).

Health services in scope of the regime must fall within one or more of the Common Procurement Vocabulary (CPV) codes, which are set out in schedule 1 to the regulations. **Annex A** lists the CPV codes that correspond to the services covered by this regime and procurement practitioners must use these to support decisions around scope. Relevant authorities must use the most relevant CPV codes for the health service they are procuring. Where a more detailed code is not available, relevant authorities are expected to use the overarching parent code for "health services".

Which organisations must not use the regime?

Only organisations defined as relevant authorities in section 10A(9) of the 2006 act can use this regime. As such, the Welsh ministers must not use it to arrange health services directly.

However, it is worth noting that bodies which operate under local health board (LHB), NHS trust, county councils (CC) or county borough councils in Wales (CBC) or special health authority (SHA). This would include, for example, the NHS Wales Joint Commissioning Committee, which is a joint committee of the 7 health boards acting collectively on their behalf.

It is possible that the Welsh ministers may commission health services from relevant authorities (that is, CCs, CBCs, LHBs, NHS trusts and SHAs). In such cases, if that relevant authority is then further subcontracting these in-scope services, that relevant authority must follow the regulations when sub-contracting.

What must not be arranged under the regime?

Arrangements that would not be considered a procurement, as they do not intend to create legal obligations, are unlikely to fall under the scope of procurement legislation. For example, arrangements considered "NHS contracts" (commonly referred to as NHS to NHS contracts) as defined under section 7 of the 2006 act, or community pharmaceutical services provided by arrangements made under the **National Health Service (Pharmaceutical Services) (Wales) Regulations 2020**.

Also, goods and services that are not health services in scope of the regime must be arranged under the regime governing wider public procurement unless they fall within the definition of a **mixed procurement set out in the regime**.

Examples of procurements not in scope of this regime are:

- goods (such as medicines, medical equipment)
- social care services
- non-health services or health-adjacent services (such as capital works, business consultancy, catering, hospital administrative services, hospital bedding services or public health marketing campaigns) that do not provide health services to an individual

Sector-specific considerations

Primary medical, dental, pharmaceutical and ophthalmic services

Some primary care services are in scope of the regime, including primary medical, primary dental[footnote 1] and eye care services. Community pharmaceutical services provided by arrangements made under the **National Health Service (Pharmaceutical Services) (Wales) Regulations 2020** are not in scope of the regulations. The way different forms of primary care may be dealt with under the regime will depend on the situation and contracts or agreements involved.

Core primary care services are often commissioned based on continuous contracts that run until terminated and do not need to be routinely rearranged by relevant authorities. When a relevant authority is arranging primary care services, it must consider which procurement process is appropriate (see **procurement processes under the regulations**). Further detail on how the regulations applies to primary care can be found in **annex C**.

Mixed procurement

Mixed procurement is defined in regulations 3(1), 3(2), 3(3), 3(4) and 3(7). "Mixed procurement" means the procurement of:

a) relevant health services for the purposes of the health service in Wales
b) goods or other services that are connected to those health services

where both the following criteria are met:

- the main subject-matter of the procurement is relevant health services for the purposes of the health service in Wales
- the relevant authority is of the view that the goods or other services could not reasonably be supplied under a separate contract

Estimated lifetime value is defined in regulations 4(1), 4(2) and 4(3).

Contracts to deliver health services may contain multiple elements, some of which are health services clearly within the scope of the regulations, and some of which, if procured alone, would be within the scope of the wider public procurement regime (see the **2023 act)**.

The regulations do not provide for the procurement of goods or non-health services alone.

When a contract comprises a mixture of in-scope health services and out-of-scope services or goods, relevant authorities may only use the regulations to arrange those services when both below requirements are satisfied:

- the main subject-matter of the contract is in-scope health services
- the relevant authority is of the view that the other goods or services could not reasonably be supplied under a separate contract

The main subject-matter of the contract is determined by which of the following is higher:

- the estimated lifetime value of the health services
- the estimated lifetime value of the other goods or services

Estimated lifetime value of a contract is its value for the time being estimated by the relevant authority in accordance with regulation 4. This will be calculated as:

- in the case of a fixed-term contract, the maximum amount the relevant authority could expect to pay
- in the case of a contract without a fixed term, the maximum amount the relevant authority could expect to pay under the contract in any one-month period, multiplied by 48
- for a framework agreement, the sum of the estimated lifetime value of all contracts that have or may be awarded in accordance with that framework agreement

Estimated lifetime value

The following examples of estimated lifetime value specifically with reference to its application to mixed procurements and the determination of the main subject matter. Regulation 13 "modifications" and regulation 7(10) "considerable change" has specific reference to estimated lifetime value therefore its application is also referred to within "**establishing that the proposed contracting arrangements are not a considerable change from the existing contract**" and "**permitted modifications**" of this guidance.

Estimated lifetime value is the total amount a relevant authority could expect to pay under a contract. This includes the value for any services that will be provided by the provider under the contract other than for payment, the value of any options for additional services, if such an option were exercised by the relevant authority, the value of any options to extend or renew the term of the contract, any additional fees payable under the contract, and any amounts

representing prizes or payments that could be payable to a provider participating in a procurement. Relevant authorities must take account of all the circumstances which are material to the estimate at the time the estimate is calculated.

When applying this to the mixed procurement criteria, relevant authorities are required to calculate both the health services and the "connected to" goods and other services components to calculate whether the total estimated lifetime value break down has a higher health service element and therefore relevant health services are the main subject-matter. Should the "connected to" goods or other services work out to be the main subject-matter (that is of greater value), the relevant authority will not be able to award a contract under the regulations and the procurement must be undertaken as per the regime on wider public procurement.

Examples of calculating estimated lifetime value in mixed procurements

Fixed term contracts

A relevant authority's estimated lifetime value for a fixed term contract is the maximum amount the relevant authority could expect to pay under the contract including, where applicable, amounts already paid.

For example:

a) If a contract is to be awarded for a 24-month period with an option to extend for a 12-month period, the total value payable to the provider for all contracted services and additional extension options exercised would be the value that would be payable over a 36-month period.

b) If a contract is awarded for a 24-month period with options included regarding additional services, premiums, fees, commissions and so on, the value that would be payable is the 24-month value plus all additional services, premiums,

and fees during payable period.

Once the relevant authority has calculated the ‘estimated lifetime value’ of the contract as a whole, they will then need to calculate the estimated lifetime value of the health services and the ‘connected to’ goods or other services components against the total estimated (a) 36-month or (b) 24-month value. Should the ‘connected to’ goods/other services be the greater value, then they will be considered the main subject matter and the relevant authority will not be able to award a contract under the regulations.

A notable area of the use of mixed procurement is the arrangement of health services and social care services together in a single contract. Such a contract would comprise of a mixture of in-scope health services and out-of-scope social care services. Should the social care services be considered ‘connected to’ the health services, the relevant authority will need to ensure that the main subject-matter of the proposed contract is health services by firstly calculating the estimated lifetime value of the whole contract and then determining the value of the health (in-scope) and social care (out-of-scope) components.

For example, if the estimated lifetime value of the proposed contract was £1m, the health services would need to be the main subject-matter of the contract and therefore the component that is higher in value. As such, for the contract to be procured under the regulations as a mixed procurement the total value of the health services would need to be £500,001 or greater (more than 50%) and the social care component £499,999 or less (less than 50%). Where the estimated lifetime value of the social care services is greater, the mixed procurement tests are not met, and the regulations do not apply. The procurement must be undertaken as per the regime on wider public procurement.

Contracts without a fixed term

A relevant authority’s estimated lifetime value for a contract without a fixed term is the maximum amount the relevant authority could expect to pay under the contract in a one-month period, multiplied by 48. For example, contracts

awarded without an agreed fixed term that is an open-ended contract awarded under the **National Health Service (General Medical Services Contracts) (Wales) Regulations 2023** (the 'GMS Regulations'), will continue to run on an ongoing basis and will not come to an end unless terminated. A relevant authority required to calculate the estimated lifetime value should use the maximum amount the relevant authority could expect to pay under the contract in a one-month period and then multiply this by 48, this figure will then represent the estimated lifetime value.

Relevant authorities are required to calculate the estimated lifetime value of the health services and the 'connected to' goods and other services components to calculate whether the total estimated value break down has a higher health service element and therefore the health services are the main subject matter. Should the 'connected to' goods or other services (out-of-scope) be the main subject matter (the greater value), the relevant authority will not be able to award a mixed procurement contract under the regulations. The procurement must be undertaken as per the regime on wider public procurement.

Framework agreements

The estimated lifetime value for a framework agreement is the sum of the estimated values of all the contracts that have or may be awarded in accordance with that framework. For example, for the purpose of calculating the main subject-matter of a framework agreement for a mixed procurement, a relevant authority must:

- calculate the estimated lifetime value of the framework agreement (that is the sum of the estimated lifetime value of all contracts that have or may be awarded under the framework)
- calculate the estimated lifetime value of the health services and the estimated lifetime value of the 'connected to' goods and other services likely to be called off the framework agreement

Should the estimated lifetime value of the health services element of the contract

be the greater, and all other mixed procurement criteria be met, a relevant authority may conclude a mixed procurement framework agreement under the regulations. Should the estimated lifetime value of the ‘connected to’ goods or other services be the greater value, the relevant authority will not be able to conclude a mixed procurement framework agreement under these regulations. The procurement must be undertaken as per the regime on wider public procurement.

Out-of-scope goods or services can only be considered as part of a mixed procurement where the relevant authority is of the view that they cannot be separated from the in-scope health services as part of the same contract. A relevant authority may only determine that other goods or services could not reasonably be supplied under a separate contract where the relevant authority is of the view that procuring the health services and the other goods or services separately would, or would be likely to, have a material adverse impact on the relevant authority’s ability to act in accordance with the procurement principles.

For example, relevant authorities may foresee difficulties in the delivery of services should they run two procurements under different procurement regimes (that is one for the health services under the regulations and other goods or services under wider procurement regime) as it could result in an award of contracts to two different suppliers. This could prove to be an issue where the two services may be to the same individual patient or group of patients and could result in a complicated delivery of services or reduced quality of service provision due to having two different providers.

Relevant authorities will need to consider this on a case-by-case basis and must keep an internal record of the rationale for their decision to undertake a mixed procurement, as this would be a reason for the decision made (see **transparency**).

Where the above tests are met, then the regulations apply, and a mixed procurement can be undertaken using the regulations. Where these tests are not met, then the regime does not apply to the out of scope services and that element of the procurement must be undertaken as per the regime on wider

public procurement (see **the 2023 act**).

Other examples of services that can be arranged under the regulations, but that might require some extent of mixed procurement of health and non-health services to achieve their core objectives, include but are not limited to:

- health services and social care services arranged under a partnership arrangement (under section 33 of the NHS Wales Act 2006) by a relevant authority with an independent or voluntary sector provider
- patient transport, which includes health services (for which the provider requires HIW or CIW registration) and non-health services (where no HIW or CIW registration is required)
- packages arranged under the integrated care fund
- Discharge to Recover then Assess (D2RA) services
- mental health aftercare services, such as support services arranged under section 117 of the Mental Health Act 1983
- prison services that include health services
- asylum seeker services that include health services
- veteran services that include health services

Footnotes

[1] Community dental services provided under s3(1)(c) of the 2006 act are also included in the scope of the regulations, although not classified as primary care services as defined in the 2006 act.

Section 3: applying the regime

General notes

The specific processes to be followed when selecting providers are detailed in the **procurement processes under the regulations** section. When following any of the procurement processes, relevant authorities must act transparently, fairly, and proportionately.

Relevant authorities are expected to also consider issues relating to governance, planning, and provider landscape when applying the regime.

The regulations allow the award of a contract to more than one provider, either jointly or otherwise.

Procurement principles

> The regulations procurement principles are set out in regulation 5.

Relevant authorities are expected to ensure that when following this regime, they make decisions in the best interests of people who use the service. To do this, they must act with a view to:

- securing the needs of the people who use the services
- improving the quality of the services

- improving efficiency in the provision of the services

Relevant authorities must also act transparently, fairly, and proportionately when procuring health services.

The regulations state that relevant authorities must also have regard to the Wales procurement policy statement published under section 14 of the 2023 act, and relevant authorities must also have regard for any other policy statement made by the Welsh ministers that is relevant to the health services being procured.

Governance

Relevant authorities are expected to establish how best to follow this regime within their wider structural and governance arrangements. This regime sets out step-by-step instruction on how to undertake a procurement process; however, it does not require decisions to be taken by specific organisational committees within relevant authorities or at a particular level within an organisational system. Relevant authorities are expected to ensure that their internal governance supports the effective application of this regime.

Planning

To apply this regime effectively, relevant authorities are expected to have a clear understanding of the services they want to arrange and the outcomes they intend the services to deliver.

These are prerequisites to any decision about selecting a provider. We expect

these intentions to be clearly established in good time via the routine planning activity that takes place across a system. Relevant authorities are expected to reflect these intentions in their commercial pipeline, and decisions taken under this regime are also expected to serve and reflect these intentions.

The regime also sets out how to deal with unplanned urgent situations (see **urgent award or contract modifications**).

Provider landscape

Relevant authorities are expected to develop and maintain sufficiently detailed knowledge of relevant providers, including an understanding of their ability to deliver services to the relevant (local / regional / national) population, varying actual / potential approaches to delivering services, and capabilities, limitations, and connections with other parts of the system. Relevant authorities may wish to consider undertaking pre-market engagement to update or maintain their provider landscape knowledge.

We expect this knowledge to go beyond knowledge of existing providers and to be a general feature of planning and engagement work, developed as part of the commissioning process rather than only at the point of contracting. Without this understanding, relevant authorities may not have enough evidence to confirm the existing provider is performing to the best quality and value, miss opportunities to improve services and identify valuable innovations, and ultimately lead providers to make representations (see **standstill period**).

Taking a proportionate approach

The regime applies to the arranging of all relevant health services; there is no minimum threshold for application of the regime. Therefore, when applying this regime, relevant authorities are expected to take a proportionate approach. They are expected to ensure that their approach to implementing this regime does not create disproportionate burden relative to the benefits that will be achieved.

It is also important that decisions are defensible and made following relevant considerations.

Due diligence, basic selection criteria and exclusions

> The basic selection criteria are set out in regulation 19 and in schedule 17. Exclusions are set out in regulation 21 and 22.

When applying this regime, relevant authorities are expected to undertake reasonable and proportionate due diligence checks on providers. Relevant authorities are expected to consider whether the provider with whom they propose to enter into a contract has the legal and financial capacities and the technical and professional abilities to deliver the contract.

For direct award process 2, the most suitable provider process, and the competitive process, and when establishing a framework agreement, relevant authorities must assess if providers are considered suitable to provide a service

by applying the basic selection criteria as outlined in schedule 17. All basic selection criteria requirements must be related and proportionate to the subject matter of the contract or framework agreement.

It is not a regulatory requirement for relevant authorities to apply the basic selection criteria when following direct award process 1, or when awarding a contract based on a framework agreement. A relevant authority may, however, consider it best practice to confirm a provider's legal/financial capacities and technical/professional abilities, when undertaking direct award process 1.

The basic selection criteria may relate to:

- The provider's suitability to pursue a particular activity. Where the provider is required to possess a particular authorisation or be a member of a particular organisation to be able to perform the required services, the relevant authority may require a provider to prove that they hold such authorisation or membership.
- The provider's economic and financial standing. The relevant authority may impose requirements ensuring that the provider possesses the necessary economic and financial capacity to perform the contract.
- The provider's technical and professional ability. The relevant authority may impose requirements ensuring that a provider possesses the necessary human and technical resources and experience to perform the contract to an appropriate quality standard.

