

Consultation Response Questionnaire

Draft Regulations and Statutory Guidance for a mandatory licensing scheme for special procedures in Wales

Organisation (if applicable):	General Osteopathic Council
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Responses to consultations are likely to be made public, on the internet or in a report. If you would prefer your response to remain anonymous, please tick here:

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Please return this form to reach the Welsh Government no later than **8 April 2024**.
The email address for responses or queries is:

SpecialProceduresMailbox@gov.wales

This form can be downloaded or the online response questionnaire accessed from the Welsh Government website here:

<https://www.gov.wales/mandatory-licensing-special-procedures-wales>

We welcome responses in Welsh or English.

Please note: this mandatory licensing scheme will be introduced on the terms set out in this document and the Regulations. We cannot therefore revisit the subject of the scheme itself or the proposals put forward in the first consultation document.

	Please give reasons for your answers when responding.
1 - The Special Procedure Licences (Wales) Regulations 202X	
1 a	Do you think these draft Regulations adequately set out how individuals are to be licensed?
	Answer: The regulations appear clear and comprehensive. The regulations are very detailed. There is sometimes a risk with overly prescriptive legislation of unintended consequences and so mechanisms for updating the regulations may need to be carefully thought about and how those updated regulations would be applied to existing licenses. Please also see our comments below.
1 b	Is there anything unclear, missing that should be included, or included that should not be?
	<p>Answer:</p> <p>Regulation 4(3) (c) 'evidence of a basic disclosure certificate'. The General Osteopathic Council requires an enhanced disclosure check for applicants to the register because of the intimate nature of treatment and we wonder if it is appropriate to also require an enhanced disclosure check for applicants for special procedure licenses too.</p> <p>Regulation 4(3)(d) 'evidence of successful completion of a regulated Level 2 Award held by the applicant'. All recognised osteopathic qualifications entitling osteopaths to register with us are at Level 6 or 7. However, for applicants who qualified before entry to the register, they will sometimes have a Diploma in Osteopathy which would have been granted over a 3 to 4 year period of training. All registered osteopaths have been assessed as meeting our Standards prior to entry onto the register and are required to keep up to date in those standards. We wonder if the addition of 'or registration as a regulated health professional' would simplify the process here whilst maintaining the required standard.</p> <p>Regulation 4(4) – see also comments below on exemption. Our understanding is that most osteopaths would not be eligible for the exemptions outlined in the Special Procedures Exempted Individuals (Wales) Regulations 202X.</p> <p>Regulation 6 – We are not clear how long a special procedure license lasts and the period of time required for renewal. We note that an inspection is required and care would need to be taken to ensure that such an approach can be resourced by the Local Authority.</p> <p>Schedule 4, rule 16 – 'The licence holder must not undertake a special procedure on a client if they suspect the client is not fit and well.' The meaning of fit and well is broad and unclear. Osteopaths are trained to take a case history, perform an examination, provide a working diagnosis and offer</p>

	<p>treatment options, one of which may be acupuncture if offered as an adjunctive therapy. (See our briefing for Devolved Administrations for further information about osteopathic education, training and practice.) Further information is outlined in our Osteopathic Practice Standards.</p> <p>Paragraphs 17 to 22 – we note the emphasis on forms signed to obtain consent as evidence of consent. However, we wonder if there should also be more emphasis on the legal principles of consent including that it should be voluntary, given by an appropriately informed person with capacity and should be continuing, i.e. it can be withdrawn at any time. Please see our standard A4 of the Osteopathic Practice Standards which outlines the standards expected of osteopaths. We also issue Consent Guidance for Osteopaths Practising in England and Wales which provides more detail about the standards expected of osteopaths. We note the requirement for the completion of pre and post treatment forms. Are these in a particular format?</p>
2 - The Special Procedures Approved Premises and Vehicles (Wales) Regulations 202X	
2 a	<p>Do you think these draft Regulations adequately set out how premises and vehicles are to be approved?</p>
	<p>Answer: The regulations appear clear and comprehensive. The regulations are very detailed. There is sometimes a risk with overly prescriptive legislation of unintended consequences and so mechanisms for updating the regulations may need to be carefully thought about and how those updated regulations would be applied to existing licenses. Please also see our comments below.</p>
2 b	<p>Is there anything unclear, missing that should be included, or included that should not be?</p>
	<p>Answer:</p> <p>Regulation 5a – there are no approval criteria listed in regulation 4. Are these specific to each local authority and if so, where would they be published so that applicants can view them?</p> <p>Regulation 14 and 16 – as above in relation to the local authority requirements.</p>
3 - The Special Procedures Exempted Individuals (Wales) Regulations 202X	
3 a	<p>Do you think these draft Regulations adequately set out how the specified individuals are to be exempt?</p>
	<p>Answer: Please see our comments below.</p>
3 b	<p>Is there anything unclear, missing that should be included, or included that should not be?</p>
	<p>Answer: We note that osteopaths are included in Column 1, Schedule 2 to the Special Procedures Exempted Individuals (Wales) Regulations 202X. Our understanding is therefore that under Regulation 4, osteopaths are not exempt from the requirement to be licensed if the osteopath wishes to perform the special procedure specified in Column 2 (acupuncture, body piercing, electrolysis and tattooing) unless they are ‘performing the special procedure in a regulated independent healthcare establishment’.</p>

