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

Policy Memorandum

Introduction

- 1. As required under Rule 9.3.3 of the Parliament's Standing Orders, this Policy Memorandum is published to accompany the Non-surgical Procedures and Functions of Medical Reviewers (Scotland) Bill, introduced in the Scottish Parliament on 8 October 2025.
- 2. The following other accompanying documents are published separately:
 - Explanatory Notes (SP Bill 77–PM);
 - a Financial Memorandum (SP Bill 77–PM);
 - a Delegated Powers Memorandum (SP Bill 77–DPM);
 - statements on legislative competence made by the Presiding Officer and the Scottish Government (SP Bill 77–LC).
- 3. This Policy Memorandum has been prepared by the Scottish Government to set out the Government's policy behind the Bill. It does not form part of the Bill and has not been endorsed by the Parliament.
- 4. The Bill primarily comprises provision related to non-surgical procedures but also includes some provision in relation to the Certification of Death (Scotland) Act 2011. These are separate elements of the Bill and are considered separately below.

Non-surgical procedures

Policy objectives of the Bill

5. The primary purpose of the Non-surgical Procedures and Functions of Medical Reviewers (Scotland) Bill is to regulate certain non-surgical procedures which pierce or penetrate the skin. Procedures which are undertaken for health care treatment purposes are not included.

SP Bill 77–PM 1 Session 6 (2025)

- 6. The Bill will ensure that those non-surgical procedures regulated by the Bill are only provided from appropriate settings (referred to in the Bill as 'permitted premises'). It will be an offence for a person to provide a procedure outwith permitted premises. It will also be an offence for a person to provide a procedure to a person who is under the age of 18. Where procedures take place in a Healthcare Improvement Scotland (HIS) regulated setting, HIS will be able to use existing powers to support high standards of safety and quality. The Bill also provides a new enforcement power for HIS to inspect settings which are not required to register with them, but where they have reasonable grounds to believe that an offence under the Bill has been/is being committed, or the setting is being used in connection with an offence.
- 7. Separately, by the end of the current Parliamentary session the Scottish Government intends to lay an order under the Civic Government (Scotland) Act 1982 establishing a licensing scheme for procedures which are lower risk and do not require the intervention of a healthcare professional and are therefore not included in the Bill. The licensing Order is not included in the scope of this Policy Memorandum, but it is intended to complement the Bill in providing a comprehensive approach to these procedures.

Background

- 8. The number of non-surgical procedures that pierce or penetrate the skin being carried out across Scotland has risen considerably over the years and continues to do so. The current size of the non-surgical cosmetics sector in Scotland is hard to assess accurately. HIS reports that most of the approximately 550 independent clinics registered with them offer procedures that would be regulated by the Bill, but the Scottish Government understands that the unregulated part of the sector may be much larger, and has estimated this part of the industry to be in the region of 1,000-1,500 businesses. This is a best estimate based on the number of providers of non-surgical procedures currently registered with HIS and the number of businesses listed as providing hair and beauty services in the Office for National Statistics Inter-Departmental Business Register. (In 2023 there were 3,955 hair and beauty services registered, but it is not possible to determine what proportion of these offer non-surgical procedures; additionally, many businesses operating may not be registered in the Business Register). As a further indication of the size of the industry at a UK wide level, the British Beauty Council's 'The Value of Beauty' report stated that "in 2022, the personal care industry supported a total GDP contribution of £24.5bn ... [and] tax contributions of £6.8bn to the UK treasury". This report also found that the sector is mainly comprised of small and medium-sized enterprises. While these figures are UKwide, and they do not exclusively relate to procedures regulated by the Bill, they demonstrate the potential importance of this industry to the Scottish economy as a whole, and to our high streets across the country.
- 9. Alongside the growth of this industry there has been increased concern about the safety of these procedures, especially, but not only, where they take place outwith a safe, hygienic and regulated setting.

