

Non-surgical Procedures and Functions of Medical Reviewers (Scotland) Bill

Delegated Powers Memorandum

Introduction

1. This Delegated Powers Memorandum has been prepared by the Scottish Government in accordance with Rule 9.3.3B of the Parliament's Standing Orders, in relation to the Non-surgical Procedures and Functions of Medical Reviewers (Scotland) Bill. It describes the purpose of each of the subordinate legislation provisions in the Bill and outlines the reasons for seeking the proposed powers.
2. The following other accompanying documents are published separately:
 - Explanatory Notes (SP Bill 77–EN);
 - a Financial Memorandum (SP Bill 77–FM);
 - a Policy Memorandum (SP Bill 77–PM);
 - statements on legislative competence made by the Presiding Officer and the Scottish Government (SP Bill 77–LC).
3. This Memorandum has been prepared by the Scottish Government in order to assist the reader of the Bill and to help inform debate on it. It does not form part of the Bill and has not been endorsed by the Parliament.

Outline of Bill provisions

4. The purpose of the Non-surgical Procedures and Functions of Medical Reviewers (Scotland) Bill is to regulate certain specified non-surgical procedures, which pierce or penetrate the skin including by means of a needle, chemical, medicine, heat or cold, laser, sound, light or electricity. These procedures are generally undertaken in order to enhance or alter an individual's appearance, strength or vitality without surgical interventions. Procedures which are undertaken by or on behalf of the NHS or for healthcare purposes (i.e. preventing, diagnosing or treating illness) are not included within the definition of non-surgical procedure.
5. The Bill will ensure that non-surgical procedures are provided from appropriate settings (referred to in the Bill as "permitted premises"). It will be an

offence for a person to provide a non-surgical procedure outwith permitted premises. It will also be an offence for a person to provide a non-surgical procedure to a person who is under the age of 18. The Bill will allow further provision to be made in respect of non-surgical procedures and, where procedures take place in settings that are regulated by Healthcare Improvement Scotland (HIS), it will allow HIS to use existing powers to support high standards of safety and quality. The Bill provides a new enforcement power for HIS to inspect settings which are not healthcare led and therefore which are not required to register with them, but where they have reasonable grounds to believe that an offence under the Bill has been or is being committed, or the setting is being used in connection with an offence. In addition the Bill introduces penalties for these offences.

6. The Bill will sit alongside secondary legislation (via a Scottish Statutory Instrument (SSI)) to establish a local authority licensing scheme under Part 1 of the Civic Government (Scotland) Act 1982 for lower risk non-surgical procedures which can be carried out by non-healthcare practitioners.

7. The Bill also includes amendments to the Certification of Death (Scotland) Act 2011 relating to reviews of certificates of cause of death by interested persons and the authorisation of cremation where deaths occur outwith the UK.

8. Section 19 makes general provision about regulation-making powers and in particular makes provision as to whether the powers in the Bill are subject to the affirmative or negative procedure.

Rationale for subordinate legislation

9. The Bill contains substantive provisions creating offences and enforcement powers which aim to protect children and young people from harm and ensure non-surgical procedures are carried out in appropriate settings. Regulation-making powers are included in the Bill for two reasons. Firstly, the non-surgical procedures sector is a rapidly changing one, where new procedures and new ways to perform existing procedures are constantly developing. This may affect, among other things, the way procedures are administered, the training and skills required to administer them, and the level of knowledge, skill or supervision that is required to perform them or respond to potential complications. Therefore it may be necessary to add new procedures that emerge on the market, or redefine procedures that have changed or developed. It may also be appropriate to impose requirements or restrictions relating to the provision of procedures such as the settings in which they take place. It may also be appropriate to add to the Bill a procedure that was previously the subject of the proposed licensing scheme to be established under an SSI referred to in paragraph 6 above: this may happen if new information came to light about the risks of such a procedure. Finally it may be necessary to impose offences, penalties and enforcement powers in relation to any requirements created within regulations.