However, our understanding is that under the relevant Act and regulations, osteopaths are exempt from registration with Healthcare Inspectorate Wales unless they are performing a listed service. Most osteopaths will not be providing or working with professionals providing listed services as outlined in the Care Act 2000 and so will likely be exempted from registration and in fact unable to apply for registration with Healthcare Inspectorate Wales.

We appreciate the policy position taken by the Welsh Government in their 2023 consultation summary document which is that: *‘However, the practitioner who is not required to have HIW premises registration and who works outside the NHS would therefore not have any regulation of their premises, which creates a more serious anomaly in our view. The Act has no mechanism to allow a practitioner in these circumstances to apply for premises approval under this mandatory scheme to enable them to claim the practitioner exemption by means of their professional registration. Therefore, such practitioners will not have an exemption and will have to obtain a practitioner licence and a premises approval certificate.’*

Our [Osteopathic Practice Standards](#) which are the standards that all osteopaths must meet provide that:

Standard C5 – ‘You must ensure that your practice is safe, clean and hygienic, and complies with health and safety legislation.’ Supporting guidance includes ‘Your practice premises must be clean, safe, hygienic, comfortable and appropriately equipped. 2. There are detailed requirements in law for health and safety in the workplace. Further details can be found on the website of the UK Health and Safety Executive. 3. You must have adequate public liability insurance. 4. You should ensure that you have appropriate procedures in place in the event of a medical emergency. 5. You should take all necessary steps to control the spread of communicable diseases.’ We have also issued supporting [Guidance on Infection Control](#).

Such an approach is similar to Standard 14 of the [HCPC standards of proficiency for physiotherapists](#).

Standard B3: You must keep your professional knowledge and skills up to date.

Supporting guidance includes ‘To achieve this, you should: 1.1 be professionally engaged, undertaking professional development activities and complying with GOsC requirements regarding continuing professional development 1.2 keep up to date with factors relevant to your practice, including: 1.2.1 GOsC guidance 1.2.2 legal requirements or changes to the law in relation to your practice, for example, in relation to data storage (see standard C3), health and safety in the workplace (see standard C5) and equality issues (see standard D6) 1.2.3 research and other relevant developments in healthcare.’

Standard D9: You must support colleagues and cooperate with them to enhance patient care. Supporting guidance includes: ‘You are responsible for all the staff you employ in your clinic (including administrative staff) and for their conduct, and any guidance or advice they give to patients. You should make sure that staff understand the importance of: 2.1 patient confidentiality 2.2 secure storage and retention of medical records 2.3 appropriate relationships with patients, colleagues and other healthcare professionals 2.4 complaints