- 10. The procedures regulated by the Bill include a range of procedures which may be carried out for a cosmetic purpose, but could also include procedures undertaken for broader wellbeing or lifestyle purposes, such as to improve vitality or focus. A "non-surgical procedure" is defined in the Bill as a procedure which penetrates the skin including by means of a needle, chemicals, medicines, heat or cold, lasers, sound, light or electricity, and which is further described in the schedule of the Bill. There are some exceptions to this for procedures undertaken as part of healthcare as described in more detail in paragraph 17.
- 11. These procedures are currently undertaken by different types of practitioners. They are sometimes carried out by regulated health care professionals, including doctors, nurses or dentists, who must be adequately trained and are subject to professional standards of competence and to investigation if concerns are raised. Procedures can also be carried out by beauty therapists who may be highly skilled and have voluntarily registered with professional organisations such as the British Association of Beauty Therapy and Cosmetology. However, in some cases individuals carry out procedures with no adequate training or oversight. Procedures are also sometimes done using unlicensed, unsuitable or low-quality products which leads to an increased risk of harm to clients.
- 12. Alongside the range of practitioners is a range of settings where procedures may be carried out. Procedures are sometimes carried out in clinical settings such as independent hospitals and clinics, subject to regular inspection by HIS. They are also carried out in beauty salons, which are not subject to inspection or external scrutiny, or sometimes in hotels, mobile vehicles or someone's home. While again some of these non-regulated settings may be kept to a good standard of hygiene, in the absence of regulation these premises are not subject to any external standards, verification or monitoring of cleanliness and safety.
- 13. When procedures go wrong, this can lead to harms ranging from mild to more serious, including permanent disfigurement. Some of these harms can require treatment from the NHS, adding pressure to these already-stretched services. While the Scottish Government is not aware of any reported deaths in Scotland, in September 2024 media reported the death in England of a 33-year-old woman following complications after undergoing a liquid buttock augmentation procedure. During discussions with healthcare and non-healthcare stakeholders throughout the development of the legislative proposals the Scottish Government has heard a range of evidence about harms that have occurred including from healthcare professionals about instances where patients have attended Accident and Emergency Departments with complications following procedures. Complications can include burns, blockages in blood vessels, infections, injury to the eyes or necrosis of cells in living tissue, which sometimes does not occur or become apparent until some time after the procedure has taken place.

Current legislation and landscape regarding non-surgical procedures

- 14. There is currently no legislation specifically governing these procedures. The Human Medicines Regulations 2012 regulate who can supply and administer medicines to patients: many non-surgical procedures either use prescription-only medicines as part of the procedure (such as Botox® injections) or require them to treat complications arising from the procedure, such as hyaluronidase to dissolve dermal fillers. As the Human Medicines Regulations are a reserved matter the Bill will not regulate these matters. The Bill will regulate the procedures undertaken in terms of where they can be carried out, not who can supply or administer medicinal products.
- 15. Part 1 of the National Health Service (Scotland) Act 1978 ("the 1978 Act") and associated secondary legislation including The Healthcare Improvement Scotland (Requirements as to Independent Health Care Services) Regulations 2011 and The Healthcare Improvement Scotland (Inspections) Regulations 2011 contain provisions for the regulation of independent health care services by HIS. Independent health care services include independent hospitals and independent clinics, and non-surgical procedures are currently carried out within some of these settings. HIS have told the Scottish Government that the majority of independent clinics registered with them offer procedures that would be regulated by the Bill. HIS provide guidance on providing an independent clinic from fixed premises, which can be used by those offering these procedures in independent clinics.
- 16. Professional regulatory bodies such as the General Medical, Dental and Pharmaceutical Councils and the Nursing and Midwifery Council set professional standards for their members and can carry out performance or fitness to practice investigations into the behaviour or performance of individual health professionals where a complaint is deemed sufficiently serious.

Key provisions of the Bill

- 17. The Bill provides a general definition of what a non-surgical procedure is, that is a procedure that:
 - pierces or penetrates a person's skin, including by means of a needle, chemical, medicine, heat, cold, light, laser, sound or electricity; and
 - is set out in schedule 1 of the Bill, such as dermal fillers, cellulite subcision, and chemical peels.