10. Secondly, regulation-making powers are required to address issues relating to training, qualifications and professions raised by the United Kingdom Internal Market Act 2020 (UKIMA). Part 3 of UKIMA introduces a system for the recognition of professional qualifications across the UK internal market, which will allow professionals qualified in one of the four parts of the UK to access the same profession in a different part without needing to requalify¹. Section 24 of that Act applies to any provision that limits the ability to practise a ‘profession’ to individuals who have certain qualifications or experience. Under UKIMA, the ability to practise a profession includes being able to undertake activities that comprise the practice of a profession, to use a particular professional title, or to be registered, licensed or similarly authorised where that is required in order to undertake such activities or use such a title. A profession is defined to include “an occupation or trade and any subdivision of, or distinct specialism within a profession”. Section 24 is only engaged by a provision that limits the ability to undertake activities that comprise the practice of a profession to individuals with certain qualifications or experience if the activities affected are, in a significant number of cases, essential to the practice of the profession in question.

11. The Scottish Government is exploring the extent to which the activities being regulated by the Bill comprise the practice of a profession. To understand the effect of the provisions in Part 3 also requires an assessment of regulation of non-surgical procedures in other parts of the UK, noting that the UK Government have recently announced their intention to legislate to regulate certain non-surgical cosmetic procedures.

12. The Scottish Government is clear in its policy intent to specify that certain non-surgical procedures must be undertaken by a medical or dental practitioner, prescribing nurse or midwife or prescribing pharmacist, while others can be carried out by other healthcare professionals or non-healthcare practitioners under the supervision of one of those five categories of healthcare professional. While the Bill does not currently make provision for this, the Scottish Government is working with the UK Government to seek to resolve these issues with a view to achieving this in future secondary legislation as soon as practicable. The intention is for the regulation-making power in section 5 to be used for this purpose. Even if provision of this nature had been put on the face of the Bill it still would have been necessary to include a power to amend such provision, to allow for changes in the training and qualification landscape and put in place appropriate provision for new or redefined procedures.

13. The Scottish Government has had regard, when deciding whether provisions should be set out in subordinate legislation rather than on the face of the Bill, to the need to:

¹ Explanatory Notes to the [United Kingdom Internal Market Act 2020](#)

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- strike the right balance between the importance of the issue and providing flexibility to respond to changing circumstances without the need for primary legislation;
- make proper use of valuable parliamentary time;
- anticipate the unexpected, which might otherwise frustrate the purpose of provisions in primary legislation approved by the Scottish Parliament;
- allow detailed arrangements to be kept up to date within the basic structures set out in the Bill; and
- take account of the likely frequency of amendment of those arrangements.

14. The delegated powers provisions are listed below. For each provision, the Memorandum sets out:

- the person upon whom, or the body upon which the power is conferred and the form in which the power is to be exercised;
- why it is considered appropriate to delegate the power; and
- the Parliamentary procedure (if any) to which the exercise of the power to make subordinate legislation is to be subject, and why it was considered appropriate to make it subject to that procedure (or not to make it subject to any such procedure).

Delegated powers

Section 1(4) – Meaning of “non-surgical procedure”

Power conferred on: the Scottish Ministers

Power exercisable by: regulations made by Scottish statutory instrument

Parliamentary procedure: negative

Provision

15. Section 1 includes a list of circumstances where a procedure would not be considered to be a non-surgical procedure for the purposes of Part 1 of the Bill. One such circumstance is where the procedure is provided for the purpose of, or in connection with, preventing, diagnosing or treating an illness by, or in accordance with the directions of, a health care professional regulated by the General Medical Council, the General Dental Council, the General Optical Council, the General Osteopathic Council, the General Chiropractic Council, the General Pharmaceutical Council, the Nursing and Midwifery Council, or the Health and Care Professions Council. Section 1(4) allows the Scottish Ministers to make provision by way of regulations to modify this list (i.e. the definition of “regulated health care professional” for this purpose).

Reason for taking power

16. A regulation-making power is required to amend the list of health care regulators to:

- add any new and relevant regulators which are established;
- remove any which are abolished; or
- make amendments where the name of any listed regulator is changed.