A relevant authority must disregard an excluded provider from participating in any of the procurement processes and may disregard an excludable provider if a provider would be an excluded or an excludable provider in accordance with section 57 and 58 of the 2023 act. Please note, for the purposes of applying sections 57 and 58 of the 2023 act under the Regulations, references to

"supplier" and "contracting authority" within the 2023 act are to be read as "provider" and "relevant authority" respectively. Under the exclusion regulation, relevant authorities are required to prevent excluded providers from participating in procurement processes and being awarded contracts, and allows relevant authorities to prevent excludable providers from participating in procurement processes and being awarded contracts.

Excluded providers are providers that would be an excluded supplier under sections 57 and 58 of the Procurement Act 2023, were the relevant authority the contracting authority and the provider a supplier under those sections, and any reference to an associated person in those sections is omitted. Providers which are on the debarment list based on a mandatory ground for exclusion must also be considered an excluded provider. Providers may also be an excluded provider by virtue of a mandatory exclusion ground applying to its sub-contractors.

Excludable providers that would be an excludable supplier in accordance with sections 57 (meaning of excluded and excludable supplier) and 58 (considering whether a supplier is excluded or excludable) of the Procurement Act 2023, were the relevant authority the contracting authority and the provider a supplier under that Act, and any references to an associated person is omitted. Providers which are on the debarment list based on a discretionary ground for exclusion must also be considered an excludable provider. Providers may also be an excludable provider by virtue of a discretionary exclusion ground applying to its sub-contractors.

If it is the case that a provider or sub-contractor is on the debarment list because the provider or sub-contractor poses a threat to national security in relation to specific types of contract, the providers or sub-contractors must be treated as an excluded provider only in relation to the contracts of the kind described in the

debarment list.

As such, a provider or sub-contractor is an ‘excluded provider’ if the relevant authority considers that a mandatory exclusion ground applies to the provider or sub-contractor, and the circumstances giving rise to the application of the exclusion ground are continuing or likely to occur again.

A provider or sub-contractor is an "excludable provider" if the relevant authority considers that a discretionary ground applies to the provider or sub-contractor and the circumstances giving rise to the application of the exclusion ground are continuing or likely to occur again.

In consideration of whether the application of an exclusion ground is continuing or likely to occur again, the relevant authority may have regard to:

- evidence that the provider or sub-contractor has taken the circumstances seriously
- steps that the provider or sub-contractor have taken to prevent the circumstances continuing or occurring again
- commitment that such steps will be taken or the provision of information to allow verification or monitoring
- elapsed period since the circumstances last occurred
- any other evidence, explanation or factor the relevant authority considers appropriate

Before determining that a provider or sub-contractor is an excluded or excludable provider, relevant authorities have a duty to give the providers a reasonable opportunity to make representations and provide evidence as to whether the exclusion grounds apply and whether the circumstances are likely to occur again (accordingly a "self-cleaning" process). When complying with this

duty it is important the relevant authorities do not make disproportionate requests for information regarding the exclusion grounds. This includes disproportionate requests for proof of the absence of grounds for exclusion, or disproportionate requests for remedial action to be taken where grounds are met.

Therefore, a provider or sub-contractor considered an "excluded provider" must be afforded a reasonable opportunity to respond to a determination that a mandatory exclusion ground applies.

If an excluded provider fails to sufficiently evidence that the matters are remedied or unlikely to occur again, the relevant authority must exclude that provider from the procurement process and not award a contract or conclude a framework agreement with the excluded provider/sub-contractor.

However, if a relevant authority considers that there is an overriding need to protect public health, it may proceed with awarding the contract or concluding the framework agreement with the excluded provider.

As such, where a relevant authority determines that not making the award to the excluded provider would likely pose a risk to patient or public safety, the relevant authority may award a contract or conclude a framework agreement with an excluded provider as set out under regulation 21(2).

Procurement processes under the regulations

> The procurement processes are set out in regulation 7.

This regime must be applied whenever relevant authorities are making decisions about procuring health services.

The first step for relevant authorities applying this regime is to identify which of the following procurement processes are applicable.

Direct award process 1 must be used when all the following apply:

- there is an existing provider of the health services to which the proposed contracting arrangements relate
- the relevant authority is satisfied that the health services to which the proposed contracting arrangements relate are capable of being provided only by the existing provider (or group of providers) due to the nature of the health services

Direct award process 1 must not be used to conclude a framework agreement.

Direct award process 2, the most suitable provider process or the competitive process may be used when all the following apply:

- the relevant authority is not required to follow direct award process 1
- the term of an existing contract is due to expire, and the relevant authority, proposes a new contract to replace that existing contract at the end of its term
- the proposed contracting arrangements are not a considerable change
- the relevant authority is of the view that the existing provider (or group of providers) is satisfying the existing contract and will likely satisfy the proposed contract to a sufficient standard

Direct award process 2 and the most suitable provider process must not be used to conclude a framework agreement.

The most suitable provider process or competitive process may be used when all the following apply:

- the relevant authority is not required to follow direct award process 1
- the relevant authority cannot or does not wish to follow direct award process 2
- the relevant authority is of the view, considering likely providers and all relevant information available to the relevant authority at the time, that it is likely to be able to identify the most suitable provider (without running a competitive process).

The most suitable provider process must not be used to conclude a framework agreement.

The competitive process must be used when all of the following apply:

- the relevant authority is not required to follow direct award process 1
- the relevant authority cannot or does not wish to follow direct award process 2 and cannot or does not wish to follow the most suitable provider process

The competitive process must be used if the relevant authority wishes to conclude a framework agreement.

Once the relevant authority has identified which of these circumstances applies and has identified the appropriate procurement process to follow, it will then need to follow that procurement process as set out in detail in the sections below.

Relevant authorities are expected to identify which procurement process is applicable sufficiently in advance of a contract coming to an end. The fact that a particular procurement process was used to select a provider in the past does

not mean the same approach must (or will be able to) be used for that service in future.

It is permitted to make certain modifications during the term of a contract to allow for changes to services or circumstances. The section on contract modifications sets out the conditions and transparency requirements for these modifications.

In limited circumstances relevant authorities may need to act rapidly, for example, to address immediate risks to patient or public safety, within which it would be impractical to follow the steps required under this regime. The section on **urgent awards or contract modifications** sets out these circumstances and how relevant authorities must act if they arise.

Direct award process 1

> The process that must be followed when awarding a contract under direct award process 1 is set out in regulations 7(4) and 8.

The type of service means there is no realistic alternative to the current provider. This process must not be used to award contracts when establishing a new service or to conclude a framework agreement or to award a contract based on a framework agreement.

Direct award process 1 must be used to award contracts to the existing provider (or group of providers) when the nature of the service means there is no realistic alternative to the existing provider (or group of providers). Even when there are

alternative providers in the market, as long as these are not considered to be realistic alternatives for the relevant authority's specific requirements, direct award process 1 must be used to award a contract.

Direct award process 1 must not be used to:

- award a contract when establishing a new service
- conclude a framework agreement
- to award a contract based on a framework agreement

Relevant authorities must follow the required transparency steps (see **transparency section** and **annex B**) when they award contracts to the existing provider (or group of providers) using this approach.

Relevant authorities must consider the exclusions in regulation 21 and 22 and apply them as appropriate.

Direct award process 2

> The process that must be followed when awarding a contract under the direct award process 2 is set out in regulations 7(5) and 9.

The existing provider is satisfying the existing contract and likely to satisfy the proposed contract, and the proposed contracting arrangements are not a considerable change from the existing contract. This process must not be used to award contracts when establishing a new service or to conclude a framework

agreement or to award a contract based on a framework agreement.

Direct award process 2 may be used to award a proposed contract to the existing provider (or group of providers), to replace an existing contract that is coming to an end, when all the tests below are met:

- the relevant authority is not required to follow direct award process 1
- the term of an existing contract is due to expire, and the relevant authority is proposing a new contract to replace that existing contract at the end of its term
- the proposed contracting arrangements are not a considerable change from the existing contract (see **establishing that a proposed contracting arrangement is not a considerable change**)
- the relevant authority is of the view that the existing provider is satisfying the existing contract to a sufficient standard, according to the detail outlined in the contract, and taking into account the key criteria and applying the basic selection criteria
- the relevant authority is of the view that the existing provider will likely satisfy the proposed contract to a sufficient standard taking into account the key criteria and applying the basic selection criteria

Direct award process 2 must not be used to:

- award a contract when establishing a new service
- conclude a framework agreement
- to award a contract based on a framework agreement

Once the relevant authority has ascertained that it can use direct award process 2, it must follow the below steps:

1. Publish a notice containing its intention to award the contract to the existing

provider (see **transparency section**) and observe the standstill period (see **standstill period**).
2. Enter into a contract with the existing provider after the standstill period has concluded.
3. Publish a notice confirming the award of the contract to the existing provider within 30 days of the contract being awarded.

Even where the tests for using the direct award process 2 are met, relevant authorities do not have to use the direct award process 2. Relevant authorities may still choose to follow the most suitable provider process or the competitive process, for example because they wish to test the market.

Relevant authorities must consider the exclusions in Regulation 21 and 22 and apply them as appropriate.

Establishing that the proposed contracting arrangements are not a considerable change from the existing contract

Considerable change is defined in regulation 7(9) and 7(10). Circumstances where a change is not a considerable change are set out in regulations 7(11) and 7(12).

To use direct award process 2, the relevant authority must be satisfied that the proposed contracting arrangements are not a considerable change, that is they do not fall within the circumstances set out in regulation 7(9) and 7(10).

Under this regime, a considerable change is where either:

a) the proposed contracting arrangements are materially different in character to

the existing contract when that existing contract was entered into

b) where the proposed contracting arrangements meet the considerable change threshold

The considerable change threshold is met where all of the following apply:

- the proposed contracting arrangements (as compared with the existing contract), is attributable to a decision made by the relevant authority
- the estimated lifetime value of the proposed contract is £500,000 or higher (that is equal to or £500,000 more) than the estimated lifetime value of the existing contract when it was entered into
- the estimated lifetime value of the proposed contract is 25% or higher (that is equal to or 25% more) than the existing estimated lifetime value of the existing contract when it was entered into

The proposed contracting arrangements do not meet the considerable change test, as set out in regulation 7(11) and 7(12), where either:

- There is a material difference in character from the existing contract (when that existing contract was entered into), but it is solely because of a change in the identity of the provider due to succession into the position of provider following corporate changes including for example takeover, merger, acquisition or insolvency and the relevant authority is satisfied that the provider meets the basic selection criteria. Additionally, the considerable change threshold is not met.
- The proposed contracting arrangements are not materially different in character to the existing contract when that existing contract was entered into, and the considerable change threshold has been met, however the change between the existing and proposed contracting arrangements is in

response to external factors beyond the control of the relevant authority or the provider. Examples of this include changes in patient or service user volume, or changes in prices in accordance with a formula provided for in the contract document.

Where the proposed contracting arrangements are materially different in character to the existing contract, this is deemed a considerable change. Where contracting arrangements are considered materially different the relevant authority cannot rely on direct award process 2 to award the proposed contract (unless regulation 7(11) is applicable).

Where the proposed contracting arrangements are not materially different in character to the existing contract, however the proposed contracting arrangements meet the considerable change threshold, the relevant authority cannot rely on direct award process 2 to award the proposed contract (unless regulation 7(12) is applicable).

The method for calculating the estimated lifetime value of a contract is set out in regulation 4.

Example of a considerable change

A. A relevant authority holds a contract with an estimated lifetime value of £3 million. The contract is coming to an end and the relevant authority wants (so attributable to a decision of the relevant authority) to continue with the current provider. The estimated lifetime value of the proposed contracting arrangements is £4million. The proposed contract is not going to be materially different in character.

The change in the estimated lifetime value of the proposed contract is £1million,

which is more than £500,000 and represents 33% of the estimated lifetime value of the existing contract, which is over the 25% threshold. Therefore, the relevant authority must not use direct award process 2 for the proposed contracting arrangements and instead must follow the approach for the most suitable provider process or the competitive process.

Example of a change that is not considerable

B. A relevant authority holds a contract with an existing provider, the contract has an estimated lifetime value of £1 million. The contract is now coming to an end and the relevant authority wishes to increase the estimated lifetime value by £400,000 when the contract is renewed. However, the remaining contracting arrangements are to be the same. The estimated lifetime value of the proposed new contract will therefore be £1.4million. The proposed contract is not going to be materially different in character. Therefore, the next consideration is whether the considerable change threshold is met.

As it is something the relevant authority wishes to do, it is attributable to a decision of the relevant authority. The £400,000 change in the estimated lifetime value of the proposed contract is 40% of the estimated lifetime value of the existing contract when the existing contract was entered into, which is over the 25% threshold. However, the last limb of the threshold is not met as the change is under the £500,000 threshold and therefore this is not a considerable change. The relevant authority can proceed with the approach under direct award process 2.

C. A relevant authority holds a contract with an existing provider, the contract has an estimated lifetime value of £10million. The contract is coming to an end and the relevant authority wishes to continue with the provider that has taken

over the existing providers organisation in a recent acquisition. The provider that has acquired the existing providers organisation meets the basic selection criteria. The estimated lifetime value of the proposed contracting arrangements is £10.2m.

The change in the estimated lifetime value of the proposed contract is £200,000 which is 2% of the estimated lifetime value of the existing contract when the existing contract was entered into. The proposed change is under the 25% and £500,000 considerable change threshold. The proposed contract is materially different in character due to the change of provider, however the material difference is solely because of a change in the identity of the provider due to the corporate change. Therefore, regulation 7(11) is applicable, and the relevant authority can rely on direct award process 2 for the proposed contracting arrangements.

D. A relevant authority holds a contract with an existing provider, the contract has an estimated lifetime value of £2million. The contract is coming to an end and the relevant authority wishes to continue with the current provider. The estimated lifetime value of the proposed contracting arrangements is £2.6m. The proposed contract is not going to be materially different in character.

The change in the estimated lifetime value of the proposed contract is £600,000 which is 30% of the estimated lifetime value of the existing contract when the existing contract was entered into. The proposed change is over the 25% and £500,000 threshold. Therefore, the considerable change threshold has been met, however the change between the existing and proposed contracting arrangements (£600,000) is due to a change in patient volume requiring the specific health service. As such, the proposed change is in response to external factors that are beyond the control of the relevant authority and the provider. Therefore, regulation 7(12) is applicable, and the relevant authority can rely on

direct award process 2 for the proposed contracting arrangements.

Establishing that the existing provider is satisfying the existing contract, and is likely able to satisfy the proposed contract to a sufficient standard

Once the relevant authority has established that the proposed contracting arrangements are not a considerable change, it must assess whether the existing provider is both:

- satisfying the existing contract to a sufficient standard, according to the detail outlined in the existing contract, and taking into account the key criteria and applying the basic selection criteria
- will likely be able to satisfy the proposed contract to a sufficient standard, according to the detail outlined in the proposed contract, taking into account key criteria and applying the basic selection criteria

To do this, the relevant authority must decide the relative importance of the key criteria for the service in question before assessing the existing provider in relation to each of the key criteria.

The relevant authority must be of the opinion, based on its assessments, that the existing provider is satisfying the existing contract and will likely be able to satisfy the proposed contract to a sufficient standard. The relevant authority must also assess whether the existing provider is continuing to meet the basic selection criteria.

If direct award process 2 is not applicable because the proposed contracting arrangements are a considerable change from the existing contract, or the existing provider is not satisfying the existing contract or is not likely to be able to

satisfy the proposed contract, then the relevant authority must follow the most suitable provider process or the competitive process.

Relevant authorities must keep records of these considerations (see **transparency**) and the resulting decisions, as they may need to disclose information on the rationale for their decision if a representation is made (see **standstill period**).

The most suitable provider process

> The process that must be followed when awarding a contract under the most suitable provider process is defined in regulations 7(5), 7(6), and 10.

The relevant authority is able to identify the most suitable provider without running a competitive exercise.