It does not include a procedure:

 that is provided by a person acting for or on behalf of the health service or by a health care provider for the prevention, diagnosis or treatment of an illness, such as the use of botulinum A toxin injections for the treatment of hyperhidrosis (excessive sweating); or

- is designated by an Order under section 44(1)(b) of the Civic Government (Scotland) Act 1982 as an activity for which a licence is required under Part 1 of that Act, including tattooing, acupuncture and skin piercing.
- 18. Advice from clinical experts, evidence from professional bodies such as the Nuffield Council on Bioethics and the British Association of Aesthetic Plastic Surgeons, along with feedback from stakeholders, including responses to the Scottish Government's <u>public consultation</u> on the regulation of non-surgical cosmetic procedures (which also covered some 'wellbeing' procedures such as vitamin infusions), made clear the view that these procedures are not suitable for young developing bodies, and that the potential physical and psychological harms that inappropriate procedures could do to young people mean they should only be carried out on adults. Therefore the Bill makes it an offence to provide a non-surgical procedure on a person under the age of 18. The Bill contains a defence for an accused person to prove that they had taken reasonable steps to establish the person's age, and that they reasonably believed them to be 18 or over. A non-exhaustive list of the types of documents that could be used to prove age is included.
- 19. The Bill also creates an offence to provide a non-surgical procedure outwith a permitted premises, with the defence that the accused reasonably believed the procedure was being provided in permitted premises. Permitted premises are an independent hospital that is registered with HIS, or an independent clinic that is registered with HIS and where services are provided or managed by a registered medical or dental practitioner, a registered nurse or midwife who is an independent prescriber or a pharmacist independent prescriber. They also include GP and dental practices which provide NHS services and registered pharmacies, which are exempt from the requirement to register with HIS under the 1978 Act and are often already regulated by the NHS and/or professional regulatory bodies.
- 20. HIS have existing powers to inspect any independent health care service under the 1978 Act, for the purposes of reviewing and evaluating the services provided, encouraging improvement, making any necessary recommendations and investigating any incident, event or cause for concern. HIS also have the ability to enter and inspect any premises, which are used or which they have reasonable cause to believe are being used to provide an independent health care service. For the purposes of this policy this means that HIS can enter a premises where they know or suspect an independent health care service is being provided, which might be carrying out non-surgical procedures.
- 21. The Bill adds a further power of entry, search and seizure under warrant, where there is a reasonable belief that an offence of carrying out a non-surgical procedure outwith permitted premises or on a person under the age of 18 has been or is being committed. This will allow persons authorised by HIS to inspect any premises where they reasonably suspect non-surgical procedures are being carried out outwith permitted premises and seize any equipment or material that provides evidence of this. This will provide a mechanism for HIS to take enforcement action where non-surgical

procedures are being performed in inappropriate settings by individuals who do not have the required skills, and it forms a key part of the proposed regulation. Premises here includes any land or building, vehicle, vessel, trailer, aircraft or hovercraft, tent or other moveable structure. The Bill adds an offence of obstructing an authorised person from doing anything they are entitled to under the legislation, or failing to comply with a request made by an authorised person to comply with a reasonable direction made by an authorised person, or to give that person such information or assistance as they may reasonably require.

22. All offences within the Bill will be liable on summary conviction to a fine not exceeding level 5 on the standard scale (currently £5,000).

Regulation-making powers

- 23. The Bill contains a number of regulation-making powers, to:
 - amend the list of regulators that oversee the regulated health care professionals (who are listed for the purpose of excluding from the Bill procedures that are also for the purpose of or in connection with preventing, diagnosing or treating and illness) in section 1(3);
 - amend the list of non-surgical procedures specified in schedule 1;
 - amend the list of documents that can be used to prove age in section 2(4);
 - amend the meaning of 'permitted premises' in section 4;
 - impose further restrictions and requirements in relation to the provision of nonsurgical procedures, which may include:
 - imposing different restrictions or 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
 provide or supervise the provision of non-surgical procedures; and
 - conferring functions relating to the enforcement of restrictions and requirements imposed by virtue of the regulations.
- 24. 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, amongst other things, the way procedures are administered, 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. Therefore it may be necessary, for instance, to add to the Bill a procedure that was previously the subject of the proposed licensing scheme to be established under SSI, or to add a completely new procedure that has come on to the market.