17. This will ensure the list of regulators remains accurate and up to date.

Choice of procedure

18. Any regulations exercising this enabling power to amend the definition of “regulated health care professional” in section 1(3) of the Bill are to be subject to the negative procedure. This is considered appropriate as the delegated power allows the amendment of a list of regulators in pursuit of the same policy aim – identifying circumstances where a procedure would not be considered to be a non-surgical procedure for the purposes of the Bill – rather than changing the nature of this provision. Although the amendment would be made to primary legislation, the change would be of a technical nature without changing the substantive policy intention. Therefore the negative procedure is considered appropriate.

Section 1(5) – Meaning of “non-surgical procedure”

Power conferred on: the Scottish Ministers

Power exercisable by: regulations made by Scottish statutory instrument

Parliamentary procedure: affirmative

Provision

19. Section 1 provides a general definition of a non-surgical procedure which includes that such a procedure be of a kind specified in schedule 1. Section 1(5) allows the Scottish Ministers to make provision by way of regulations to modify the list of procedures in schedule 1.

Reason for taking power

20. A regulation-making power is required to amend the list of procedures in schedule 1:

- to add any new non-surgical procedure which may be developed, or where a non-surgical procedure previously covered by the local authority licensing scheme needs to be carried out in a permitted premises, for example, due to a change in how the procedure is performed;

- to amend the description of any non-surgical procedure in schedule 1 which may arise due to a change in how the procedure is performed; or
- to remove any procedures which are no longer being practised, or where a change in how they are performed means they no longer need to be carried out in a permitted premises.

Choice of procedure

21. Amendments made relying on the new enabling power would involve amending primary legislation, for which affirmative procedure is usually the most appropriate parliamentary procedure. The list of procedures in schedule 1 directly relates to the offences of providing a non-surgical procedure outwith permitted premises or to a person under the age of 18. To add or remove a procedure from this schedule could represent a change in policy in terms of what non-surgical procedures are covered by the legislation, criminalising behaviour that was previously lawful or decriminalising behaviour that was previously prohibited. For these reasons the higher level of parliamentary scrutiny afforded by the affirmative procedure would appear appropriate.

Section 2(6) – Offence of providing a non-surgical procedure to person under 18

Power conferred on: the Scottish Ministers

Power exercisable by: regulations made by Scottish statutory instrument

Parliamentary procedure: negative

Provision

22. Section 2 creates a new offence of providing a non-surgical procedure to a person (“a client”) under the age of 18 years. It is a defence for anyone charged with this offence to show that they had taken reasonable steps to establish the client’s age and reasonably believed the client to be aged 18 or over. One way in which an accused person can demonstrate that they had taken reasonable steps to establish the client’s age is if they were shown a document listed in section 2(4) and that document would have convinced a reasonable person as to the client’s age. The documents listed are:

- a passport,
- a UK driving licence,
- a European photocard driving licence,
- a Ministry of Defence Form 90 (Defence Identity Card),
- a photographic identity card that includes the national Proof of Age Standards Scheme hologram,

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- a national identity card issued by a member State, Norway, Iceland, Liechtenstein or Switzerland, or
- a Biometric Immigration Document issued in accordance with the Immigration (Biometric Registration) Regulations 2008 (S.I. 2008/3048).

23. Section 2(6) provides the Scottish Ministers with the power to make regulations which may add or remove a document from this list or vary the description of an existing entry.

Reason for taking power

24. A regulation-making power is proposed to be taken to add or remove a document from this list, or to amend the description of a document, to cover any instances in future where further documents become available that would be considered acceptable proof of age or where documents listed are no longer in use.

Choice of procedure

25. Amendments made relying on this new enabling power will follow the negative procedure, as it allows the amendment of a list of documents in pursuit of the same policy aim – one way of demonstrating acceptable proof of age – rather than changing the nature of this provision. Although the amendment would be made to primary legislation, the change would be of a technical nature, and the power could not be used to change the underlying policy.

