

SL(6)527 – The Special Procedures Approved Premises and Vehicles (Wales) Regulations 2024

Background and Purpose

Part 4 of the Public Health (Wales) Act 2017 (the “**Act**”) establishes a mandatory licensing scheme for individuals wishing to perform special procedures in Wales. The special procedures are:

- acupuncture
- body piercing
- electrolysis
- tattooing

Under the new licensing scheme, an individual who performs a special procedure on someone else, in the course of a business, must be licensed, unless they are exempt.

In addition, special procedures must be performed at a premises or in a vehicle that has been approved by a local authority for that purpose unless that premises or vehicle is exempt. If a local authority is satisfied the premises or vehicle meets the requirements for approval, they will issue an approval certificate authorising that approval.

These Regulations make provision in relation to such premises and vehicles, including:

- the criteria that must be met for a new approval certificate to be granted, and the application form to be used;
- what an approval certificate will look like once an approval has been granted and the mandatory conditions that an approval certificate will be subject to;
- the premises and vehicles that will be exempt from the requirement to be approved by the local authority;
- provision in relation to variations, voluntary termination, renewal and replacement of approval certificates;
- provision for fees in relation to approval certificates;
- what a local authority is required to do if they intend to refuse an application and the applicant’s right to make representations to the local authority; and
- the appeals process in respect of applications that are refused.

Procedure

Draft Affirmative.



The Welsh Ministers have laid a draft of the Regulations before the Senedd. The Welsh Ministers cannot make the Regulations unless the Senedd approves the draft Regulations.

Technical Scrutiny

The following seven points are identified for reporting under Standing Order 21.2 in respect of this instrument.

1. Standing Order 21.2(vi) – that its drafting appears to be defective or it fails to fulfil statutory requirements

Part 7 of the Regulations makes provision in relation to variations of approval certificates.

If an application to vary an existing approval certificate has been made, the relevant local authority must either grant or refuse such application. However, we consider the drafting of regulations 15(2) and 15(3) to leave room for ambiguity. Regulation 15(2) states:

If the local authority is satisfied that an application to vary in accordance with Part 7 has been made, the local authority must grant the application to vary an approval certificate and issue the varied approval certificate to the certificate holder.

On a wide interpretation, this could be construed as a duty on the local authority to grant a variation, merely if an application to vary has been made (notwithstanding that it does not comply with the requirements or conditions in Part 7).

This can be contrasted with regulations 9(2) and 21(2) where the drafting is much clearer:

*If the local authority is satisfied that **all of the approval criteria set out in regulation [8 and 20]** are met, the local authority must grant the application for an approval certificate and issue an approval certificate to the applicant, approving a premises or vehicle in respect of performance of special procedure.*

In our view, the drafting of regulations 15(2) and 15(3) would be more certain by amending in line with regulations 9(2) and 21(2).

2. Standing Order 21.2(v) – that for any particular its form or meaning needs further explanation.

Part 11 of the Regulations makes provision in relation to voluntary termination of premises or vehicle approval certificates by certificate holders.

Regulation 29(g) provides that a certificate holder proposing to voluntarily terminate an approval certificate must provide to the local authority:

*"the name **of any persons** that the certificate holder thinks likely to be affected by the notice." [emphasis added]*



This provision places a broad requirement on certificate holders. Please can the Welsh Government confirm the underlying rationale for regulation 29(g)?

Further, the information required to be included in a voluntary termination notice is relatively detailed and extensive. Did the Welsh Government consider adding a Schedule to the Regulations with a model 'notice' to be used by certificate holders in these circumstances?

3. Standing Order 21.2(v) – that for any particular reason its form or meaning needs further explanation.

In the application form for an approval certificate set out in Schedule 1 to the Regulations, the applicant must state the name of the relevant issuing authority. To assist the applicant, guidance note 1 states:

When applying for an approval certificate—

(a) [...]

(b) if the vehicle is considered to be, or is likely to be, driven, used or kept in the area of the local authority, an application is to be made to that local authority.

Our understanding is that an approval certificate issued by one local authority permits the certificate holder to use a vehicle for the performance of special procedures anywhere in Wales (as articulated in guidance note 10).

That is, applicants need not obtain separate approval certificates for each local authority where their vehicle may be driven and used to perform special procedures.

Assuming this is correct, we consider it would be useful to update guidance note 1 to clarify this point for the benefit of persons completing the application form.

4. Standing Order 21.2(vi) – that its drafting appears to be defective or it fails to fulfil statutory requirements

Schedule 1 to the Regulations contains a standard 'Form of application for an approval certificate'. Guidance notes are provided to assist applicants with completing the form.

Guidance note 12 relates to Part 5, Section 5.2 of the form. It states:

*The "licence number" means the reference number given by the local authority to **the approval certificate** which is unique to that **certificate** and which is specified in it.*

Given the context of Section 5.2 of Part 5, it appears that the underlined reference above should refer to 'special procedure licence', rather than 'approval certificates'. It also appears that "certificate" should read "licence".