- 25. In addition to the restriction to performing non-surgical procedures in permitted premises, the Scottish Government also proposes that it is necessary to restrict the type of person who can undertake specific procedures. Under these proposals some procedures should only be performed by one of the healthcare professionals listed in the definition of permitted premises, and who has the appropriate experience and expertise, because of the high level of anatomical or physiological skill required. Other procedures do not appear to require this level of protection and can be safely carried out by a suitably trained non-healthcare practitioner under the supervision of a healthcare professional. It has however not been possible to include these provisions in the Bill due to the effects of the United Kingdom Internal Market Act 2020 (UKIMA).
- 26. 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 regualify¹. Section 24 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. 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 has recently announced its intention to legislate to regulate certain nonsurgical cosmetic procedures.
- 27. 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 non-healthcare practitioners under the supervision of one of those healthcare professionals. The Scottish Government is working with the UK Government to seek to resolve these issues so that this can be done as soon as possible in future legislation.

Alternative approaches

28. The Scottish Government considered whether it would be possible to regulate all non-surgical procedures that pierce or penetrate the skin via a local authority licensing scheme, such as the one proposed for lower risk procedures mentioned above at paragraph 7 above. This would have given new statutory powers to local authority environmental health officers (EHOs) who currently respond to complaints about the

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¹ Explanatory Notes to the <u>United Kingdom Internal Market Act 2020</u>

provision of non-surgical procedures in non-healthcare settings using powers under health and safety legislation.

- 29. This approach would not, however, take into account several factors: that many of these procedures are performed in independent health care settings that are or should be regulated by HIS; that they require anatomical or physiological knowledge which necessitates an aspect of medical expertise in their regulation; that some procedures require the use of prescription-only medications, which have their own regulatory environment outwith the sphere of knowledge of EHOs; and that some procedures should only be undertaken or supervised by a healthcare professional with the appropriate level of anatomical and physiological training and so that regulation can only effectively be undertaken by individuals who understand what that requires. HIS was the obvious choice to carry out that more specialist regulation, for the reasons rehearsed in paragraph 20 above.
- 30. The Scottish Government is aware that the UK Government has published its response to its 2023 public consultation on the licensing of non-surgical cosmetic procedures in England, and indicated an intention to further consult on proposals for these procedures. These proposals would currently appear to place a greater range of procedures under local authority licensing, but the model of supervision that would be required has not yet been settled. The Scottish Government remains confident that its proposed model is the most appropriate one for Scotland given the existing regulatory regime, and allows the Scottish Government to address the public safety concerns about the safety of these procedures that currently exist in this sector while being proportionate to the aim of reducing the health harms to clients/consumers of unsafe procedures.

Public consultation and stakeholder engagement

- 31. A <u>public consultation</u> on these proposals ran from 20 December 2024 to 14 February 2025. 2,207 responses were received, 94% of which came from individuals. 45% of all respondents stated a connection with the delivery of non-surgical procedures, as a practitioner themselves or the representative of an organisation providing these procedures. The consultation asked for views on both the proposed regulation scheme that is the subject of this Bill, and the proposed licensing scheme, which will be established by the SSI mentioned in paragraph 7 above. It contained questions about: the grouping of non-surgical procedures and whether they could be undertaken under the licensing scheme by non-healthcare practitioners (referred to in the consultation as group 1), or by a healthcare professional (group 3) or under the supervision of a healthcare professional (group 2); the detail of the licensing scheme; proposed age restrictions; and, specifically in relation to the proposals covered by the Bill, it asked about:
 - Setting standards of training and insurance/indemnity for the provision of nonsurgical procedures (73% and 81% of respondents respectively strongly agreed that these standards should be set):