This procurement process is designed to allow relevant authorities to make an assessment on which provider (or group of providers) is most suitable to deliver the proposed contracting arrangements based on consideration of the key criteria and the basic selection criteria, and to award a contract without running a competitive exercise.

This procurement process gives relevant authorities a mechanism for a reasonable and proportionate process without running a competitive exercise. It is suitable for circumstances where a relevant authority is of the view, taking into account likely providers and all relevant information available to it at the time

(see **provider landscape**), that it is likely to be able to identify the most suitable provider to deliver the health services to the relevant population (local / regional / national). Relevant authorities are advised to follow this procurement approach only when they are confident that they can, acting reasonably, clearly identify all likely providers capable of providing the health services and passing any key criterion or sub-criterion which has been designated as pass/fail.

The most suitable provider process must not be used to conclude a framework agreement or to award a contract based on a framework agreement.

Following this procurement process

This procurement process may be followed where any of the following apply:

- the relevant authority is not required to follow direct award process 1
- the relevant authority is changing an existing contracting arrangement considerably (such that it must not be continued under direct award process 2)
- a new service is being arranged
- the existing provider no longer wants to provide the services
- the relevant authority wants to consider potential providers (even where the proposed contracting arrangements are not a considerable change or otherwise), as this is in the best interest of people who use the service, but there is no benefit to running a competitive process or it is disproportionate to do so

When following the most suitable provider process, the relevant authority:

1. Is advised to take account of any relevant existing contractual provisions relating to termination and contract exit where there is an existing contract

with an existing provider in place, whether the existing provider no longer wants to or is no longer able to provide the services.

2. Is advised to consider undertaking a pre-market engagement exercise (see **provider landscape**) to help identify all suitable providers and develop the service specification.
3. Must decide the relative importance of each of the key criteria for the service in question (see **key criteria**), carefully considering the relative importance of the value criterion. It is advised that for procurement processes with higher contract values, greater focus is given to value for money and the quality and efficiency of the services to be provided, unless this means the service does not best meet the needs of the population it is serving.
4. Must be of the view that, considering providers it understands are likely to have the ability to deliver services to the relevant (local / regional / national) population and all relevant information available at the time (see provider landscape), it is likely able to identify the most suitable provider.
5. Must publish a notice setting out its intention to follow the most suitable provider process (see **transparency**). The relevant authority must not proceed to the assessment of likely providers until at least 14 days after the day on which the notice of intention is submitted for publication. The relevant authority is also advised to make potential providers aware that they are being considered for the award of the contract.
6. Is advised to ask the providers it identified as likely to have the ability to deliver services to the relevant (local / regional / national) population, and any providers that responded to the notice publishing the intention to follow the most suitable provider process, for further information that would help the procurement process, as necessary.
7. Must identify potential providers that may be the most suitable provider, taking into account the providers it understands are likely to have the ability to deliver services to the relevant (local / regional / national) population and any providers that responded to its notice publishing the intention to follow

the most suitable provider process, with reference to the key criteria and the basic selection criteria.

8. Must assess the potential providers identified, considering the key criteria and applying the basic selection criteria, and the exclusion criteria set out in Regulation 21 and 22, in a fair way across them (that is on the same basis), and choose the most suitable providers with which to make an award.
9. Must publish a notice containing its intention to award the contract to the chosen provider (see **transparency**) and observe the standstill period (see **standstill period**).
10. May enter into a contract with the chosen provider after the standstill period has concluded.
11. Must publish a notice confirming the award of the contract within 30 days of the contract being awarded.

Relevant authorities are expected to use their established knowledge of potential providers (see **provider landscape**). Relevant authorities may approach providers and ask for information as necessary but are advised to take a proportionate approach.

Relevant authorities must be able to demonstrate that they have understood the alternative providers and reached a reasonable decision when selecting a provider – but this does not need to be via a formal competitive exercise. Relevant authorities must keep robust records of these considerations and follow the relevant transparency requirements (see **transparency**). They may need to disclose information on the rationale for their decision if a representation is made (see **standstill period**).

If at any point in the most suitable provider process the relevant authority has insufficient information to make an assessment under the most suitable provider process, for example, because it did not receive sufficient information to help its

procurement process, it is advised to use the competitive process. If the relevant authority fails to identify the most suitable provider (or a group of providers), then it must follow the competitive process to select a provider or **abandon the procurement** process altogether if appropriate.

If the relevant authority decides to change from the most suitable provider process to either the direct award process 2 or the competitive process after it has published intention to follow the most suitable provider process, then the relevant authority must abandon the most suitable provider process before commencing the direct award process 2 or competitive process.

Relevant authorities must consider the exclusions in regulation 21 and 22 and apply as appropriate.

Further information

Relevant authorities are expected to develop and maintain a sufficiently detailed knowledge of relevant providers that have the capability to meet the needs of patients within the relevant geographical footprint, which can be used to identify suitable providers (see **provider landscape**). Relevant authorities may identify suitable providers through market research, regular engagement with providers, registers of relevant providers or responses to their intention to follow the most suitable provider process notice.

The competitive process

> Regulations 7(5), 7(6), 7(7), and 11 set out the process that relevant authorities must follow when awarding a contract under the competitive process.

Conducting a competitive procurement exercise

This procurement process must be followed when the relevant authority is not required to follow direct award process 1, or where the relevant authority cannot or does not wish to follow direct award process 2 or the most suitable provider process (for example, because it has not been able to identify a most suitable provider or because it wishes to test the market).

This procurement process must be used when concluding a framework agreement and may be used when awarding a contract based on a framework agreement, in accordance with the terms of that framework agreement (see **framework agreements**).

Following this procurement process

The steps outlined in the regulations and the transparency requirements must be adhered to. Relevant authorities may determine additional procedures to be applied in selecting a provider using the competitive process, taking into account the specificities of the services being procured to design a bespoke procedure.

When following the competitive process, relevant authorities:

1. Will need to develop a service specification setting out the relevant authority's requirements for the service. In doing so, relevant authorities may consider undertaking a pre-market engagement exercise.
2. Must determine the contract or framework award criteria for the service being procured, taking into account the key criteria and applying the basic selection criteria (see **key criteria** and **basic selection criteria**).
3. Must formally publish the opportunity to bid (see **transparency**) and ensure providers are given a reasonable timeframe to respond. The publication of the opportunity must include information relating to how bids will be assessed, including whether the award criteria will be assessed in stages.
4. Must assess any bids received by following the assessment process – that is, against the award criteria, and the exclusion criteria set out in regulation 21 and 22, in a fair way across all bids (that is on the same basis). This may be done in stages, in accordance with step 3 above.
5. Must identify the successful provider (or group of providers).
6. Must inform in writing the successful provider (or group of providers) of its intention to award a contract or conclude a framework agreement, and must also inform in writing each unsuccessful provider that its bid has been unsuccessful.
7. Must publish a notice of its intention to award the contract to or conclude a framework agreement with the chosen provider (or group of providers) (see **transparency**) and observe the standstill period (see **standstill period**).
8. May enter into a contract or conclude a framework agreement with the chosen provider (or group of providers) after the standstill period has concluded.
9. Must publish a notice confirming the award of the contract within 30 days of the contract being awarded.

The award criteria referred to above consists of the basic selection criteria, the key criteria and any other elements of the contract award. These components can be assessed in stages – for example, a provider that does not meet the basic selection criteria may be discounted without further assessment.

Relevant authorities may engage in dialogue or negotiate with all bidders or with shortlisted bidders prior to determining to whom to award a contract and with a view to improving on initial offers, provided that they do so in a fair and proportionate way and treat all bidders equally.

Relevant authorities must keep records of the procedure followed to select a provider (including details of the bespoke procedure), of how each bid performed against the award criteria, and the rationale for selecting the successful bidder (see **transparency**).

Relevant authorities must consider the exclusions in regulation 21 and 22 and apply as appropriate.

Framework agreements

> Framework agreements are defined in regulation 16.

Relevant authorities may establish framework agreements under the regulations to arrange health services in scope of the regime (or that are categorised as mixed procurements within the regime).

What is a framework agreement?

Framework agreements for the purposes of this regime are agreements in relation to health services in scope of this regime between one or more relevant authorities and one or more providers. Framework agreements set out the terms and conditions based on which the provider may enter into one or more contracts with a relevant authority during the period the framework agreement is in place.

The relevant authority (or relevant authorities) that may award contracts based on the framework agreement must be identified in the framework agreement (either by name or by describing the type of relevant authority). Contracts awarded based on a framework agreement must only be between the relevant authority (or relevant authorities) identified in the framework agreement and a provider that is party to the framework agreement.

The length of a framework agreement must not exceed eight years, other than in exceptional cases where the relevant authority is satisfied that the subject matter of the framework agreement justifies a longer term.

The terms and conditions of a framework agreement may be modified in line with the requirements for contract modification for this regime (see **contract modifications**).

Concluding a framework agreement

> The process that must be followed when concluding a framework agreement is set out in regulation 16.
>
> The process that must be followed when adding providers to an existing framework agreement is set out in regulation 17.

When concluding a framework agreement, relevant authorities must use the competitive process to select providers to be party to the framework agreement.

During the term of a framework agreement, the relevant authority must commence a competitive process to allow additional providers to be selected to be party to the framework agreement. This must be commenced at least once during the first four years of the initial framework agreement, and then at least once in the proceeding four years.

Framework agreement, further competitive process examples

During the term of the framework agreement the relevant authority is required to allow further providers to be selected to be party to the framework agreement.

Example A: a framework agreement is concluded for a 6-year period under the regulations, from 1 April 2025 to 31 March 2031

The relevant authority determines it appropriate to run a further competitive exercise to select additional providers to be party to the framework agreement

on the one-year anniversary of the initial award of the framework agreement (that is on the 1 April 2026, undertaken within the first four years of the award of framework meeting the regulations (regulation 17(1)(a)). The relevant authority is then required to undertake another competitive exercise for additional providers to be party to the framework agreement by the 5th anniversary of the initial framework agreement award (1 April 2030). In completing the further competitive exercise by the 1 April 2030, the relevant authority will be within the four years from the commencement of the first competitive process to select additional providers (1st year anniversary – 2 April 2026), therefore meeting the requirements set out under regulation 17(1)(b).

Example B: a framework agreement awarded for an 8-year period under the regulations, 1 April 2025 to 31 March 2033

The relevant authority determines it appropriate to run a further competitive exercise on the four-year anniversary of the initial award of the 8-year framework agreement (1 April 2029, commenced within the first four years of the award of framework meeting regulation 17(1)(a)). The relevant authority is not required to commence another competitive exercise for additional providers to bid and be assessed, to meet regulation 17(1)(b) due to the four-year period and the expiration date of the framework agreement being coterminous.

Relevant authorities are not restricted in the number of times they commence competitive processes to select additional providers to a framework agreement. Relevant authorities may determine it appropriate to open a framework agreement to further providers more frequently than the minimal period set out within the regulations. Relevant authorities should ensure that the frequency of opening the framework agreement is transparent, fair, and proportionate.

Relevant authorities are advised to set out how and when a framework agreement will be opened for additional providers to be selected within the terms and conditions of that framework agreement. Relevant authorities must use the approach for the competitive process to select additional providers to the framework agreement, and relevant authorities are advised to use the same award criteria as when setting up the original framework agreement.

When concluding a framework agreement, relevant authorities must set out the duration of the framework agreement and which relevant authorities can award contracts based on the framework agreement. Relevant authorities are expected to set out:

- the procedures for calling off the framework agreement
- the terms and conditions for any contracts awarded based on the framework agreement
- how additional providers can be added to the framework agreement at a later date

Relevant authorities must not conclude a framework agreement with a provider and may exclude a provider from the procurement process if the provider meets the exclusion criteria detailed in regulation 21 and 22. Relevant authorities are advised to set out in the terms and conditions of their framework agreement that they may remove a provider from the framework agreement if that provider meets the exclusion criteria.

Awarding contracts based on a framework agreement

> The processes that must be followed when awarding a contract based on a framework agreement are defined in regulation 18.

Only relevant authorities that are identified as being able to award contracts under the framework agreement may award contracts to providers that are party to that same framework agreement. Relevant authorities may decide that the award criteria for awarding contracts under a framework agreement are different from those for concluding the framework.

Relevant authorities must award a contract under a framework agreement in accordance with the terms and conditions of that framework agreement.

Relevant authorities may award a contract based on a framework in one of the following ways:

- without competition if the framework agreement only includes one provider (via a direct award)
- if the framework agreement includes more than one provider, choose whether to award the contract:
  a) without a further competition (via direct award), or
  b) by following the competitive process (via a mini competition)

In all these scenarios, relevant authorities must make decisions in accordance with the framework agreement.

If awarding a contract based on a framework agreement without competition (via a direct award), relevant authorities must:

- publish a notice confirming the decision notice within 30 days of the contract being awarded (see **transparency section** and **annex B**).

If awarding a contract based on a framework agreement following a competitive process (via a mini-competition), relevant authorities must:

- follow the process for competitive process, substituting step 2 (the step advertising the opportunity to the market, regulation 11(5)), and instead must invite providers party to the framework to submit an offer
- follow the terms and conditions of the framework agreement, including how competitions must run when awarding a contract based on that framework agreement (if this is set out)
- follow the relevant transparency requirements (see **transparency** and **annex B**)
- observe the standstill period as required for the competitive process (see **standstill period**)

When awarding a contract based on a framework agreement, the term of the contract may exceed the length of the framework agreement.

Contracts awarded from a framework agreement are expected to not exceed the total estimated lifetime value of the framework agreement.

Abandoning a procurement process

> The process that must be followed when abandoning a procurement

process is set out in regulation 15.

The content of the notice confirming the decision to abandon a procurement process is set out in schedule 16.

Relevant authorities may decide to abandon the procurement process (and not award a contract or conclude a framework agreement) at any time before an award is made, provided that this decision is transparent, fair, and proportionate. If a relevant authority decides to abandon a procurement process during the standstill period, the authority may only abandon the procurement process after the standstill period has ended.

After deciding to abandon a procurement process, relevant authorities are expected to notify providers that were being considered for the award of a contract or framework agreement (such as in response to a tender under the competitive process) of the abandonment. Relevant authorities must also submit for publication a notice of the decision to abandon and must include the information set out in schedule 16. This notice must be submitted within 30 days of the decision to abandon a procurement process, or if the decision was made during the standstill period, then within 30 days after the end of the standstill period. Where the decision to abandon a procurement process is made during the standstill period, relevant authorities must ensure that they follow the necessary steps set out in regulation 12 (see the **standstill period**).

Relevant authorities must also keep a record of their reasoning for abandoning a procurement process (see **record keeping**).

Repeating a step in a procurement process

> The process that must be followed when returning to an earlier stage in the procurement process and repeating steps is set out in regulation 15.

When following direct award process 2, the most suitable provider process or the competitive process, relevant authorities may choose to return to an earlier step in a procurement process. All providers that have previously been notified that they are being considered for the award of a contract, or to be a party to a framework agreement, must be informed in writing that the relevant authority is returning to an earlier stage in the procurement process, including the stage and any changes to timeframes. Where the decision to return to an earlier step in a procurement process is made during the standstill period, relevant authorities must ensure that they follow the necessary steps set out in regulation 12. For the avoidance of doubt, if the relevant authority is repeating a step as a response to a representation received during the standstill period, they do not need to communicate this decision twice (see **standstill period**).

Relevant authorities should not use the option to return to an earlier step in a procurement process as an opportunity to modify the selection parameters (that is to modify the key criteria or change the service specifications). If relevant authorities need to modify the selection parameters, then they should abandon the procurement process (in accordance with the regulations) and start a new one.

Section 4: key criteria

Overview

> The regulations key criteria are defined in regulation 6.