	<p>and associated procedures for handling them 2.5 maintaining a safe work environment 2.6 health and safety 2.7 equality duties and good practice’</p> <p>As with any breach of our standards framed as ‘must’ failure to comply may put the osteopath at risk of fitness to practise proceedings.</p> <p>As part of our CPD scheme, osteopaths must demonstrate CPD across all four themes of the Osteopathic Practice Standards (OPS) including Theme A: Communication and Patient Partnership, Theme B: Knowledge, Skills and Performance, Theme C: Safety and Quality in Practice and Theme D: Professionalism and this must be signed off by a regulated health professional through a peer review process.</p> <p>Please also see our previous response to the 2023 consultation outlined again in response to Question 9 below which confirms that osteopaths must meet the standards outlined in the OPS when providing acupuncture.’ (For completeness, these include standards to ‘recognise and work within the limits of your training and competence.’ (See standard B2)’.</p> <p>So whilst we disagree with the statement that osteopaths do ‘<i>not have any regulation of their premises,</i>’ because we do set standards related to premises, it is right to say that there is no right to inspect osteopathic premises in the way that Healthcare Inspectorate Wales does have the right to inspect for premises registered with it.</p> <p>Our understanding is that a similar position applies to private physiotherapists working in Wales and regulated by the HCPC (see for example: https://www.csp.org.uk/networks/independent-practitioners/governance-support/regulatory-professional-requirements#:~:text=Most%20self%2Demployed%20physiotherapists%20and,Scotland%3B%20Regulation%20and%20Quality%20Improvement) in that they do not have to be regulated by Healthcare Inspectorate Wales. If our understanding is correct, we are therefore unclear about the application of the rationale outlined in the Welsh Government 2023 Policy response for osteopaths to be included in Schedule 2 rather than with physiotherapists as outlined in Schedule 3.</p> <p>This Briefing about Osteopathic Regulation provides more information about the osteopathic regulatory framework.</p> <p>We also consider that thought should be given as to whether a clause be added which reflects that those establishments that have been previously approved for a special licence procedure as being part of the exemptions.</p>
4 - The Special Procedure Licensing Committees (Wales) Regulations 202X	
4 a	Do you think these draft Regulations adequately set out how licensing committees are to operate for the purposes of this mandatory licensing scheme?
	Answer: No comment
4 b	Is there anything unclear, missing that should be included, or included that should not be?
	Answer: No comment
5 - The Prescribed Objects for Body Piercing (Wales) Regulations 202X	

5 a	Do you think these draft Regulations provide an adequate definition of ‘object’ for the purposes of non-intimate body piercing within this licensing scheme?
	Answer: No comment
5 b	Is there anything unclear, missing that should be included, or included that should not be?
	No comment
6 - Statutory Guidance	
6 a	Do you think the draft Statutory Guidance adequately explains how a local authority should determine a ‘person’s fitness to perform a special procedure’ for licensing purposes under the mandatory licensing scheme, where this has been called into question?
	Answer: No view
6 b	Is there anything unclear in the draft Statutory Guidance that should be explained further?
	Answer: We would request that information about findings under the local authority fitness to practice procedures be communicated to the General Osteopathic Council where they involve an osteopath. This is to enable the General Osteopathic Council to take investigate and if necessary action to ensure ‘protection of the public’ in accordance with it’s statutory objective under the Osteopaths Act 1993.
6 c	Is there anything in relation to determining a ‘person’s fitness to perform a special procedure’ that is unclear or missing from the draft Statutory Guidance?
	Answer: No view
Statutory Questions	
7	<p>We would like to know your views on the effects that the mandatory licensing scheme for Special Procedures in Wales would have on the Welsh language, specifically on opportunities for people to use Welsh and on treating the Welsh language no less favourably than English.</p> <p>What effects do you think there would be? How could positive effects be increased, or negative effects be mitigated?</p>
	Answer: No view
8	<p>Please also explain how you believe the proposed mandatory licensing scheme for Special Procedures in Wales could be formulated or changed so as to have</p> <ul style="list-style-type: none"> positive effects or increased positive effects on opportunities for people to use the Welsh language and on treating the Welsh language no less favourably than the English language, and no adverse effects on opportunities for people to use the Welsh language and on treating the Welsh language no less favourably than the English language.
	Answer: No view
9	We have asked a number of specific questions. If you have any related issues which we have not specifically addressed, please use this space to report them.

Answer: We responded with the following response to the 2023 consultation last year. We understand that this was not treated as a consultation response although it was received and logged. We note that the Welsh Government Policy Decision is that inspection of premises is required to mitigate risk hence, osteopaths not being exempted from the premises inspection. We have provided additional comments on this point in our response to Question 3.

From: Standards <standards@osteopathy.org.uk>

Sent: Friday, April 14, 2023 3:44 PM

To: Sarah.Jones058@gov.wales; SpecialProceduresMailbox@gov.wales

Cc: Matthew Redford <mredford@osteopathy.org.uk>; Fiona Browne <fbrowne@osteopathy.org.uk>; Steven Bettles <sbettles@osteopathy.org.uk>; Jessica Davies <jdavies@osteopathy.org.uk>

Subject: RE: Mandatory licensing of special procedures in Wales - Exempted Individuals enquiry

Dear Dr Jones,

Thank you for your email of 2 March requesting our observations about the intention of the Llywodraeth Cymru / Welsh Government to not provide osteopaths with a blanket exemption for all four special procedures (Tattooing including semi-permanent make up, body piercing, acupuncture including dry needling and electrolysis) as outlined in Section 60 Public Health (Wales) Act 2017.