- The role of a supervising healthcare professional in performing these procedures (over 70% of respondents agreed with each suggestion, that the supervising healthcare professional should conduct initial consultations, prescribe any medication required during or after the procedure, remain available for the duration of the procedure, be responsible for ensuring the practitioner is suitably trained and that the practice will be undertaken safely, and be themselves suitably trained for the procedure); and
- Whether the list of healthcare professionals who can undertake non-surgical procedures should be limited (53% of respondents believed that these procedures should only be undertaken by specific healthcare professionals, with over 50% in each case suggesting this should be medical or dental practitioners or registered nurses).
- 32. These responses showed a high level of overall support for our proposal to regulate non-surgical procedures. While there was a good level of agreement with the procedures that were proposed to be in groups 1 and 3, responses were more mixed with regard to proposals for group 2. For example, a number of respondents, including many from a healthcare background felt that some of the proposed group 2 procedures should be placed into group 3, while other respondents, including many working in the currently unregulated non-clinical part of the sector believed that the same procedures should be placed in Group 1, where they would be subject to the proposed licensing scheme, but not restricted to HIS regulated settings. In addition, between 64% (for the lowest risk procedures which could potentially be carried out by non-healthcare professionals under the local authority licensing scheme described at paragraph 7 above) and 88% (for the highest risk procedures which should only be carried out by a healthcare professional) of respondents felt there should be an age restriction of 18 years and above for each group of non-surgical procedures. Further information is available in the Scottish Government's analysis of the consultation.
- 33. In February 2025 officials hosted two engagement events for non-healthcare business owners, in support of the Business and Regulatory Impact Assessment (BRIA). 71 people attended; they were not opposed to proposals for regulation in general but voiced concerns about the impact on their businesses if healthcare professionals needed to supervise procedures, and the strongly held view that healthcare professionals had unfairly influenced Scottish Government proposals. The Scottish Government has continued to engage with these businesses through development of the BRIA, recognising their perception that the policy development has been led by healthcare professionals and that the two groups hold different views with regard to the level of regulation required for non-surgical procedures.
- 34. Officials met with a range of stakeholders as policy proposals developed, to discuss the policy intent behind the Bill and the potential legislative change. This has led to aspects of the proposals being revised, such as the groupings of non-surgical procedures, Scottish Government consideration of training and qualifications standards, and how the proposals will interact with existing professional regulation and standards. Key stakeholders include:

- Healthcare Improvement Scotland;
- Non-healthcare business owners;
- Healthcare professionals working in the non-surgical cosmetic and wellbeing procedures sector;
- Professional regulators including the General Medical Council, the Nursing and Midwifery Council, the General Dental Council, the General Pharmaceutical Council and the Health and Care Professions Council;
- Representatives of the British College of Aesthetic Medicine, British Association of Medical Aesthetic Nurses, British Association of Beauty Therapy and Cosmetology and Confederation of Beauty Therapy and Cosmetology through their membership of the Scottish Cosmetic Interventions Expert Group;
- The Joint Council for Cosmetic Practitioners;
- Save Face (a UK Government approved register of providers of aesthetic procedures);
- The Scottish Medical Aesthetics Safety Group; and
- Local authority environmental health officers.

Effects on equal opportunities, human rights, island communities, local government, sustainable development etc.

Equal opportunities

- 35. A combined Equality and Fairer Scotland Impact Assessment has been carried out in respect of the proposals contained in the Bill and will be published separately on the Scottish Government's website. It found that in general the proposals would have a positive impact on all of the groups covered by these categorisations: regulation will lead to improved safety in non-surgical procedures for all clients through ensuring they are carried out by suitably trained and qualified practitioners, in safe and hygienic settings using appropriate products and equipment. However the BRIA has found that there will be a significant impact on some businesses due to increased costs relating to the potential need for non-healthcare practitioner led businesses to employ prescribing healthcare professionals, register with HIS, undertake further training and possibly make alterations to their premises to comply with HIS standards, as well as potential loss of revenue from not being able to offer certain procedures if they do not take these steps.
- 36. The absence of regulation and therefore of statistical data means that there is limited information available on the locations of businesses and the demographic or socio-economic profiles of those employed within this sector. The Scottish Government's understanding, based on engagement with a wide range of stakeholders, and the views expressed in the public and BRIA consultations, is that the majority of practitioners and businesses owners in this sector are women. There is concern that the proposals will therefore affect women's economic independence and family

stability. While the proposals allow for businesses to adapt, for example by employing healthcare professionals to carry out or supervise non-surgical procedures and seeking registration with HIS, the Scottish Government will continue to take business impact into account throughout implementation of the legislation and work with stakeholders and business/enterprise support organisations to mitigate the effects as far as possible, while still ensuring improvements to safety in the sector are achieved. Regulation will allow data about businesses offering non-surgical procedures to be captured by local authorities or HIS, meaning future monitoring will be possible, for example of the type of services offered, the location of businesses and the types of healthcare professional being employed by otherwise non-healthcare businesses to allow them to offer the procedures covered by the Bill.