Relevant authorities must consider five key criteria when making procurement decisions under direct award process 2, the most suitable provider process, and the competitive process of the regime. **Annex D** of this guidance provides detail on what each criterion covers. In summary, these criteria are:

- quality, that is the need to ensure good quality services
- value, that is the need to strive to achieve good value in terms of the balance of costs, overall benefits, and the financial implications of a proposed contracting arrangement
- collaboration and service sustainability, that is the extent to which services can be provided in:
  - a collaborative way
  - a sustainable way (which includes the stability of good quality health services or service continuity of health services)
  - in a way that improves health outcomes
- improving access and reducing health inequalities, that is ensuring accessibility to services and treatments for all eligible patients and improving health inequalities
- social responsibility, that is whether what is proposed might improve economic, social, environmental, and cultural well-being in the geographical area relevant to a proposed contracting arrangement

Application of key criteria

Relevant authorities must consider each of the key criteria in the regime when making decisions under direct award process 2, the most suitable provider process and the competitive process (including when concluding a framework agreement and when awarding a contract based on a framework agreement using the competitive process). Relevant authorities must be able to justify their decisions when following these procurement processes in relation to the key criteria and keep a record of this. Further detail on recording procurement processes and transparency can be found in the **transparency section**.

How relevant authorities assess providers against the key criteria, including what evidence they consider, may vary according to the service they want to procure. A relevant authority may wish to address specific priorities; these priorities are expected to be described as part of the key criteria and can be considered when deciding the relative importance of the key criteria.

Relevant authorities must be aware that equalities duties in the **Equality Act 2010**, including the **public sector equality duty**, are relevant to all criteria and due regard to these requirements must be given when considering each criterion.

Balancing the key criteria

The relative importance of the key criteria is not predetermined by the regulations or this guidance and there is no prescribed hierarchy or weighting for each criterion. Relevant authorities must decide the relative importance of the key criteria for each decision they make under this regime, based on the proposed contracting arrangements and what they are seeking to achieve from them/the services, including scenarios where a particular criterion is "pass/fail", or where certain key criteria are of equal importance. All criteria must be considered, and none is expected to be discounted when following a

procurement process.

The regime does not specify how relevant authorities must balance the key criteria; however, relevant authorities are expected to be aware of wider requirements or duties when considering procurement decisions. For example, CCs, CBCs, LHBs, NHS trusts and SHAs are expected to adhere to the Welsh Government's net zero ambitions and carbon budget, the social partnership and Public Procurement Act 2023, the Wales procurement policy statement, "a healthier Wales", and the need to ensure value for money when arranging health services (this list is not exhaustive). The flexibilities offered by the regime does not mean that relevant authorities are exempt from complying with their other obligations.

Relevant authorities are advised to consider particularly carefully the relative importance of the value criterion when making assessments under the most suitable provider process.

It is advised that for procurement processes with higher contract values, greater focus is given to value for money and the quality and efficiency of the services to be provided, unless this means the service does not best meet the needs of the population it is serving.

When making assessments against the key criteria under direct award process 2 and the most suitable provider process, relevant authorities are expected to use information and evidence from a range of sources, as well as their knowledge and experience of working with providers. They can ask providers for further information to assist with this assessment if they wish. The explanation of each criterion in **annex D** includes examples of relevant sources where appropriate.

When following the competitive process relevant authorities must only use the information contained in the bid to assess the bid, except when applying regulation 21 and 22 exclusions. Relevant authorities may set out in their tender documents that wilful misrepresentation of a bid by a provider will result in exclusion from the procurement process.

Relevant authorities must justify and record how they have given relative importance to each of the key criteria for the service they are arranging. Further detail on recording the procurement process can be found in the transparency section.

Relevant authorities must ensure they meet other relevant statutory duties when deciding the relative importance of each of the criteria, including normal public law procurement principles around reasonableness of decisions. Relevant authorities are also expected to consider other national and local policies and non-statutory guidance when deciding the relative importance of each of the criteria.

Further detail

Further details on how relevant authorities are expected to use the key criteria can be found in **annex D**.

Section 5: transparency

> Regulation 20 sets out the process to be followed where relevant authorities are required to submit a notice for publication under the regulations.
>
> The relevant information keeping requirements are detailed in regulation 26.
>
> The requirements for the transparency notices, including the content of the notices, are detailed in schedules 2 to 16.

Relevant authorities are required to evidence that they have properly exercised

the responsibilities and flexibilities conferred on them by the regime, to ensure that there is proper scrutiny and accountability of decisions made about the procurement of health services. This section sets out the steps that relevant authorities must take to be transparent in their procurement process under this regime.

There are several elements to the transparency requirements under this regime – these apply differently according to which procurement process is being applied. **Annex B** provides detailed information about the transparency requirements for all processes under the regulations. Relevant authorities must follow the transparency requirements relevant to the approach being followed.

In all circumstances, relevant authorities must keep internal records of their procurement processes and must publish notices confirming their decision to award a contract.

When following the most suitable provider process relevant authorities must also make their intentions clear in advance by submitting a notice for publication.

When following direct award process 2, the most suitable provider process and the competitive process (including when concluding a framework agreement and when awarding a contract based on a framework agreement using the competitive process) relevant authorities must also communicate their decision to award a contract publicly and observe a standstill period during which representations can be made. The standstill period must end before contracts can be awarded.

All transparency notices referred to in this section must be published using the central digital platform, Find a Tender Service (FTS) by first submitting a notice on the Welsh digital platform, Sell 2 Wales (S2W). Should the Welsh digital platform (S2W) be unavailable, a relevant authority may publish a notice or information on the central digital platform (FTS) or on the central digital platform (FTS) by using an alternate online system. Where the Welsh digital platform is unavailable, this is to be considered as meeting the requirement to submit a notice for publication once specific conditions are met.

Where the central digital platform is unavailable, a relevant authority may submit a notice for publication on the Welsh digital platform only, or if the Welsh digital platform is also unavailable, on an alternative online system. A relevant authority using the Welsh digital platform (S2W) or an alternate online system must cooperate with the Cabinet Office to ensure the notice or information is subsequently published on the central digital platform and accessible by providers and members of the public. If using an alternate system to FTS or S2W, relevant authorities are also required to ensure that such a system publishes information that is free of charge and is readily accessible to providers and disabled people. Should the Cabinet Office reject the submission of a notice or information, the relevant authority's publication will no longer be considered as meeting the requirement to submit a notice for publication as set out in the regulations.

The information that must be included in the notices is set out in **annex B** and relevant authorities should refer to the separate guide to publishing these notices on the central digital platform (FTS).

In addition to the notices required under the various procurement processes, relevant authorities must publish notices when they are abandoning a procurement process, making an urgent award or contract modification, or undertaking certain non-urgent contract modifications. **Annex B** contains further information about the requirements for each of these scenarios.

Keeping records of procurement processes

> The relevant information requirements are detailed in regulation 26.

Relevant authorities must make and keep clear records detailing their procurement process and rationale. This must be done for all procurement processes (direct award process 1, direct award process 2, the most suitable

provider process, and the competitive process), when concluding a framework agreement, and when awarding a contract based on a framework agreement regardless of whether it was done with or without competition. This includes where a procurement process was abandoned or where the relevant authority decided to return to an earlier step in the process. Records must include:

- the name of the provider to which the contract has been awarded or the name of any provider who is a party to a framework agreement and either the address of their registered office or principal place of business
- the procurement process followed to select a providers, including details of the procedure used when the competitive process is followed
- the reasons for decisions made under the regulation
- particulars of any excluded or excludable providers
- the reasons for an excludable provider being excluded or not from a procurement process
- where a contract has been awarded or a framework agreement concluded with an excluded provider because it was considered necessary to protect public health, a description of this decision
- details of the individuals making decisions (this may be the name of a committee or job titles of individuals making the decision, as appropriate)
- any declared or potential conflicts of interest for individuals involved in the procurement process and how these were managed or will be managed
- where a procurement is abandoned, the date on which it was abandoned

Relevant authorities should ensure that records are kept when contracting for mixed procurements, including how the procurement meets the requirements for mixed procurements under this regime.

When following direct award process 2 or the most suitable provider process, records must also include a description of the way in which the key criteria (such as weighting, hierarchy, or more informal description of importance) were taken into account, and how the basic selection criteria were assessed when making decisions. This includes the relative importance of the key criteria that the relevant authority used to make a decision, the rationale for the relative importance of the key criteria, and the rationale for choosing the provider with

reference to the key criteria.

When following the competitive process (including when concluding a framework agreement or when awarding a contract based on a framework agreement following the competitive process), records must also include a description of the way in which the key criteria were taken into account, the basic selection criteria were assessed, and contract or framework award criteria were evaluated when making a decision. We expect that this includes the relative importance of the key criteria that the relevant authority used to make a decision, the rationale for the relative importance of the key criteria, and the rationale for choosing the provider with reference to the key criteria.

When concluding a framework agreement, we expect that records include the terms and conditions that will be laid down by the framework agreement and which relevant authorities are included on the framework agreement.

When awarding a contract from a framework agreement, records should include which framework agreement the contract is being awarded from.

Relevant authorities must be aware that they may need to disclose information on the rationale for their decision-making under the regulations if a representation is made (see **standstill period**). We expect relevant authorities to keep their records for a period that is in line with their organisation's record keeping policies and any applicable legislation.

Relevant authorities are also expected to keep records of their decisions and procurement processes when modifying a contract.

Keeping records of procurement processes in urgent circumstances

When awarding or modifying a contract in an urgent circumstance, relevant authorities must make and keep clear records detailing their procurement process and rationale. Records must include:

- justification for using the urgent circumstances exemption
- name of the providers to which the contract has been awarded and either the address of its registered office or principal place of business
- the approach taken to select a provider and the process followed (that is urgent award or modification)
- the estimated lifetime value of the contract or modification, and where the records refer to an urgent modification, any change in value or length of the contract
- details of the individual/individuals making the decision (this may be the name of a committee or job titles of individuals making the decision, as appropriate)
- any declared or potential conflicts of interest of individuals making the decision (not including individual names) and how these were managed or are to be managed

We expect that records are kept when contracting for mixed procurements, including how the procurement meets the requirements for mixed procurements under this regime.

Annual summary

> The annual summary requirements are set out in regulation 27.

Relevant authorities must publish a summary of their application of the regulations annually online (such as via the relevant authorities annual reports or annual governance statement). The first annual summary should relate to contracts awarded using the regulations between 28 October 2024 to 31 March 2025, and should be published no later than 6 months following the end of 2024 to 2025 financial year. Following the first annual summary, all other annual summaries must be published no later than 6 months following the end of the

financial year to which it relates.

This must include, in the year to which the summary relates, the:

- number of contracts directly awarded under direct award process 1 and direct award process 2
- number of contracts awarded under the most suitable provider process
- number of contracts awarded under the competitive process
- number of framework agreements concluded
- number of contracts awarded based on a framework agreement
- number of framework agreements where a competitive process was completed to allow further providers to be party to the framework
- number of further providers (if any) that were selected to be party to the framework agreement
- number of urgent contracts awarded and urgent modifications (in line with the **urgent awards or contract modifications section**)
- number of new providers awarded contracts
- number of providers who ceased to hold any contracts with the relevant authority
- details of representations received, including:
  - the number of representations received in writing and during the standstill period in accordance with regulation 12(3)
  - a summary of the nature and outcome of those representations
- number of providers that were excluded from a procurement process
- number of providers that were excludable from a procurement process and of those the number that were excluded from a procurement process under regulation 21(3) or 22(4)

Monitoring requirements

> The monitoring requirements are set out in regulation 28.

Relevant authorities must monitor their compliance with the regulations. The results of the monitoring must be published online annually (and may be integrated into other annual reporting requirements) and include processes, decisions made under the regulations, contract modifications, and declaration and management of conflicts of interests. Relevant authorities may use internal auditors to fulfil these requirements.

If a compliance report finds instances of non-compliance, relevant authorities must put in place actions to address this issue and to improve adherence with the regime.

Section 6: reviewing decisions during the standstill period

Introduction to reviewing decisions during the standstill period

> The standstill period requirements, including for the reviewing of decisions, are detailed in regulations 12 and 14(4). Provision for independent expert advice is set out in regulation 25 (see the section on the **procurement feedback service**). This includes how the procurement feedback service may provide advice during the standstill period.

This section explains how certain decisions made under the regime can be reviewed during the standstill period before they are finalised, and how a contract is awarded under certain procedures.

What is the standstill period?

The standstill period must be observed once a notice of intention to make an award to a provider under direct award process 2, the most suitable provider process, or the competitive process has been published. This includes concluding a framework agreement or awarding a contract based on a framework agreement following a mini competition.

The standstill period follows a decision to select a provider and must end before the contract can be awarded. It gives time for any provider who might otherwise have been selected to provide the services to which the contract relates to make representations and for relevant authorities to consider and respond to those representations as appropriate. See the section below on receiving representations for further details.

The standstill period must last for a minimum period of 8 working days. The standstill period begins on the day the notice of intention to award a contract or conclude a framework agreement is published and, unless a written representation is made, ends at midnight of the 8th working day after the day the standstill period begins (see worked examples below). If any representations are received during this period, then the standstill period will remain open until the relevant authority provides any requested information, considers the representations, and makes a further decision.

Relevant authorities are expected to be aware of the process and timeline for the review of decisions under this regime and are expected to plan the arrangement of services accordingly. They are expected to ensure that the review of the procurement process can be completed, and the proposed contract awarded before the existing contract ends.

When does the standstill period end?

Care must be taken when calculating the end of the standstill period. The standstill period starts the day the publication of an intention to award a contract or conclude a framework agreement. Representations must be received before midnight on the 8th working day after that day.

The standstill period will end at midnight on the 8th working day, if:

- no representations are received by midnight on the 8th working day
- representations received do not meet the required conditions (set out below)

Where representations meeting the required conditions are received, the standstill period continues until the relevant authority:

- completes its review
- communicates its further decision (with reasons) to the provider who submitted the representations and to the provider to whom it intended at the beginning of the standstill period to award the contract to
- concludes it is ready to award the contract, or that it wishes to return to an earlier step in the procurement process or abandon the process

Where representations meeting the required conditions are received, the end of the standstill period must be at least five working days after the relevant authority has communicated its decision to the relevant providers. The minimum five working days' notice allows for providers that remain unsatisfied about the response given by a relevant authority to their representations to seek the involvement of the procurement feedback service (see **procurement feedback service**).

Where the relevant authority's decision is to award the contract (rather than return to an earlier step in the process or abandon the process), the standstill period should end when the relevant authority concludes it is ready to award the contract and there has been at least five working days since the relevant

authority communicated its further decision. Where, within five working days of receiving the relevant authorities further decision, the provider requests an independent review from the procurement feedback service, the standstill period should continue, other than in exceptional circumstances. See the **procurement feedback service** section for further details on its process and how to request a review.

If the procurement feedback service accepts the request, the standstill period should not end until the relevant authority makes a further decision having considered the advice provided by the procurement feedback service. The relevant authority must again give at least five working days' notice of its further decision before the standstill period can come to an end and the relevant authority proceeds to take forward its further decision.

The standstill period must end before a contract is awarded and a confirmation of the decision is published (or before returning to an earlier step in the process or abandoning a process). The transition of services must only take place after the standstill period has ended and the contract has been awarded.

Receiving representations

Providers may make a representation to the relevant authority within 8 working days following the start of the standstill period (that is 8 working days starting with the day the intention to award notice has been published). Providers cannot submit a representation after that period, even if the standstill period has been extended in response to a representation from another provider.

The purpose of making a representation is to seek a review of the decision made, to determine whether a relevant authority has applied the regime correctly and made an appropriate procurement decision.