Section 4(4) – Meaning of “permitted premises”

Power conferred on: the Scottish Ministers

Power exercisable by: regulations made by Scottish statutory instrument

Parliamentary procedure: affirmative

Provision

26. Section 4 sets out the meaning of a permitted premises for the purposes of the Bill. It is an offence to provide a non-surgical procedure outwith permitted premises (section 3). Some of the permitted premises listed involve the provision or management of services by specified healthcare professionals. Section 4(4) provides that the Scottish Ministers may, by regulations, modify the meaning of “permitted premises”.

Reason for taking power

27. The non-surgical procedures sector is a rapidly changing one, where new procedures and new ways of performing existing procedures are constantly developing. This may affect, among other things, the way procedures are administered, the type of settings they take place in, the training and skills required

to administer them, and the level of healthcare intervention that is required to perform them or respond to potential complications. In order to future-proof the Bill, it is necessary to be able to amend the meaning of permitted premises to change, add or remove settings in which non-surgical procedures can be offered.

Choice of procedure

28. Amendments made relying on the new enabling power would involve amending primary legislation, for which affirmative procedure is usually the most appropriate. In addition the definition of permitted premises directly relates to the offence of providing non-surgical procedures outwith such premises. To increase or narrow the scope of this definition could represent a change in policy, criminalising behaviour that was previously lawful or decriminalising behaviour that was previously prohibited. For these reasons, higher level of parliamentary scrutiny afforded by the affirmative procedure would appear appropriate.

Section 5 – Power to make further provision about non-surgical procedures

Power conferred on: the Scottish Ministers

Power exercisable by: regulations made by Scottish statutory instrument

Parliamentary procedure: affirmative

Provision

29. Section 5 allows the Scottish Ministers to impose further restrictions and requirements in relation to the provision of non-surgical procedures. Such regulations may include:

- imposing different restrictions and requirements by reference to categories of non-surgical procedure as specified in the regulations;
- specifying persons or descriptions of persons who may provide or supervise the provision of a non-surgical procedure;
- specifying requirements about the training or qualifications of persons who may provide or supervise the provision of a non-surgical procedure;
- creating an offence in connection with a contravention of a restriction, or failure to comply with a requirement, imposed by virtue of the regulations; or
- conferring functions relating to the enforcement of provisions made under the regulations.

30. Section 5 also allows any regulations made under the power to modify any enactment (including the Bill).

Reason for taking power

31. As discussed above, the rapidly changing nature of the non-surgical procedures sector requires an element of future-proofing to take account of new procedures and new ways of performing existing ones. As the market develops new evidence may arise about safer or riskier practice, and this power would allow provision to be made to enforce or restrict such practice accordingly. This could require making different provision for specific procedures, for example, in relation to the specific way in which a particular procedure is carried out. For example, this power could be used to impose requirements relating to the conditions (e.g. relating to hygiene) under which procedures may be being carried out. Alternatively, the power could be used to restrict the provision of certain procedures to particular groups if it emerged that a new procedure could put the health of a particular group of people at risk (e.g. pregnant women or people with a particular health condition etc.).

32. It may also be necessary to make provision for offences and penalties for a person who contravenes a restriction imposed in the regulations (including exceptions or defences to any offences).

33. The Scottish Government proposes that certain non-surgical procedures should be undertaken by appropriate healthcare professionals, and that a standard of training and qualification is appropriate for non-healthcare professional practitioners, who should also be required to work under supervision. For example, for certain procedures that are associated with a higher level of risk, a requirement could be imposed under the regulations that that kind of procedure may only be performed by a regulated health care professional. In addition, for other procedures that are associated with a slightly lower level of risk, a requirement could be imposed under the regulations that that kind of procedure may be performed by a person only if the person is acting under the supervision of another person who is a regulated health care professional. This power would allow provisions to be put in place to that effect, and to change such provisions in response to a developing education and training market, or developments in the landscape of regulated professionals.