Human rights

- 37. The Bill's provisions are compatible with rights under the European Convention on Human Rights (the Convention) and act to promote certain rights most specifically Article 2, the right to life, which requires that states have in place adequate regulation and controls to promote high standards in healthcare. Similarly, Article 12 of the International Covenant on Economic, Social and Cultural Rights provides that all persons have a right to enjoy the highest attainable standard of physical and mental health. Scottish Government proposals support these principles in establishing standards for the safe provision of non-surgical procedures and the reduction of harm.
- 38. A Child Rights and Wellbeing Impact Assessment will be published on the Scottish Government's website following publication of the Bill. While the Scottish Government's decision to restrict non-surgical procedures to individuals aged 18 and over may be seen to have a negative impact on children's rights in regard to articles 5 of the UNCRC (parental guidance and a child's evolving capacities) and article 12 (respect for the views of the child), we consider that, as the nature of the majority of non-surgical procedures makes them unsuitable to be carried out on children and young people, the protection offered to children and young people by this restriction supports article 3 (the best interests of the child), article 24 (right to the best possible health) and article 36 (protection from exploitation).
- 39. The Scottish Government does not consider that the rights of any specific groups, including women are compromised, and this is addressed further in the Equality and Fairer Scotland Duty Impact Assessment which will be published separately on the Scottish Government's website. While there will potentially be some impact on businesses, the majority of which appear to be operated by women, this is felt to be the minimum level of disruption that still allows the public safety concerns that exist in this sector currently to be addressed, and that are proportionate to the aim of reducing the health harms to clients/consumers of unsafe procedures. The Scottish Government is working with business gateway organisations to explore support for businesses in changing their business models. Women also make up the majority of recipients of non-surgical procedures, and this group will be positively impacted by improvements to safety.

Statement of compatibility under section 23(1) of the United Nations Convention on the Rights of the Child (Incorporation) (Scotland) Act 2024 (UNCRC)

40. The Cabinet Secretary for Health and Social Care, Neil Gray MSP, has made the following statement regarding children's rights:

"In accordance with <u>section 23(1) of the United Nations Convention on the Rights of the Child (Incorporation) (Scotland) Act 2024</u>, in my view, the provisions of the Non-surgical Procedures and Functions of Medical Reviewers (Scotland) Bill are compatible with the UNCRC requirements as defined by <u>section 1(2) of that Act.</u>"

Island communities

- 41. The Bill's provisions will apply equally to all parts of Scotland. While the unregulated nature of the sector makes it difficult to ascertain where services are currently situated, it is reasonable to suspect that in small, widely dispersed communities, including those found on islands, and in remote and rural mainland areas, service provision will be low. The requirement that non-surgical procedures take place in premises licensed by the local authority or regulated by HIS may limit the availability of services further and make it difficult for clients to get the procedures they want in a convenient location. This may mean individuals have to travel further to obtain procedures, which may add to costs for the individual. However, due to the nature of the issues which the policy aims to address, it is not possible to make exceptions or alternatives for island communities. Non-surgical procedures must be licensed or regulated in a consistent way across the country, so that the regime is fair and straightforward for providers, and for local authorities and HIS, who must administer it.
- 42. It may be possible to mitigate some of the effects of these proposals. For example, practitioners who require the services of a healthcare professional for supervision or a prescriber for the use of prescription-only medicines may be able to schedule their clients in such a way that any appointment requiring a prescriber or other healthcare professional is scheduled on certain days of the week or month when they can be present in the area, thus avoiding the need for their attendance every day or at ad-hoc times. Licence fees will be a matter for discussion with the relevant local authorities.
- 43. It should be noted that the procedures covered by the Bill are not a public service and are made available to members of the public on a private business basis (as mentioned above, any requirement for such procedures which are medically necessary will not be affected by these proposals and will continue to be available via relevant medical pathways).