Relevant authorities are only obliged to respond to representations that meet all the following conditions:

- the representation comes from a provider that might otherwise have been a provider of the services to which the contract relates
- the provider is aggrieved by the decision of the relevant authority
- the provider believes that the relevant authority has failed to apply the regime correctly and is able to set out reasonable grounds to support its belief
- the representation is submitted in writing (which includes electronically) to the relevant authority within 8 working days of the start of the standstill period

When awarding a contract based on a framework agreement, such as following a mini-competition, only providers that were party to the framework agreement and took part in the mini-competition but were unsuccessful, or were excluded from the mini-competition, may make a representation to the relevant authority.

If they wish, relevant authorities may also respond to representations that do not meet the conditions above.

Relevant authorities must follow the relevant transparency requirements for the approach they take and must keep internal records of their procurement process (see **transparency**).

Example of calculating the minimum length of the standstill period during which representations can be made

Example A

The intention to award a contract notice is published on Thursday 7 November 2024. The standstill period begins 7 November 2024. Representations can be made for up to 8 working days after the day the standstill period begins. Therefore, the standstill period would end at midnight on Tuesday 19 November 2024.

Example B

The intention to award a contract notice is published on Friday 8 November 2024. The standstill period begins 8 November 2024. Representations can be made for up to 8 working days after the day the standstill period begins. Therefore, the standstill period would end at midnight on Wednesday 20 November 2024.

Example C

The intention to award a contract notice is published on Wednesday 13 November 2024. The standstill period begins 13 November 2024. Representations can be made for up to 8 working days after the day the standstill period begins. Therefore, the standstill period would end at midnight on Monday 25 November 2024.

In each of the examples, midnight is the zero point in time when we start to build up 24 one-hour periods of time to make up a new day.

Considering representations

Relevant authorities should ensure that appropriate internal governance mechanisms are in place to deal with representations made against procurement decisions. To this end, relevant authorities should, where possible, ensure that decisions are reviewed by individuals not involved in the original decision. Where this is not possible, relevant authorities should ensure that at least one individual not involved in the original decision is included in the review process.

If the relevant authority is considering representations on the same issue from multiple providers, it may consider these together if appropriate.

Where a representation is received within the 8 working days of the standstill period starting, the relevant authority:

1. must ensure that the aggrieved provider is afforded an opportunity to explain or clarify its representation(s) if they are not clear
2. must provide any information requested by the provider that the relevant authority is required to keep under the regime (see record keeping) as soon as possible, except where this:
    - would prejudice the legitimate commercial interests of any person, including the relevant authority
    - might prejudice fair competition between providers
    - would otherwise be contrary to the public interest

Please note this provision sits alongside existing information and data collection and disclosure obligations, including those in the Freedom of Information Act 2000 and Data Protection Act 2018, which relevant authorities should consider in relation to the information and data they receive during a procurement process for relevant health services.

3. is expected to provide an indicative timeframe for when the representation might be considered, and when the provider might reasonably expect a decision to be made

The aggrieved provider that made the representations is expected to respond promptly and concisely to questions from the relevant authority about the points it has made, and if it cannot respond within a reasonable timeframe then it is expected to provide a justification. We expect the relevant authority to allow sufficient time and opportunity for the provider that made the representations to respond to questions from the relevant authority. In the event that the provider fails to respond/communicate, then it is for the relevant authority to decide whether to complete its assessment of the representations and communicate their decision to the provider.

Where a relevant authority has completed the above steps, they must then:

4. review the evidence and information used to make the original decision, taking into account the representations made
5. consider whether the representation has merit (for example, it identifies that the process has not been correctly followed or brings to light information that has a bearing on the decision reached)

Outcome of representations

Where the relevant authority finds that a representation has merit (such as it identifies that the process has not been followed correctly or brings to light information that has a bearing on the decision reached), it must further consider whether this impacts on the intention to award a contract to the selected provider. It must then decide whether to:

- enter into a contract or conclude the framework agreement as intended
- go back to an earlier step in the selection process, either to the start of the process or to where a flaw was identified, rectify this, and repeat that step and subsequent steps (see **repeating a step**)
- abandon the procurement process (see **abandoning a process**)

The relevant authority must communicate the decision described above promptly and in writing to:

- the provider that made the representation
- the provider to which the relevant authority intended at the beginning of the standstill period to award the contract, or all providers with which the relevant authority intended at the beginning of the standstill period to conclude the framework agreement

The standstill period can only end once the relevant authority has reviewed its decision, shared its conclusion (in writing) with the relevant providers, and concluded that it is ready to award the contract, or that it's going to return to an earlier step in the process, or abandon the process.

The relevant authority must allow at least five working days following the day on which they sent their response to the provider before the standstill period comes to an end. This time allows the provider to consider the response of the relevant authority, seek further clarifications, and to consider whether to request a further review by the Procurement Feedback Service (PFS). This time also allows the relevant authority to reconsider their decision and make any subsequent decisions if necessary. The relevant authority must communicate any such further decision in writing to the provider (as outlined above).

If a PFS review is requested and accepted, then the standstill period would usually continue until after the PFS has given its advice and the relevant authority has made a further decision in light of that advice.

Procurement feedback service

If a provider remains unsatisfied about the response given by a relevant authority to their representations, then that provider may seek the involvement of the PFS. The PFS may consider whether the relevant authority complied with the regulations and may provide advice to the relevant authority. The relevant authority should then make a further decision about how to proceed.

> Further detail on how the PSR Wales will operate within the PFS function is currently being considered by Welsh Government in conjunction with the wider procurement reforms taking place as part of the Procurement (Wales) Regulations 2024.
>
> The processes set out below may be subject to change once the final details on the operation of the PFS function and the regulations are confirmed prior to the commencement of the regime.
>
> Relevant authorities are advised to check the details in the statutory

guidance at the point of commencement of the regulation.

The regulations review process of the procurement feedback service

If a provider wishes to request the Procurement Feedback Service (PFS) to consider their representation further, then they must submit their request within five working days of receiving the relevant authority's decision following the relevant authorities review of their representation. If the provider submits a request for advice from the PFS, the relevant authority will be notified, and the relevant authority should:

- keep the standstill period open for the duration of the panel's review
- make a further decision once it has considered the independent expert advice from the PFS

In exceptional circumstances, the relevant authority may conclude that it is necessary to enter a new contract before the PFS can complete its review and share its advice. In those circumstances, the relevant authority is expected to note the advice of the PFS for the next time they use the regulations to arrange health services.

Where multiple providers seek the involvement of the PFS in relation to the same procurement process, the PFS may choose to address the points raised by each provider individually or consider all the points together. The standstill period should continue until the last advice is provided (unless in exceptional circumstances).

If the provider does not submit their request to the PFS within the five working day period of receiving the relevant authority's decision following the relevant authorities review of their representation, or the PFS does not accept the request for advice, then the relevant authority can bring the standstill period to

an end and proceed to award the contract to their chosen provider.

Urgent contract modifications during the standstill period

Where the relevant authority is awaiting the advice of the PFS during the standstill period, the relevant authority may urgently modify the existing contract in accordance with regulation 14(3), subject to all the below applying:

- there is an existing contract for the health services to which the proposed contracting arrangement relates, and the relevant authority considers that the term of the existing contract is likely to expire before the end of the standstill period
- the relevant authority considers it necessary or expedient to modify the existing contract prior to the proposed contract taking effect to ensure continuity between the existing contract and award of the proposed contract
- the relevant authority considers that it is not possible to satisfy the requirements of regulations 7 to 13 before the term of the existing contract expires

The relevant authority may only extend the length of the existing contract and must not otherwise modify the contract. The relevant authority is expected to only extend the contract for as long as necessary to ensure continuity between the existing contract and the proposed contract.

Outcome of procurement feedback service review

Once the relevant authority has considered the advice of the PFS, it may make a further decision, to be its final decision, replacing the previous decision, to either:

- enter a contract or conclude the framework agreement as intended
- go back to the start of the procurement process or to the step where a flaw was identified, and repeat that step and subsequent steps (see **repeating a step in a procurement process**)

- abandon the procurement (see **abandoning a procurement process**)

The relevant authority must share this further decision promptly, in writing, with reasons, with the provider who made a representation and the provider to which the relevant authority intended, at the beginning of the standstill period, to award the contract. The relevant authority must set out the outcome and a full and transparent justification for their decision, and it is expected that this will include whether they changed their original decision because of the advice of the PFS. After sharing the further decision, the relevant authority must wait at least five working days before concluding it is ready to award the contract and bring the standstill period to an end, or before it returns to an earlier step in the process, or before it abandons the procurement.

Section 7: modification of contracts and framework agreements

Overview

> The requirements for the modification of contracts or framework agreements during their term are detailed in regulation 13.

There will be situations where contracts or framework agreements need to be modified to reflect or account for changes to services or circumstances during their term.

One aim of the regime is to avoid processes that only bring limited value to people who use the services. Therefore, this regime allows for certain modifications to be made to contracts or framework agreements during their term without the need for a new procurement process.

Depending on circumstances, permitted modifications can be made without following a new procurement process, but some cases will require the publication of notices.

Modifications which make an existing contract or framework agreement materially different in character are not permitted under the regime and require a new procurement process to be undertaken. Further information on permitted and not permitted modifications is given below.

Relevant authorities are expected to consider this section in conjunction with the modifications (variations) provisions of the relevant contract or sub-contract (for example, the variation of the contract/specification of the NHS Wales standard terms and conditions).

The provisions in this section must only be used for modification of contracts during their term and not to circumvent the regulations when a contract ends and a new one needs to be awarded.

Permitted modifications

Under this regime, some modifications are permitted and do not require a new procurement process.

Modifications to contracts originally awarded under direct award process 1

Where the original contract was awarded under direct award process 1 and the modification does not materially alter the character of the contract, then the modification is permitted.

If that modification is attributable to a decision of the relevant authority and the cumulative change in the estimated lifetime value of the contract since it was

entered into is £500,000 or more, the modification is still permitted, but the relevant authority must publish a notice.

Modifications to contracts originally awarded under direct award process 2 or the most suitable provider process, or contracts or framework agreements originally awarded or concluded under the competitive process, or to contracts or framework agreements that were originally awarded or concluded under the Public Contracts Regulations 2015

Where the original contract was awarded under direct award process 2 or the most suitable provider process, or contracts or framework agreements originally awarded or concluded under the competitive process (including framework agreements) or the public contracts regulations 2015, then modifications are permitted in the following instances:

- the modification is clearly and unambiguously provided for in the contract or framework agreement documents (that is the scope and nature of the potential change has been described in detail in the existing contract)
- the modification is solely a change in the identity of the provider due to succession into the position of provider following corporate changes (such as as the result of a corporate takeover, merger, acquisition or insolvency), and where the relevant authority is satisfied that the provider meets the basic selection criteria
- the modification does not render the contract or framework agreement materially different in character and is made in response to external factors beyond the control of the relevant authority and the provider, including but not limited to changes in:
    1. patient or service user volume
    2. prices in accordance with a formula provided for in the contract documents (such as index linking)
- the modification is attributable to a decision of the relevant authority, does not materially alter the character of the contract or framework agreement,

and the cumulative change in the estimated lifetime value of the contract or framework agreement is under £500,000 or under 25% when compared to the estimated lifetime value of the contract or framework agreement when it was entered into or concluded

If the relevant authority makes a permitted modification to a contract that was originally awarded under direct award process 2 or the most suitable provider process, or to contract or framework agreement that was originally awarded or concluded under the competitive process or the Public Contracts Regulations 2015), it must publish a notice where all the below apply:

- that modification is attributable to a decision of the relevant authority
- the cumulative change in the estimated lifetime value of the contract or framework agreement is £500,000 or more

Cumulative change is the value of all permitted modifications under the regulations when added to the estimated lifetime value of the contract or framework agreement since it was entered into or concluded. For example, if the estimated lifetime value of a contract is £1m at the time the agreement was entered into, a modification has been made to the contract that was attributable to a decision of the relevant authority to the value of £350,000 (35%) the cumulative change value is £350,000. Should a further modification to the contract be required that is attributable to a decision of the relevant authority, the value of that change must not exceed £150,000 in value as this would result in the cumulative change in the estimated lifetime value of the contract being £500,000 and 50% of the lifetime value of the contract when it was entered into. Therefore, further modifications with a value greater than £150,000 would exceed the permitted modification values under the regulations.

To note:

- contracts entered before the commencement of the regulations must be modified in accordance with this regime

Modifications that are not permitted

Where the decision to make the modification is attributable to the relevant authority and that modification makes the existing contract or framework agreement materially different in character, the modification is not permitted under this regime and a new procurement process will need to be undertaken.

In addition, modifications are not permitted where the original contract was awarded following direct award process 2 or the most suitable provider process, or the original contract or framework agreement was awarded or concluded following the competitive process or under the Public Contracts Regulations 2015, and where the modification represents:

- a cumulative change in the estimated lifetime value of the contract or framework agreement when it was entered into or concluded of £500,000 or more
- a cumulative change in the estimate lifetime value of the contract or framework agreement when it was entered into or concluded of 25% or more

In such a case, a new procurement process will need to be undertaken and the relevant authority must follow the appropriate procurement process to select a provider (or group of providers) for the substantially changed service.

Examples of modifications to existing contract awards under regulation 13(4)(d)

Example 1

A relevant authority enters into a contract with an estimated lifetime value of £5million when the contract was entered into. There have been no modifications to the contract thus far. The relevant authority proposes to modify the contract. The modification does not render the contract materially different in character,

and the modification is valued at £600,000. While this modification is over £500,000, it only represents 12% of the estimated lifetime value of the existing contract when that contract was entered into. Therefore, the modification is allowable under regulation 13(4)(d).

Example 2

A relevant authority enters into a contract with an estimated lifetime value of £4million. The contract has previously been modified, with modifications thus far totalling £600,000, which represents a cumulative change in the estimated lifetime value of the contract of 15%. No single modification has exceeded £500,000 thus far. The relevant authority proposes to modify the contract further. The modification does not render the contract materially different in character. This modification's estimated lifetime value is £600,000, which when combined with the previous modifications, exceeds the £500,000 change in cumulative value of the estimated lifetime value of the contract. The cumulative change in value (now £1.2million) represents a 30% increase, therefore is more than the allowable 25%. This modification is therefore not allowable under regulation 13(4)(d).

Example 3

A relevant authority has a contract value of £1million. This contract has not previously been modified. The relevant authority proposes to modify the contract. The modification has an estimated lifetime value of £600,000. This exceeds the £500,000 cumulative change limit and represents a 60% cumulative change to the estimated lifetime value of the contract. This modification is therefore not allowable under regulation 13(4)(d).

Contract modifications in urgent situations

Contract modifications may need to be made urgently. In these circumstances, relevant authorities must still be transparent about their procurement process. Details of when contracts can be modified on the basis of urgent situations and what needs to be published and when, can be found in the **urgent awards or contract modifications sections**.

Section 8: conflicts of interest

Overview

> The conflicts of interest requirements are detailed in regulation 23.

The routine declaration and management of conflicts of interest is a key aspect of good governance, and critical both in maintaining public confidence in procurement processes and in protecting staff, councillors, executives, and trustees from allegations that they have acted inappropriately.

Relevant authorities must take appropriate measures to effectively prevent, identify and remedy conflicts of interest arising during the application of the regulations. Relevant authorities must ensure that their governance arrangements for making procurement decisions can manage conflicts that arise. They may wish to give board committees or non-executive directors (or other senior persons independent of the procurement process) a role in managing and resolving conflicts of interest relating to procurement decisions.

The way conflicts of interest are managed needs to be sympathetic to the vision of joint working set out in "a healthier Wales" and to the planned vision to bring

seamless local health and social care. Therefore, relevant authorities should follow and have regard to that vision and plan when managing conflicts of interest around procurement decisions.