You explain that your intention is that any registrant 'of the General Osteopathic Council should not have a blanket exemption for all four special procedures. The exemptions set out in regulation should be tailored to take into account the practices undertaken by your members and that any named procedure should be within that member's area of expertise and be considered in scope and therefore subject to indemnification.'

Summary

We explain below that osteopaths are regulated and required to have professional indemnity insurance. They are required to act in accordance with the Osteopathic Practice Standards in all areas of their work and to act within the limits of their competence. We have specific Guidance on adjunctive therapies and non-osteopathic forms of care or treatment which states '*To protect patients, the OPS applies to all areas of an osteopath's work. This includes all osteopathic techniques and adjunctive therapies. For example, an osteopath must meet the standards set out in the OPS whether they are treating a patient with spinal manipulation or with acupuncture.*'

We agree that your example that 'a registered Osteopath could be exempt from having a licence to perform acupuncture but required to have a licence for the other 3 special procedures' would seem an appropriate conclusion which would not 'create gaps in the regulatory framework which compromise client/patient safety.' Our observations are informed by the views of some Welsh osteopaths, most of whom are in agreement with the proposal.

Detail

Osteopathy is a statutorily regulated health profession in the four UK countries. The key objective of all statutory regulators is protection of the public. It is illegal to practise as an osteopath in the four UK countries unless the person is on the GOsC Register. We have statutory functions to set standards of education and training, set standards of competence and conduct, hold the Register and ensure that osteopaths on the Register meet our standards and fitness to practise powers to remove or restrict practice where necessary. All osteopaths must practice in accordance with the [Osteopathic Practice Standards](#). The Osteopathic Practice Standards map to the standards expected of all regulated health professionals, for example, making the care of the patient their first concern, working in partnership with the patient, being personally accountable for professional practice and prepared to justify actions, keeping up to date, working within the limits of competence, practising within an ethical framework including confidentiality, boundaries, integrity etc. In addition as part of their registration, osteopaths must have a professional indemnity insurance arrangement which provides appropriate cover of £5,000,000 in accordance with the requirements of the Osteopaths Act 1993 and the current [Professional Indemnity Insurance Rules](#).

Osteopaths, like many regulated independent health professionals grow and develop throughout their professional life ensuring that they ‘recognise and work within the limits of [their] training and competence’ and ‘keep [their] professional knowledge and skills up to date’ and they do this through ongoing CPD. Many osteopaths practice therapies adjunct to osteopathy as part of their practice. For example, we know that around half of osteopaths in a 2021 professional body survey practised acupuncture and or dry needling.

In 2022, we published [Guidance on adjunctive therapies and non-osteopathic forms of care or treatment](#). This guidance states that ***‘The purpose of the OPS is to protect patients by making sure that osteopaths always practise in a way that is safe and in the patients’ best interests. To protect patients, the OPS applies to all areas of an osteopath’s work. This includes all osteopathic techniques and adjunctive therapies. For example, an osteopath must meet the standards set out in the OPS whether they are treating a patient with spinal manipulation or with acupuncture.’***

Therefore osteopaths employing adjunctive therapies as part of their practice are still subject to the Osteopathic Practice Standards, and regulated by us. You explain that ‘The exemptions set out in regulation should be tailored to take into account the practices undertaken by your members and that any named procedure should be within that member’s area of expertise and be considered ‘in scope’ and therefore subject to indemnification.’

You ask ‘specifically whether your members could safely perform any of the named special procedures without a licence’. We know that many osteopaths practice dry needling and acupuncture and in order to do so they must be competent and insured.

However, we do not know how many osteopaths undertake the other procedures mentioned namely Tattooing including semi-permanent make up, body piercing, and electrolysis and these would not typically form a part of osteopathic practice, although, if questions were raised about an osteopath performing these activities (for example in relation to integrity), these matters could be considered by the General Osteopathic Council.

So in conclusion, your example that 'a registered Osteopath could be exempt from having a licence to perform acupuncture but required to have a licence for the other 3 special procedures' would seem an appropriate conclusion which would not 'create gaps in the regulatory framework which compromise client/patient safety.' Our observations are informed by the views of some Welsh osteopaths, most of whom are in agreement with the proposal.

Please do not hesitate to contact me if you have any questions.

Kind regards

Matthew Redford
Chief Executive and Registrar
General Osteopathic Council