Local government

44. The establishment of the scheme to regulate the procedures covered by the Bill does not affect local authorities, with HIS being the key regulatory agency in relation to

the proposals. The associated secondary legislation, which will establish a licensing scheme for lower risk procedures, will incur additional responsibilities for local authorities in assessing licence applications and inspecting premises, but the associated costs are likely to be met through licensing fees. Restriction of certain procedures to permitted premises may have a positive impact on local authorities insofar as it may reduce the reactive role played by environmental health officers in relation to concerns about the safety of these procedures being undertaken outwith clinical settings.

Sustainable development

45. The potential environmental impact of the Bill has been considered. A prescreening report confirmed that the Bill has minimal or no impact on the environment and consequently that a full Strategic Environmental Assessment does not need to be undertaken. It is therefore exempt for the purposes of section 7 of the Environmental Assessment (Scotland) Act 2005. The Bill supports the United Nations Sustainable Development Goal 3 (ensure healthy lives and promote wellbeing for all at all ages), by establishing a regulatory regime to improve the safety of non-surgical procedures and reduce the risk of harm.

Certification of death

Background

- 46. The Certification of Death (Scotland) Act 2011 ("the 2011 Act") was introduced to improve the quality and accuracy of death certification in Scotland. The 2011 Act creates functions for medical reviewers who are employed by HIS (working in the Death Certification Review Service (DCRS)) and who carry out the key functions under the 2011 Act. One of the key functions is to review a random selection of Medical Certificates of Cause of Death (MCCDs) to check the quality and accuracy of the MCCD and improve the way that information about deaths is recorded. Of all eligible MCCDs, 10% are randomly selected for a Level 1 review (which involves checking the MCCD and a discussion with the certifying doctor) and 2% are selected for a Level 2 review (which involves an additional, more detailed review of the clinical information surrounding the death and the MCCD).
- 47. In addition to random reviews, section 4 of the 2011 Act provides for interested person reviews. This enables medical reviewers to undertake a review of a MCCD upon request by any of the following persons:
 - a person who is required or stated to be qualified to give information concerning the deceased's death.
 - a health care professional (or other carer) who was involved with the deceased's care prior to the deceased's death,
 - the funeral director responsible for the funeral arrangements of the deceased,

- the person having charge of the place of disposal of the body of the deceased.
- 48. The main purpose of an interested person review is to provide a further measure of public and professional reassurance, over and above the randomised review process as it allows specific issues in relation to the content of the MCCD to be investigated more fully.
- 49. Medical reviewers also review applications for repatriation where the deceased died abroad but is to be buried or cremated in Scotland. Where the body is to be cremated, the 2011 Act requires the application must be considered by a medical reviewer to determine whether it is safe to cremate and provide the applicant with a certificate authorising cremation.

Current legislation and landscape

50. Death certification and registration processes vary across the UK, particularly when a coroner is involved. In Scotland, a death must be registered before a body can be buried or cremated. In contrast, in other parts of the UK, a coroner may release a body for burial or cremation while an inquest is ongoing before the death is formally registered. A new medical examiner system came into force in England and Wales in September 2024 as set out in the Cremation, Coroners and Notification of Deaths (England and Wales) (Amendment) Regulations 2024. The differences in procedure and the changes brought in by the 2024 Regulations have highlighted variations in legislative requirements, especially when a body is repatriated to Scotland from another UK nation. As a result, proposals to amend the 2011 Act to address this have been put forward in this Bill. There are no further amendments that require addressing in legislation at this time.

Interested person review

- 51. Currently, where a MCCD has already been randomly selected for review by DCRS, it becomes ineligible for an interested person review. This means that an interested person is not able to request a review and therefore cannot seek what may be a more detailed review and allow specific issues in respect of the MCCD to be investigated. The Senior medical reviewer at DCRS identified this anomaly and considered that interested persons should not be barred from requesting a review due to the MCCD already being randomly selected. The Scottish Government agreed that interested persons should have the option to request a review. The Bill therefore seeks to amend this provision to allow for an interested person review in cases where a random review has been undertaken to enable a fuller investigation of the issue.
- 52. There is no direct impact on the funeral sector in allowing interested person reviews and those working in the sector have no role in these reviews.