Conflicts of interest are defined in regulation 23(3) as including:

> “ […] any situation where an individual has, directly or indirectly, a financial, economic, or other personal interest which might be perceived to compromise their impartiality and independence in the context of the procurement process. ”

Any such individual is required to recuse themselves from the procurement process, unless the individual meets one of the conditions as set out in regulation 23(6), namely:

- the individual is the only person with expertise in an area that requires assessment in accordance with the contract or framework agreement award criteria
- the individual is the only person with the appropriate qualifications or knowledge available to act in relation to a procurement process

Should one or both of the above conditions be met, a relevant authority may determine that the individual is not required to recuse themselves and that the relevant authority will take reasonable steps to ensure that the conflict of interest does not put a provider at an unfair advantage or disadvantage in relation to the procurement process. Reasonable steps may include requiring a provider to take necessary measures to ensure that they are not put at an unfair advantage or disadvantage.

Where a relevant authority considers that a conflict of interest puts a provider at an unfair advantage in relation to the award of a public contract and the provider will not take steps that the relevant authority considers necessary to ensure that the provider is not at an unfair advantage, the relevant authority must (in relation to the award of a contract or conclusion of a framework) treat the provider as an

excluded provider. As a result, the relevant authority must not award a contract to the provider under direct award process 1 or 2, assess any such provider under the most suitable provider process, or assess any offers from any such provider under the competitive process.

We advise this section is read in conjunction with other relevant regulations and statutory guidance, as applicable to relevant authorities.

Principles of management

We expect the management of conflicts of interest to be based on the following principles:

1. All decisions made under this regime must be clearly and objectively directed towards meeting the statutory functions and duties of relevant authorities directed towards the delivery of a service which the relevant authority has power to provide. Individuals involved in decisions relating to these functions are expected to act clearly in service of those functions and duties, rather than furthering their own direct or indirect financial, economic, or other personal, professional, or organisational interests.
2. The personal and professional interests of all individuals involved in decisions about procurement need to be declared, recorded, and managed appropriately, following the relevant authority's established conflicts of interest arrangements. This includes being clear and specific about the nature of any interest and of any conflict that may arise regarding a particular decision, and how any conflicts are managed for each decision. To fulfil the transparency requirements under this regime, relevant authorities must keep internal records of individuals' conflicts of interest, how these were managed or how they will be managed (see **transparency**).
3. Any conflicts of interests and how they were or are to be managed must be published alongside the confirmation of the decision to select a provider (see **transparency**). When the decision is made by a committee/group, it is advised that the interests of the committee/group are declared and not the

names of individuals in the committee/group to whom they relate. When the decision is made by an individual, it is advised that conflicts of interest are declared against the individual's job title rather than their name.

4. Actions to mitigate conflicts of interest when making procurement decisions are expected to be in line with the regulations, proportionate and to seek to preserve the spirit of collective procurement decisions wherever possible. Mitigating actions are expected to account for a range of factors, including the impact that the perception of an unsound decision might have, and the risks and benefits of having a particular individual involved in making the decision. Mitigations may include:
    - excluding a conflicted person from both the discussion and the procurement process, where the conditions set out under regulation 23(6) are not met or do not apply
    - excluding the conflicted individual and securing technical or local expertise from an alternative, unconflicted source, where the conditions set out under regulation 23(6) are not met or do not apply
    - arranging procurement decision structures so a range of views and perspectives are represented, rather than potentially conflicted individuals being in the majority
    - convening a committee without the conflicted individual present, such as when dealing with particularly difficult or complex decisions where members may not be able to agree, or to prevent an unsound decision being taken and/or the appearance of bias
5. We expect relevant authorities to distinguish clearly between those individuals who are involved in a formal procurement process and those whose input informs decisions but who are not involved in a procurement process itself (such as through shaping the relevant authority's understanding of how best to meet patients' needs and deliver care for its population). The way conflicts of interest are managed is expected to reflect this distinction. For example, where independent providers (including those in the Voluntary, Community and Social Enterprises (VCSE) sector) hold contracts for services, it would be appropriate and reasonable for the relevant authority to involve them in discussions, such as about pathway design and service delivery, particularly at placement level. However, this

would be clearly distinct from any considerations around contracting and commissioning, from which they would be excluded.

6. Where decisions are being taken under the competitive process, any individual who is associated with an organisation that has a vested interest in the procurement must recuse themselves from the procurement process during that procurement process, where the conditions set out under regulation 23(6) are not met or do not apply.
7. The way conflicts of interest are declared and managed is expected to contribute to a culture of transparency about how decisions are made.

Section 9: urgent award or contract modifications

Urgent award or contract modifications

> The requirements for an urgent award or contract modification are detailed in regulations 14(1), 14(2), and 14(4).

There are limited occasions where relevant authorities may need to act urgently and award or modify contracts to address immediate risks to patient or public safety.

These circumstances include where:

- a new service needs to be arranged rapidly in an unforeseen emergency or local, regional, or national crisis, such as to deal with a pandemic
- urgent quality or safety concerns pose risks to patients or the public and necessitate rapid changes
- an existing provider is suddenly unable to provide services under an existing contract (such as a provider becomes insolvent or experiences a sudden lack of critical workforce) and a new provider needs to be found

In urgent situations, relevant authorities may make the following decisions without following the steps required under this regime:

- re-award contracts held by the existing providers
- award contracts for new services
- award contracts for considerably changed services
- make contract modifications (without limitation)

An urgent award or modification of a contract must only be made by a relevant authority when all the below apply:

- the award or modification must be made urgently
- the reason for the urgency was not foreseeable by and is not attributable to the relevant authority
- delaying the award of the contract to conduct a full application of the regime would be likely to pose a risk to patient or public safety

Relevant authorities must not use the urgent award or contract modification provisions in this regime if the urgency is attributable to the relevant authority not leaving sufficient time to make procurement decisions or run a procurement process – poor planning is not an acceptable reason to use these provisions.

In these urgent circumstances, relevant authorities:

- Are expected to limit the contract term or contract modification term to that which is strictly necessary. This is advised to be long enough to address the urgent situation and to conduct a full application of the regulations for that service at the earliest feasible opportunity. We anticipate that contracts awarded under regulation 14 will have a duration of no longer than 12 months. If the duration is to be longer, relevant authorities must justify and record this decision.
- Must keep records of their procurement process, including a justification for using an urgent award (see **transparency** and **annex B**).
- Must be transparent about their decision through issuing an urgent award notice (see **transparency** and **annex B**).

Relevant authorities may also make specific urgent modifications to extend the length of an existing contract during the standstill period if advice is being sought from the procurement feedback service, in accordance with regulation 14(3).

Section 10: termination of contracts

Termination of contracts

> The requirements for contract terminations are set out in regulation 24.

Relevant authorities must ensure that each contract awarded contains provisions enabling its termination by the relevant authority if:

- the contract requires modification but the modification is not permitted under the regime (see **contract modifications**) without following a new procurement process
- the provider, at the time of the contract award, should have been excluded from the procurement process in line with the **exclusion criteria** set out in regulation 21 and 22

The provisions allowing the termination of a contract may address how such terminations would take place, such as by setting out notice for terminations and by addressing any consequential matters that may arise from that termination. If the contract does not contain specific provisions allowing the relevant authority to terminate on the grounds specified above, there is an implied term of any contract awarded under the regulations that the relevant authority may do so by giving reasonable notice.

Annex A: common procurement vocabulary codes

Annex A: common procurement vocabulary (CPV) codes

> The CPV codes are listed in Schedule 1.

The CPV codes adopted by the regulations were defined by **Regulation (EC) No 2195/2002 of the European Parliament and of the Council** as amended from time to time.

Health services in scope of the regime must fall within one or more of the adopted CPV codes.

The list below of CPV codes corresponds to services covered by the regime. This list must be used by relevant authorities to support decisions around scope. Relevant authorities must use the most specific CPV code they can, rather than an overarching one. For example, where relevant authorities are commissioning cycles for in vitro fertilisation, relevant authorities must use the CPV code for "in vitro fertilisation" rather than one for "gynaecologic or obstetric services". However, as the list of CPV codes does not cover all types of health services, relevant authorities may in some situations use the overarching parent code for "health services" when a more detailed CPV code is not available. If a more detailed CPV code is available, but not included in the list below, then the service is out of scope.

CPV code 85100000-0

Description:

Health services.

CPV code 85110000-3

Description:

Hospital and related services.

CPV code 85111000-0

Description:

Hospital services.

CPV code 85111100-1

Description:

Surgical hospital services.

CPV code 85111200-2

Description:

Medical hospital services.

CPV code 85111300-3

Description:

Gynaecological hospital services.

CPV code 85111310-6

Description:

In vitro fertilisation services.

CPV code 85111320-9

Description:

Obstetrical hospital services.

CPV code 85111400-4

Description:

Rehabilitation hospital services.

CPV code 85111500-5

Description:

Psychiatric hospital services.

CPV code 85111600-6

Description:

Orthotic services.

CPV code 85111700-7

Description:

Oxygen-therapy services.

CPV code 85111800-8

Description:

Pathology services.

CPV code 85111810-1

Description:

Blood analysis services.

CPV code 85111820-4

Description:

Bacteriological analysis services.

CPV code 85111900-9

Description:

Hospital dialysis services.

CPV code 85112200-9

Description:

Outpatient care services.

CPV code 85120000-6

Description:

Medical practice and related services.

CPV code 85121000-3

Description:

Medical practice services.

CPV code 85121100-4

Description:

General-practitioner services.

CPV code 85121200-5

Description:

Medical specialist services.

CPV code 85121210-8

Description:

Gynaecologic or obstetric services.

CPV code 85121220-1

Description:

Nephrology or nervous system specialist services.

CPV code 85121230-4

Description:

Cardiology services or pulmonary specialist services.

CPV code 85121231-1

Description:

Cardiology services.

CPV code 85121232-8

Description:

Pulmonary specialist services.

CPV code 85121240-7

Description:

ENT or audiologist services.

CPV code 85121250-0

Description:

Gastroenterologist and geriatric services.

CPV code 85121251-7

Description:

Gastroenterologist services.

CPV code 85121252-4

Description:

Geriatric services.

CPV code 85121270-6

Description:

Psychiatrist or psychologist services.

CPV code 85121271-3

Description:

Home for the psychologically disturbed services.

CPV code 85121280-9

Description:

Ophthalmologist, dermatology or orthopaedics services.

CPV code 85121281-6

Description:

Ophthalmologist services.

CPV code 85121282-3

Description:

Dermatology services.

CPV code 85121283-0

Description:

Orthopaedic services.

CPV code 85121290-2

Description:

Paediatric or urologist services.

CPV code 85121291-9

Description:

Paediatric services.

CPV code 85121292-6

Description:

Urologist services.

CPV code 85121300-6

Description:

Surgical specialist services.

CPV code 85130000-9

Description:

Dental practice and related services.

CPV code 85131000-6

Description:

Dental-practice services.

CPV code 85131100-7

Description:

Orthodontic services.

CPV code 85131110-0

Description:

Orthodontic-surgery services.

CPV code 85140000-2

Description:

Miscellaneous health services.

CPV code 85141000-9

Description:

Services provided by medical personnel.

CPV code 85141100-0

Description:

Services provided by midwives.

CPV code 85141200-1

Description:

Services provided by nurses.

CPV code 85141210-4

Description:

Home medical treatment services.

CPV code 85141211-1

Description:

Dialysis home medical treatment services.

CPV code 85141220-7

Description:

Advisory services provided by nurses.

CPV code 85142000-6

Description:

Paramedical services.

CPV code 85142100-7

Description:

Physiotherapy services.

CPV code 85143000-3

Description:

Ambulance services.

CPV code 85144000-0

Description:

Residential health facilities services.

CPV code 85144100-1

Description:

Residential nursing care services.

CPV code 85145000-7

Description:

Services provided by medical laboratories.

CPV code 85146000-4

Description:

Services provided by blood banks.

CPV code 85146100-5

Description:

Services provided by sperm banks.

CPV code 85146200-6

Description:

Services provided by transplant organ banks.

CPV code 85148000-8

Description:

Medical analysis services.

CPV code 85149000-5

Description:

Pharmacy services, but not including community pharmacy services that are arranged under the **National Health Service (Pharmaceutical Services) (Wales) Regulations 2020**.

CPV code 85150000-5

Description:

Medical imaging services.

CPV code 85160000-8

Description:

Optician services.

CPV code 85323000-9

Description:

Community health services, but only in respect of community health services which are delivered to individuals.

CPV code 85312330-1

Description:

Family-planning services, but only insofar as such services are provided to individuals to support sexual and reproductive health.

CPV code 85312500-4

Description:

Rehabilitation services, but only insofar as such services are provided to individuals to tackle substance misuse or for the rehabilitation of the mental or physical health of individuals.

Annex B: transparency

Transparency requirements

> Regulation 20 sets out the process to be followed where relevant authorities are required to submit a notice for publication under the regulations.
>
> The requirements for the notices, including the content of the notices, are detailed in schedules 2 to 16.

The steps outlined in the regulations and the transparency requirements must be adhered to. Relevant authorities are required to evidence that they have properly exercised the responsibilities and flexibilities conferred on them by the regime, to ensure that there is proper scrutiny and accountability of decisions made about health services. This annex sets out the steps that relevant authorities must take to be transparent in their procurement process under this regime. Relevant authorities must follow the transparency requirements relevant to the approach being followed.

All notices referred to in this section must be published using the central digital platform, Find a Tender Service (FTS) by first submitting a notice on the Welsh digital platform, Sell 2 Wales (S2W). Should the Welsh digital platform (S2W) be unavailable, a relevant authority may publish a notice or information on the central digital platform (FTS) or on the central digital platform (FTS) by using an alternate online system. Where the Welsh digital platform is unavailable, this is to be considered as meeting the requirement to submit a notice for publication once specific conditions are met.

Where the central digital platform is unavailable, a relevant authority may submit a notice for publication on the Welsh digital platform (S2W) only, or if the Welsh

digital platform is also unavailable, on an alternate online system. A relevant authority using the Welsh digital platform or an alternate online system must cooperate with the Cabinet Office to ensure the notice or information is subsequently published on the central digital platform and accessible to providers and members of the public. If using an alternate system to FTS or S2W, relevant authorities are also required to ensure that this system publishes information that is free of charge, readily accessible to providers and disabled people.

Should the Cabinet Office reject the submission of a notice, the relevant authority's publication will no longer be considered as meeting the requirement to submit a notice for publication as set out in the regulations.

Table 1: notices that require publication under the regulations processes

Notices needed for the award of contracts under the procurement processes:

	Direct award process 1	Direct award process 2	Most suitable provider process	Competitive process
Clear intentions: publish a notice of the intended approach in advance			Yes	
Clear intentions: publish a notice inviting offers for a competitive tender				Yes
Communicating decisions: publish a notice of the intention to award		Yes	Yes	Yes

	Direct award process 1	Direct award process 2	Most suitable provider process	Competitive process
Confirming decisions: publish a notice confirming award	Yes	Yes	Yes	Yes
Contract modification: publish a notice for contract modifications	Yes	Yes	Yes	Yes

Notices needed for processed in relation to framework agreements:

	Establishing a framework agreement (following the competitive process)	Contracts based on a framework agreement without competition	Contracts based on a framework agreement following competition
Clear intentions: publish a notice inviting offers for a competitive tender	Yes		
Communicating decisions: publish a notice of the intention to award	Yes		Yes
Confirming decisions: publish a notice confirming award	Yes	Yes	Yes

	Establishing a framework agreement (following the competitive process)	Contracts based on a framework agreement without competition	Contracts based on a framework agreement following competition
Contract modification: publish a notice for framework modifications	Yes	Yes	Yes

Transparency requirements for direct award process 1 and for contracts based on a framework agreement without competition

Where relevant authorities are making decisions under direct award process 1, and when awarding a contract based on a framework agreement without competition, the following requirements must be observed.

> The content of the contract award notice that must be published in these direct award processes is set out in schedule 2.