Our understanding is that the term 'approval certificate' is only applicable in the context of premises and vehicles, rather than licensed persons.



5. Standing Order 21.2(vii) – that there appear to be inconsistencies between the meaning of its English and Welsh texts.

Regulation 8 provides for the criteria to be applied in granting approval certificates.

Regulation 8(2)(b) states that an applicant must “provide evidence that the applicant holds a regulated Level 2 Award [in ‘Infection Prevention and Control for Special Procedures Practitioners’]”.

The translation states that the applicant must:

*“darparu tystiolaeth bod y ceisydd yn meddu ar Ddyfarniad Lefel 2 a reoleiddir **yn llwyddiannus**”* [emphasis added].

The addition of the words “yn llwyddiannus” (i.e. successfully) in the Welsh text appear to be superfluous and inconsistent with the English text.

6. Standing Order 21.2(v) – that for any particular its form or meaning needs further explanation.

Guidance note 6 in Schedule 1 to the Regulations defines the term ‘workstation’ to assist applicants in completing the application form for an approval certificate.

The guidance note explains that the applicant should ensure there is sufficient space between each workstation to enable the safe and hygienic performance of the special procedure. The final sentence states:

Please see the non-statutory guidance for further information.

The guidance note does not provide a link to the ‘non-statutory guidance’, and it is unclear which resource in particular this refers to.

The Welsh Government is asked to confirm the same, and to consider updating guidance note 6 to signpost applicants to the relevant guidance.

7. Standing Order 21.2(v) – that for any particular its form or meaning needs further explanation.

Schedules 3 and 4 to the Regulations contain the mandatory approval conditions which apply to approval certificates and temporary approval certificates, respectively.

Approval certificates are issued subject to the mandatory approval conditions. Approval certificates must be displayed at premises and vehicles, and mandatory approval conditions must be “readily available for inspection upon request” by authorised officers and clients.

We note that key terms such as “certificate holder”, “special procedure”, “licence holder”, “approved premises”, “special procedure licence” are not defined in the mandatory approval conditions.



Therefore, if a lay client requested sight of the mandatory approval conditions, the terminology would be impenetrable.

We note that there is a definitions section at the bottom of the Schedules. However, in our view, the conditions would be more accessible if they contained a section at the top to explain the key terms in plain language in the style of a modern consumer contract.

Merits Scrutiny

The following two points are identified for reporting under Standing Order 21.3 in respect of this instrument.

8. Standing Order 21.3(ii) – that it is of political or legal importance or gives rise to issues of public policy likely to be of interest to the Senedd

The Public Health (Wales) Act 2017 received Royal Assent on 3 July 2017. These Regulations will come into force on 29 November 2024. This means it will have taken over seven years for the new rules on approved premises and vehicles to be implemented.

In 2017, the Explanatory Memorandum that accompanied the Public Health (Wales) Bill specified the “*known and well reported health risks connected to*” special procedures and the “*complications that can arise*” with special procedures.

The Explanatory Memorandum to the Bill also referred to the current legislation being “*inadequate to sufficiently protect the public*”. The Explanatory Memorandum also noted the costs to the NHS under the current regime: “The main benefit of the licensing system is savings to the NHS, in terms of treatment costs, and to individuals’ health”.

Given all of the above, it is unclear why it has taken over seven years to implement the new rules on approved premises and vehicles set out in the 2017 Act.

9. Standing Order 21.3(ii) – that it is of political or legal importance or gives rise to issues of public policy likely to be of interest to the Senedd

We note the following extracts from the Explanatory Memorandum regarding the consultation undertaken in respect of these Regulations:

5.2. The Welsh Government consulted on the principles of the special procedures licensing scheme (from here referred to as the ‘first consultation’) with a view to informing draft Regulations that would enable the commencement of the provisions of Part 4 and Schedule 3 of the Act. That 12-week consultation ran between 25 January and 19 April 2023 and the draft version of the RIA formed part of the consultation materials along with an Integrated Impact Assessment. [...]



5.9. A further consultation (from here referred to as the 'second consultation') ran for eight weeks between 12 February and 8 April 2024 and followed on from the first consultation referred to above.

5.10. As the policy proposals for the mandatory licensing scheme had already been consulted upon, this second consultation was considered a technical consultation specifically on the wording of the draft Regulations and draft Statutory Guidance, although the draft Regulations provided further detail around the new scheme, including those subjects where the statutory duty to consult under section 64 of the Act applied. For this reason, the Cabinet Secretary for Health and Social Services gave her consent for the consultation to run for eight weeks instead of the standard 12-week period.

Welsh Government response

A Welsh Government response is required to all points, save for the final Merits point.

Committee Consideration

The Committee considered the instrument at its meeting on 30 September 2024 and reports to the Senedd in line with the reporting points above.