34. The provision of training or qualification standards or the restriction of procedures (and their supervision) to particular professionals has not been provided for in the Bill on introduction due to the Scottish Government's current understanding of the impact of UKIMA, which may prevent such provision from being enforceable, as mentioned in paragraphs 10-12 above. As such, the regulation-making power in section 5 is also required to put in place such provision in the future. The Scottish Government is currently working with the UK Government to seek to understand the impact of UKIMA, so that in future legislation can specify that certain non-surgical procedures must be undertaken or supervised by certain healthcare professionals. The regulation-making power will enable the Scottish Government to do that.

35. The ability to modify any enactment (including the Bill) is needed from a future-proofing perspective. If the power is used, for example, to create new offences

or to introduce training and qualification requirements, it may be desirable to amend the Bill itself so that the regulation of non-surgical procedures is set out in one place rather than in separate regulations. In addition, it may be that the introduction of requirements using this power, for example in relation to training and qualification requirements, results in the need for consequential amendments to be made to other legislation such as the National Health Service (Scotland) Act 1978, for example.

Choice of procedure

36. Amendments made relying on the new enabling power may involve amending primary legislation, for which affirmative procedure is usually the most appropriate. This power allows provision to be made to allow the legislation to keep pace with the non-surgical procedures sector and what is required to continue to ensure it is safe and the public is adequately protected. It will allow provision to be made in relation to training or qualification standards or the restriction of procedures (and their supervision) to particular professionals in the future. Provision made in these powers can be supported by new offences, or enforcement powers. As such the higher level of parliamentary scrutiny afforded by the affirmative procedure appears appropriate.

Section 18 – Ancillary provision

Power conferred on: the Scottish Ministers

Power exercisable by: regulations made by Scottish statutory instrument

Parliamentary procedure: affirmative if amending primary legislation, otherwise negative

Provision

37. Section 18 provides the Scottish Ministers with the power to make, by regulations, such incidental, supplementary, consequential, transitional, transitory or saving provision as they consider appropriate in connection with or for giving full effect to the Bill, any provision of the Bill or any provision made under it.

Reason for taking power

38. Such provision is standard in Bills to provide flexibility to make any adjustments that may arise in light of experience in relation to the operation of the Act as timeously as possible. The Scottish Government recognises the potentially broad application of this power, which includes the power to modify primary legislation, and to alter the provisions of the Bill. Any incidental or supplementary use of the power would be strictly construed. While the Scottish Government has given careful consideration to the provisions of the Bill, this power is considered necessary to ensure that any unexpected issues which require further changes can be dealt with effectively and so that the purpose of the Bill is not inadvertently obstructed.

Choice of procedure

39. Section 19 provides that regulations made under section 18 which contain a provision which adds to, replaces or omits any part of the text of an Act (i.e. where the regulations amend primary legislation) are subject to the affirmative procedure. Otherwise, regulations made under this section are subject to the negative procedure. This approach is typical for ancillary powers of this type and is considered to provide an appropriate level of scrutiny where there is a proposal to amend primary legislation.

Section 20(2) – Commencement

Power conferred on: the Scottish Ministers

Power exercisable by: regulations made by Scottish statutory instrument

Parliamentary procedure: laid, no procedure

Provision

40. Section 20 provides for the Scottish Ministers, by regulations, to appoint a day when the provisions of the Bill come into force. Certain sections are excepted from this power, namely sections 15, 18, 19, 20 itself and 21, as they come into force on the day after Royal Assent.

Reason for taking power

41. The Scottish Ministers consider it appropriate for the provisions of the Bill not coming into effect on Royal Assent to be commenced at such a time as the Scottish Ministers consider to be suitable. It is standard practice for the commencement provisions to be dealt with by subordinate legislation.

Choice of procedure

42. As is usual for commencement regulations, the default laying requirement applies (as provided for by section 30 of the Interpretation and Legislative Reform (Scotland) Act 2010). This is considered appropriate because the policy behind the provisions will already have been considered by Scottish Parliament during the passage of the Bill. Any regulations made under this section will be laid before the Scottish Parliament as soon as practicable after being made.

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