The relevant authority must publish a notice of the award within 30 days of the contract award. This must be published in accordance with the procedure set out above (see **transparency requirements**), as a contract award notice.

The notice must include the information set out in schedule 2 to the regulations.

For the purposes of awarding a contract based on a framework agreement without competition, we expect the notice to also include whether:

- this is a new or existing service
- this is a new or existing provider

To note, when following direct award process 1, or when awarding a contract based on a framework agreement without competition (in accordance with the terms of that framework agreement), there is no requirement to make intentions clear in advance or to have a standstill period.

If the relevant authority cannot or does not wish to award a contract, they must follow the process for abandoning a procurement process.

Transparency requirements for direct award process 2

Where relevant authorities are making decisions under direct award process 2 the following requirements must be observed.

Intention to award (direct award process 2)

> The content of the intention to award notice is set out in schedule 3.

If the relevant authority intends to use direct award process 2, the relevant authority must publish a notice setting out its intention to award a contract using that procurement process. This must be published in accordance with the procedure set out above (see **transparency requirements**) as a contract award notice and must include the information set out in schedule 3 to the regulations.

We expect the notice to also include the dates between which the services are intended to be provided, if known.

The publication of the intention to award marks the start of the standstill period.

Notice following award (direct award process 2)

> The content of the notice following a contract award is set out in schedule 4.

Once the standstill period has ended the relevant authorities can award the contract. The relevant authority must publish a confirmation of the award within 30 days of the contract award. This must be published in accordance with the procedure set out above (see **transparency requirements**) as a corrigendum to the contract award notice (that was published prior to the standstill period as an intention to award) and must include the information set out in schedule 4 to the regulations.

If, following the standstill period, the relevant authority cannot or does not wish to award a contract, it must follow the process for abandoning a procurement process.

Transparency requirements for the most suitable provider process

Where relevant authorities are making decisions under the most suitable provider process, the following requirements must be observed.

Intention to follow the most suitable provider process

> The content of the intention to follow the most suitable provider process notice is set out in schedule 5.

After the relevant authority has decided to follow the approach for the most suitable provider process, it must publish its intention to follow this approach. This must be published in accordance with the procedure set out above (see **transparency requirements**) as a prior information notice, and must include the information set out in schedule 5 to the regulations.

The prior information notice for the most suitable provider process is not expected to include details of which provider(s) are under consideration as suitable providers.

The relevant authority must not proceed to assess providers until at least 14 days after the day on which the notice of intention is submitted for publication, so that providers are aware of the approach the relevant authority is taking to choose a provider.

Intention to award to the chosen provider under the most suitable provider process

> The content of the intention to award notice is set out in schedule 6.

After the relevant authority has selected a provider, it must publish its intention to award a contract. This must be published in accordance with the procedure

set out above (see **transparency requirements**) as a contract award notice, and must include the information set out in schedule 6 to the regulations.

We expect the notice to also include:

- whether this is a new or existing service
- whether this is a new or existing provider
- dates between which the services are intended to be provided, if known

The publication of the intention to award marks the start of the standstill period.

Notice following award (the most suitable provider process)

> The content of the notice following a contract award is set out in schedule 7.

Once the standstill period has ended, the relevant authority can award the contract. The relevant authority must publish a confirmation of the award within 30 days of the contract award. This must be published in accordance with the procedure set out above (see **transparency requirements**) as a corrigendum to the contract award notice (that was published prior to the standstill period as an intention to award), and must include the information set out in schedule 7 to the regulations.

If following the standstill period, the relevant authority cannot or does not wish to award a contract, it must follow the process for abandoning a procurement process.

Transparency requirements for the competitive

process

Where relevant authorities are making decisions under the competitive process, including in relation to the conclusion of a framework agreement, the following requirements must be observed.

Inviting Offers (the competitive process and when establishing a framework agreement)

> The content of the notice inviting bids is set out in schedule 8.

When the relevant authority has decided to follow the competitive process (including the establishment of a framework agreement), it must publish a notice that will initiate the competitive tender.

While not required, a relevant authority may publish a prior information notice (PIN) in advance of the notice of a competitive tender opportunity. If publishing a PIN, relevant authorities are advised to include details of the service required, the proposed contract length and any proposed provision for extension or early termination, and any other matters (known or anticipated) that are likely to be of interest to prospective providers.

The invitation to offer bids in a competitive tender must be published in accordance with the procedure set out above (see **transparency requirements**). The contract notice, or the documents provided in the content of the notice (e.g. tendering documents), must include the information set out in schedule 8 to the regulations.

Inviting offers (when awarding a contract based on a

framework agreement following the competitive process)

> The content of the notice inviting bids are detailed in schedule 15.

When awarding a contract based on a framework agreement following the competitive process, the relevant authority must invite all providers that are part of the framework agreement to submit an offer (bid). This invitation does not have to be published.

The invitation must include the information set out in schedule 15 to the regulations.

Intention to award (the competitive process, when establishing a framework agreement or when awarding a contract based on a framework agreement following the competitive process)

> The content of the intention to award notice is set out in schedule 10.

After the relevant authority has identified the successful provider(s) (including when establishing a framework agreement or awarding a contract based on a framework agreement), it must publish its intention to award a contract to the successful provider(s). This must be published in accordance with the procedure set out above (see **transparency requirements**) and must include the information set out in schedule 10 to the regulations.

We expect the notice to also include:

- whether this is a new or existing service
- whether this is a new or existing provider
- dates between which the services are intended to be provided, if known

Communication to unsuccessful providers

> The content of communications to unsuccessful providers is set out in schedule 9.

After having identified the successful provider(s), relevant authorities must communicate their decision in writing to unsuccessful providers before publishing the intention to award notice. Relevant authorities must provide unsuccessful providers with written information on why their bid was unsuccessful. This must include the information set out in schedule 9 to the regulations.

We advise that an address to which written representations should be sent is also provided in the communication (which may be an email address).

Relevant authorities may also choose to give feedback to unsuccessful providers on what they did well and what they could have done to improve their bid.

The publication of the intention to award notice marks the start of the standstill period. When awarding a contract based on a framework agreement, e.g. following a mini-competition, only providers that were party to the framework agreement and took part in the mini-competition but were unsuccessful, or were excluded from the mini-competition, may make a representation to the relevant authority.

Notice of award following a competition (the competitive process, when establishing a framework agreement, and when awarding a contract based on a framework agreement following the competitive process)

> The content of the notice confirming the decision following the competitive process is set out in schedule 11.

Once the standstill period has ended, the relevant authority can award the contract (including those awarded based on a framework agreement) or conclude the framework agreement. The relevant authority must publish a notice confirming the award within 30 days of the contract award. This must be published in accordance with the procedure set out above (see **transparency requirements**) as a corrigendum to the contract award notice (that was published prior to the start of the standstill period as an intention to award), and must include the information set out in schedule 11 to the regulations.

If following the standstill period, the relevant authority cannot or does not wish to award a contract, the relevant authority must follow the process for abandoning a procurement process.

Transparency requirements for abandoning a procurement process

> The content of the notice confirming the decision to abandon a procurement process is set out in schedule 16.

Where relevant authorities are abandoning a procurement process, the following transparency requirements apply.

Relevant authorities must publish a confirmation of the decision to abandon the procurement process and not to award a contract. This must be published in accordance with the procedure set out above (see transparency requirements) as a corrigendum to the last notice published, within 30 days of the decision, and must include the information set out in schedule 16 to the regulations.

Transparency requirements for contract or framework agreement modifications

> The content of a contract or framework agreement modification notice is set out in schedule 12.

Where relevant authorities are making a **contract modification** permitted under this regime that requires a notice, the requirements below must be observed.

Confirmation of modification

The relevant authority must publish a confirmation of the modification within 30 days of the contract modification. This must be published in accordance with the procedure set out above (see **transparency requirements**) as a modification notice, and must include the information set out in schedule 12 to the regulations.

Transparency requirements for urgent

circumstances

In some circumstances, relevant authorities may need to act rapidly to address immediate risks to safety and quality of care. See the **urgent award or contract modifications** section.

In these urgent circumstances relevant authorities must still be transparent about their procurement process and follow the requirements below.

Confirmation of contract award in urgent circumstances

> The content of an urgent award notice is set out in schedule 13.

The relevant authority must publish a confirmation of the decision to award a contract in urgent circumstances within 30 days of the contract award. This must be published in accordance with the procedure set out above (see **transparency requirements**) as a contract award notice, and must include the information set out in schedule 13 to the regulations.

Confirmation of modification in urgent circumstances

> The content of an urgent modification notice is set out in schedule 14.

In urgent circumstances, relevant authorities must publish a confirmation of their decision to make a modification to a contract within 30 days of the contract modification being made (unless the modification is a permitted modification

without transparency, see **contract modifications**). This must be published in accordance with the procedure set out above (see **transparency requirements**) as a modification notice, and must include the information set out in schedule 14 to the regulations.

Annex C: primary care services

Annex C: primary care services

Annex C provides additional information about how the regime is expected to be applied when undertaking a procurement process for the delivery of primary care services, where those services are in scope of the regime.

Full details of annex C will be provided in due course.

Annex D: key criteria

Annex D: key criteria

> The key criteria are defined in regulation 6.

Further detail on the key criteria is set out below, detailing what is covered by each of the key criteria and matters that relevant authorities must give due consideration to when establishing their key criteria.

All the key criteria must be considered when following direct award process 2, the most suitable provider process, or the competitive process, and how they are considered must be recorded. We expect that none of the key criteria are

discounted. The regime does not specify how relevant authorities must balance the key criteria, however relevant authorities are expected be aware of wider requirements or duties when considering procurement decisions, such as:

- the **Social Partnership and Public Procurement (Wales) Act 2023**
- **a healthier Wales**
- the **Wales procurement policy statement**
- the Welsh Government's net **zero ambitions and carbon budget**
- the need to ensure value for money when arranging health services

The flexibilities offered by the regime do not mean that relevant authorities do not have to comply with those obligations.

Relevant authorities are expected to consider the weightings and their consequences when considering the service to be delivered, and before beginning a procurement process.

Criterion 1: quality

Quality

Relevant authorities must give due consideration to the quality of services to be provided by a provider.

What is high quality health services?

The **Welsh Government's quality and safety framework** refers to the characteristics of quality in healthcare that were described by the then Institute of Medicine in 1999. They are:

- safe: avoid harm
- effective: evidence based and appropriate

- person-centred: respectful and responsive to individual needs and wishes
- timely: at the right time
- efficient: avoid waste
- equitable: an equal chance of the same outcome regardless of geography, socioeconomic status and so on

These characteristics of quality align with our prudent health and care principles:

- achieve health and wellbeing with the public, patients, and professionals as equal partners through co-production (person centred)
- care for those with the greatest health need first, making most effective use of all skills and resources (timely, efficient, effective)
- do only what is needed: do no less, do no harm (safe, efficient)
- reduce inappropriate variation using evidence-based practices consistently and transparently (equitable, effective, efficient)

Relevant authorities are advised to consider relevant local and national information on the quality of the service provided, where available.

Relevant authorities are advised to consider the extent to which the desired outcomes in terms of quality will be maintained or improved because of the provider/arrangements being considered.

Where a new or innovative service is being considered and no data on quality is available, relevant authorities are advised to weigh the potential value of the new or innovative service against the risk that the service does not deliver the anticipated quality and understand how performance will be assessed, risks managed, and the service evaluated.

We advise that the procurement process for any new or innovative service includes an assessment of how the service will provide information or data on the quality-of-service provision and monitor safety of operations (given it will not be able to rely on existing methods or indicators).

Relevant authorities are advised to consider the provider's willingness and ability to identify, monitor and mitigate risks on an ongoing basis, engage with clinical

governance processes, and involve service users in service planning and oversight.

Assessing the evidence on quality

Assessing the quality of a provider's services is complex and requires a good understanding of the context in which those services are to be provided. It also requires an understanding of which evidence sources are available as well as which best provide evidence in relation to the provider in question.

Sources of information may include (but are not limited to):

- provider service model
- all recent regulator inspection reports (including any issues related to quality described in the report, overall quality ratings and data on innovation adoption), such as inspection reports from Health Inspectorate Wales (HIW), Care Inspectorate Wales (CIW) or the General Pharmaceutical Council
- HIW or CIW insight
- NHS Wales performance framework
- where commissioning a specialised service, all national clinical audits or outcome reviews relevant to that service
- contract management data
- key performance indicator (KPI) data, including data on equalities and health inequalities
- commissioner or lead provider satisfaction with quality delivered in previous contracts or subcontracts (where applicable)
- evidence that patients and unpaid carers with relevant lived experience are engaged as partners in improving experience and quality
- feedback about service delivery from patients and unpaid carers, including survey results, and action being taken in response
- data relating to the uptake of proven innovation

Regard for Llais representations

When considering relevant local and national information on the quality of the service provided, relevant authorities must have regard for any representations received from Llais.

Llais is an independent statutory body, set up by the Welsh Government to give the people of Wales more say in the planning and delivery of their health and social care services – locally, regionally, and nationally.

From 1 April 2023 Llais replaced the seven Community Health Councils who have represented the interests of people in the NHS in Wales for almost 50 years. Llais are building on the work of the community health councils with additional powers to grow the public's influence on shaping NHS services and social care services in Wales. Llais's work is driven by the concerns of the people of Wales, supporting and understanding concerns raised and ensuring that all are represented, in particular the voices of those that are not normally heard.

Section 15(1) of the **Health and Social Care (Quality and Engagement) (Wales) Act 2020** ("the 2020 act") provides the Citizen Voice Body (CVB) (operationally known as Llais) with a power to make representations to an NHS body and local authority (both of which are listed as relevant authorities for the purposes of the regulations) about anything it considers relevant to the provision of a health service or the provision of social services. Section 15(3) states that relevant authorities must have regard to representations made to them by Llais in exercising any function to which the representations relate.

In the context of the regulations, relevant authorities must have regard to such representations received from Llais which relate to any services commissioned by them from, or provided under contract by, third parties.

The statutory guidance accompanying the 2020 act provides that relevant authorities should have procedures in place to deal with such representations

and (in particular **paragraph 25**):

> “ make provision to share the [Llais] representations with appropriate responsible persons for the provider(s) concerned and give them the opportunity to contribute to the response. ”

In addition, while concerns about the care or treatment of individuals will normally be taken forward through the relevant complaint’s procedure rather than section 15 representations, **paragraph 27** of the guidance states that relevant authorities:

> “ should follow their relevant procedures to ensure that any individual subject to allegations contained within representations from the CVB has their right of due process protected. ”

Innovation

Relevant authorities may, where appropriate, also assess the extent to which an arrangement with a provider may generate and maximise improvements in the promotion and adoption of proven innovations in care delivery.

When assessing innovation, relevant authorities are advised to give due consideration to any particular innovative approaches offered by providers that may help deliver better health outcomes.

Relevant authorities may, where appropriate, consider how their decisions may improve or limit the longer-term ability of all relevant authorities to continue to innovate and meet health needs. They are expected to take into account whether an arrangement with a provider may stifle the development and adoption of innovations, and how their decisions may affect the ability of the provider market to support access to, or the development of, new or innovative services for patients in future.

Relevant authorities may, where appropriate:

- consider how their decisions may improve or exacerbate inequalities in access to, experience of, or outcomes from, health services
- operate with the view of securing quality improvement of services in connection with the prevention, diagnosis, and treatment of illness
- consider when entering into an agreement with a provider the impact on reducing inequalities in the accessibility of health services, and the quality of outcomes achieved for all eligible persons following the provision of health services

Relevant authorities may where appropriate consider how providers are able and willing to engage with and undertake health research and are advised to make arrangements that promote and support clinical research and use of research evidence on matters relevant to the health service.

Duties related to quality

Section 12A, 20A and 24A of the **National Health Service Act (Wales) 2006** (as amended by **the Health and Social Care (Quality and Engagement) (Wales) Act 2020)** places a duty on local health boards, NHS Trusts, and shared health authorities respectively to exercise their functions with a view to securing continuous improvement in quality of health services. Quality is defined as including, but not limited to quality in terms of the effectiveness of health services, the safety of health services, and the experience of individuals to whom health services are provided.

Criterion 2: value

Value

Relevant authorities must give due consideration to the need to ensure good

value in terms of costs, overall benefits, and financial implications of an arrangement. When assessing the value of a service or arrangement with a provider, relevant authorities are expected to consider:

- the benefits of the arrangement with a provider; benefits may be evaluated in relation to the other criteria in the regime and may relate to patients (in terms of patient outcomes or experience), the population (in terms of improved health and wellbeing) and to taxpayers (by reducing the cost burden of ill-health over the whole life of the arrangement within the resources available)
- the costs (or likely costs) of the arrangement, including but not limited to the efficiency of the service, the cost over the length of contract, value for money, the historical market valuation of certain services and any benchmarking of costs against other similar services
- any relevant local or national financial goals

When judging value, relevant authorities are expected to consider both the costs and the benefits of an arrangement with a provider over the expected contractual term, including fluctuations in external trends and the potential variation of the value of the service over the length of the contract.

Relevant authorities are advised to consider whether a particular arrangement with a provider may positively or negatively impact the costs or benefits of other related services or other commissioning priorities.

Relevant authorities are advised to consider the costs for the provider of changing existing arrangements or establishing new ones, alongside the anticipated cost of the contract itself when assessing value. For example, arranging a service with a new provider may offer a financial saving to the relevant authority over a relatively long contract duration, but if the anticipated cost of switching to a new provider, including any start-up funding required, outweighs the savings the new provider offers, then consideration needs to be given as to whether such an arrangement is still in the best interests of taxpayers.

Relevant authorities may:

- use published data (such as a benchmarking tool) to benchmark costs
- ask providers for the information needed to establish the value they offer (such as a cost breakdown)
- use the competitive process to establish the value providers offer (see the competitive process)

Duties related to value

Section 172 and 175 of the 2006 act (as amended by the **National Health Service Finance (Wales) Act 2014)** places financial duties on local health boards and strategic health authorities respectively to not exceed the capital and revenue resource limits set each financial year.

Section 21 and paragraph 2(1) of schedule 4 to the 2006 act places a duty on NHS trusts to:

> “ ensure that its revenue is not less than sufficient, taking one financial year with another, to meet outgoings properly chargeable to revenue account. ”

In addition to these statutory duties, a healthier Wales - which applies to county councils, county borough councils, local health boards, NHS Trusts and strategic health authorities - obliges those bodies to have due regard for the "wellness" system, which aims to support and anticipate health needs, to prevent illness, and to reduce the impact of poor health, through an equitable system where services and support will deliver the same high quality of care, and achieve more equal health outcomes, for everyone in Wales.

Value based health care

A healthier Wales sets out the need for services to transform so they can meet the challenges of the future and help deliver the best results. In Autumn 2019, **a**

national action plan for value based health care in Wales was launched which detailed a three-year programme to embed the value-based health care methodology to ensure the best outcomes for patients while using resources well.

Developing and delivering value-based health care approaches includes improved outcome data collection and use, and the redesigning of clinical pathways. Relevant authorities are expected, where appropriate, to consider clinical audit and outcome reviews, and Patient Reported Outcome Measures (PROMs) to enable a value-based health care approach to be used for service planning and delivery.

Where appropriate, relevant authorities are advised to ensure that the procurement process is part of a value-based health care redesign and that decisions are consistent with a value-based health care approach around services for patients. When assessing this criteria, relevant authorities are expected to consider the extent to which the provider under consideration will be able to support clinical audits, outcome reviews and PROMs, and whether a decision may either improve or adversely impact outcome data collection of related services. Relevant authorities are also expected to consider the extent to which the work undertaken by the provider will help the relevant authority to move in the direction of providing a value-based health and care service.

Criterion 3: collaboration and service sustainability

Collaboration

Relevant authorities must consider the extent to which the services can be provided in a collaborative way.

Relevant authorities are advised to ensure that their decisions are consistent with local and national plans around services for patients.

When assessing this criteria, relevant authorities are expected to consider the extent to which the provider under consideration will be able to collaborate with other related services in a way that improves care (recognising that collaboration of services does not necessarily mean all those services have to be delivered by the same provider).

What are collaborative services?

Collaborative services are services delivered cooperatively in a seamless and co-ordinated way, to promote accessible, comprehensive, and continuous health services.

Services may be collaborative at different geographical footprints (such as neighbourhood, place or system level).

Relevant authorities are expected to consider whether a decision may either improve or adversely impact the care pathways and patient journeys of other related services, as well as the service being considered, and seek to avoid unnecessary disruption or fragmentation of services where possible.

Relevant authorities are expected to consider whether collaboration may:

- improve the quality of those services (including the outcomes from their provision)
- reduce inequalities between persons with respect to their ability to access those services
- reduce inequalities between persons with respect to the outcomes from the provision of those services

When considering the potential benefits of collaborative working, relevant authorities are advised to consider any existing relationships between the providers under consideration and connected organisations, and whether these

are likely to sufficiently improve to lead to tangible benefits for patients and service users.

Relevant authorities are expected to consider:

- whether the flow of patient data will be improved or impeded by the decision
- whether the respective working practices, culture, infrastructure, and systems of the providers involved across linked services are likely to enable better collaboration
- the location of services proposed by providers and whether this may impact on the providers' ability to integrate

Partnership

A healthier Wales sets out the need for services to transform so they can meet the challenges of the future and help deliver the best results. Such changes require "a strong sense of shared values and partnership". Working in partnership is important to meeting the needs of the Welsh population. Partnership working has historically allowed "community-based care which cut[s] across traditional organisation and service boundaries", allowing for improvement in "the health and wellbeing of everyone in Wales" which "is something which we can all [continue to] contribute to, through a new kind of public partnership approach".

Relevant authorities may, where appropriate, support current and future partnership arrangements that allow:

- strategic partnership opportunities that deliver new models of seamless care and the delivery of integrated services
- a holistic approach to supporting health and wellbeing
- patients to recover their independence
- new models of partnership between providers and individuals, enabling people to minimise their hospital stay

Relevant authorities may where appropriate consider whether a decision may either improve or adversely impact partnership working across the NHS and Social Care in Wales. Relevant authorities may, where appropriate:

- seek to ensure that the decisions they make about which providers should provide services are aimed at maximising partnership arrangements for the improvement of patient care
- consider how the arrangements with providers under consideration may impact on current and future partnership arrangements
- consider the extent to which providers may act to increase partnership arrangements within their own activities, and how such activities may lead to other improvements in health outcomes for patients

Service sustainability

Relevant authorities must consider whether and how the decisions they make about which providers should provide services might impact on the stability and sustainability of patient care locally.

When assessing service sustainability, relevant authorities are expected to consider several factors, including but not limited to the:

- financial impact on other services
- impacts on continuity of other related services
- potential impact on quality of other related or dependent services (including those arranged by other bodies)
- stability and sustainability of other providers in the short, medium, and long term
- impact on the ability of the wider market to provide required services in the future

Relevant authorities are expected to consider whether and how the decisions they make about which providers should provide services might have a sustained and material impact on the local health services workforce, including

but not limited to:

- the retention of a skilled local workforce
- the ongoing availability of relevant training opportunities for the local workforce (such as apprenticeship, training structure, clinical placements)
- the impact on well-established teams
- whether the models of employment used by providers are consistent with current NHS workforce policy priorities

Relevant authorities are expected to avoid destabilising providers through their procurement process. If the proposals are likely to have a negative impact on the stability, viability, or quality of other good quality services immediately or over time, relevant authorities are advised to consider whether this is justified by the wider benefits of the proposal.

Criterion 4: improving access and reducing health inequalities

Improving access

Relevant authorities are expected to consider the extent to which the arrangements with a provider may support local population health needs, and ensure services are as easy to access as possible for all patient groups.

Relevant authorities are advised to consider how providers may best be able to:

a) meet needs of local groups who experience poorer than average access
b) improve the access to services, and experience and patient outcomes, for deprived and vulnerable groups and groups with protected characteristics
c) relate to and understand the populations they are seeking to serve
d) expand access to services via their delivery models
e) address digital exclusion
f) provide services at locations accessible for patients

Reducing health inequalities and disparities

The **Public Health Outcomes Framework** (PHOF) helps raise understanding of the impact which our individual behaviours, public services, programmes, and policies have on health and wellbeing in Wales.

The PHOF reflects both a life-course approach and the wider economic, environmental, and social factors that can positively or negatively influence the health and well-being of an individual, community, or society. From birth to older age, these determinants can only be tackled by concerted and collective action, by a range of services working in partnership at a local and national level. The PHOF is a tool intended to be used by everyone involved in the design or delivery of policies or services which can contribute directly or indirectly to changes or positive outcomes in population health.

Relevant authorities are expected to consider the ways in which the arrangement with a provider will impact on health inequalities and in arranging services, seek to reduce health inequalities and disparities. For example, some population cohorts may require additional support to exercise choice and this support is expected to be proactively offered and provided.

What are health inequalities?

Health inequalities are unfair and avoidable differences in health across the population, and between different groups within society. These include how long people are likely to live, the health conditions they may experience, and the care that is available to them. They arise because of the conditions in which we are born, grow, live, work and age. These conditions influence how we think, feel and act, and can impact on both our physical and mental health and wellbeing. Within this wider context, health service inequalities are about the access people have to health

services and their experience and outcomes.

Examples of the wider determinants of health are often interlinked, and include the factors below (this is not an exhaustive list):

- socio-economic status and deprivation, such as:
  - unemployed
  - low income
  - people living in deprived areas (such as poor housing, poor education or unemployment)
- protected characteristics:
  - age
  - disability
  - gender reassignment
  - marriage or civil partnership
  - pregnancy and maternity
  - race
  - religion or belief
  - sex
  - sexual orientation
- vulnerable groups of society or "inclusion health" groups, such as:
  - vulnerable migrants
  - Gypsy, Roma, and traveller communities
  - rough sleepers and homeless people
  - sex workers
- geography, such as:
  - urban
  - rural

Duties related to reducing health inequalities and disparities

A healthier Wales places duties on county councils, county borough councils, local health boards, NHS trusts and strategic health authorities. The duties include:

- a need to have a focus on prevention
- health improvement and inequality as key to sustainable development
- wellness and wellbeing for future generations of the people of Wales
- proactively supporting people throughout the whole of their lives
- through the whole of Wales, making an extra effort to reach those most in need to help reduce the health and wellbeing inequalities that exist
- reducing health inequalities and improving the population of Wales health outcomes

The **Public Sector Equality Duty (PSED) (Section 149)** and the wider obligations in the **Equality Act 2010** require public authorities, in the exercise of their functions, to have due regard to the need to eliminate unlawful discrimination or harassment, advance equality of opportunity between those with a protected characteristic and those who do not share it and foster good relations.

The aim of the PSED is to ensure that those subject to it consider advancement of equality when carrying out their day-to-day business.

Criterion 5: social responsibility

Social responsibility

Relevant authorities must seek to ensure that the decisions they make about which providers should provide services are aimed at maximising well-being outcomes by contributing to improvements in social, economic, environmental,

and cultural outcomes aligned to local priorities.

Relevant authorities are advised to be aware of other requirements and duties not set out in legislation. For example, county councils, county borough councils, local health boards, NHS trusts and strategic health authorities are expected to adhere to the:

- **Wales procurement policy statement**
- **Welsh public sector net zero: baseline and recommendations**
- the application of **net zero and carbon budget requirements** in the procurement of NHS goods and services

The **Social Partnership and Public Procurement (Wales) Act 2023** provides a framework to enhance the well-being of Wales by improving public services through social partnership working, socially responsible public procurement and promoting fair work. The act includes a statutory duty on certain public bodies to carry out socially responsible public procurement, to set objectives around well-being goals, and to publish a procurement strategy and annual reports. It also requires bodies to ensure that socially responsible outcomes are pursued through supply chains.

In assessing social responsibility, relevant authorities are expected to think about how the arrangements with providers under consideration impact on:

a) environmental issues and sustainable development, including addressing climate change, making, and meeting commitments around reducing emissions, air pollution and consumption and waste, through promoting circular economy principles as well as enhancing the natural and built environment as applicable

b) delivery in a way that improves the economic, social, environmental, and cultural well-being of their areas, specifically by contributing to the achievement of the well-being goals listed in section 4 of the **Well-being of Future Generations Act 2015**

c) inclusive and "good" **employment characterised by fair work principles** where workers are fairly rewarded, heard and represented, secure and able to

progress in a healthy, inclusive environment where rights are respected, and supports opportunities for local people or population groups experiencing health or other inequalities and addresses risks of modern slavery

d) community cohesion and the wider health and wellbeing of the population, including by helping communities to manage and recover from the impact of COVID-19

e) social determinants of health (such as employment, income, housing, local environment, food, transport, community, safety)

Relevant authorities are advised to consider the extent to which providers have acted to increase well-being outcomes within their own activities, and how this can lead to other improvements in health outcomes.

Relevant authorities are advised to consider social responsibility in relation to the other criteria in this regime. For example:

- improved integration that leads to fewer patient journeys may also enable environmental gains to be made
- a service that leads to improved air quality may contribute to improved health outcomes over time and hence projected savings

Relevant authorities are advised to consider how a provider's policies and practices align with:

- moving towards net zero in the procurement of goods and services
- increasing the impact of organisations providing health services as anchor institutions and partners in place

Relevant authorities are expected not to make arrangements with providers that stifle the potential for development and adoption of sustainability within the services or result in a local provider market that may not be able to support the development of new or sustainable services for patients in the future.

Duties and guidance related to well-being outcomes

- **The Social Partnership and Public Procurement (Wales) Act 2023**
- **The Well-being of Future Generations (Wales) Act 2015**
- **Wales procurement policy statement (Welsh Government 2012 and 2015)**
- **community benefits: delivering maximum value for the Welsh pound 2014**
- all Wales plan 2021 to 2025: working together to reach net zero
- **Welsh procurement policy note WPPN 06/21: decarbonisation through procurement: taking account of carbon reduction plans**

Duties are placed on relevant authorities to deliver net zero and take action to mitigate the impacts of climate change in their operations and supply chains.

Foundational economy

The **foundational economy programme** weighs up how we can spend money in Wales to yield beneficial outcomes. More than half of Welsh Government's budget is allocated on health and social care services, so it is important to focus on how this money is spent and ensure that all decisions are made in a way that will bring the maximum benefit for the people of Wales and our economy.

The foundational economy programme focuses on:

- the direct goods or services we buy (such as food for hospitals)
- the workforce we directly employ
- how the location and co-location of our services affects communities and how they can access services

Looking at a means by which goods and services that we procure can help the Welsh economy and support the Welsh population. Such focus should support

Welsh companies to provide jobs and training within a local supply chain which will also make improvements to our environment. Such considerations will help ensure opportunities to train or find work and ensure that services are accessible to the local population.

Relevant authorities may, where appropriate:

- seek to ensure that the decisions they make about which providers should provide services are aimed at maximising the "foundational economy"
- consider how the arrangements with providers under consideration may impact on the people of Wales and our economy
- have a focus on how the goods and services procured can help the Welsh economy and support the Welsh population by increasing spending in Wales to support Welsh companies providing jobs and training within a local supply chain
- consider the extent to which providers may act to increase the foundational economy within their own activities, and how such foundational economy improvements may lead to other improvements in health outcomes from the creation of stronger and more resilient communities

Relevant authorities are expected not to make arrangements with providers that may impact negatively upon the workforce they directly employ or may directly employ or would impact negatively on the accessibility of services within our communities.