Repatriation

- 53. Section 18 of the 2011 Act makes provision for cases where a person dies outwith Scotland but is to be cremated in Scotland. Section 18 requires referral to a medical reviewer, who will examine the case to determine whether it is safe for the body to be cremated. That will typically involve checking for information about whether the deceased had a pacemaker or other implant which may create a hazard during the cremation process. The medical reviewer will then issue a certificate to the applicant authorising cremation.
- 54. This process applies in respect of all deaths which occur outwith Scotland, so includes cases where a person has died in other parts of the UK. Where a death occurs in England, Wales or Northern Ireland the procedure to ensure there are no risks or any risks are identified before cremation in each of those nations is set out below. The Scottish Government and DCRS consider there is no need for DCRS authorisation for cremation for deaths which occur in other parts of the UK, as this would lead to duplication of work already undertaken in different nations and may lead to significant delays in repatriation. These nations have robust death certification systems in place which Scotland recognises.

Deaths in England and Wales

- 55. Medical examiners scrutinise the cause of death provided by the medical practitioner completing the MCCD. The statutory system of medical examiners was introduced in September 2024, in response to the findings of numerous independent inquiries, including the Shipman Inquiry. All deaths not investigated by the coroner must receive appropriate scrutiny by a medical examiner.
- 56. The MCCD asks the medical practitioner to indicate if they believe there are any hazards, such as an implantable medical device inside the body, to ensure there is no risk to cremate. The information on the MCCD about implantable medical devices will be transferred to the certificate for burial or cremation.

Deaths in Northern Ireland

57. The majority of deaths which are reported to the coroner are dealt with immediately and administratively, either by way of a MCCD or when a coroner, having received an assurance from a doctor as to the cause of death, notifies the Registrar of Deaths that the death may be registered via Form 14 (Pro Forma Letter). The doctor who assumes responsibility for dealing with the death will check the deceased to ascertain whether there are any implants which may create a hazard during the cremation process. This information is included in the notification of death to the Coroner's Office, but is separate to the Pro Forma.

Key provisions of the Bill

58. The Bill includes amendments to two separate aspects of the 2011 Act. Officials had discussion with DCRS and other UK government officials about the procedures in each jurisdiction. The assurances in place when considering authorising repatriation and cremation are robust. Officials also consulted with DCRS in relation to interested person reviews to consider any impact as a result of making the amendments.

Interested person review

- 59. Section 16 of the Bill will amend section 4 of the 2011 Act (application for review of certificate by interested person) to extend the circumstances in which an interested person can request a review of a MCCD. Each year, a random selection of MCCDs is reviewed as a means of further scrutiny ("a randomised review") and to extend the power of medical reviewers to reject an application.
- 60. The amendments will allow an interested person to request the review of a MCCD in cases where a randomised review or a review upon request of another interested person has already been carried out, as different interested parties may request a review for different purposes. The power of medical reviewers to reject applications is also extended, as it is currently limited to vexatious requests, to ensure that there is no obligation to carry out a review in the same terms more than once.

Medical reviewers to authorise cremation

- 61. Section 17 will amend section 18 of the 2011 Act (medical reviewers to authorise cremation) to apply where a person has died "outwith the UK" rather than "outwith Scotland". The effect of the amendment is to change the requirement for applications for cremations in Scotland to be made and reviewed by medical reviewers where the death has occurred outwith the UK by removing the requirement for medical reviewers to review cases where the death has occurred in England, Wales or Northern Ireland.
- 62. This is because where a death occurred in another part of the UK and the deceased is to be buried or cremated in Scotland, the MCCD would already have gone through the requisite review processes in that country, and further review in Scotland would not be required. The amendment to section 18 of the 2011 Act is intended to recognise the reciprocal checks within the UK, avoiding unnecessary duplication of this work.

Effects on equal opportunities and island communities and sustainable development

63. The Bill's provisions in relation to the amendments to the 2011 Act will have no impact on equal opportunities or sustainable development. They will apply equally to all parts of Scotland and there are no impacts on island communities.

Crown consent

64. Paragraph 7 of Schedule 3 to the Scotland Act 1998 requires that Crown consent be signified to the Parliament if the same Bill would need such consent were it passed by the UK Parliament. Crown Consent is therefore required where a Scottish Bill impacts the Royal prerogative, the hereditary revenues of the Crown or the personal property or interests of the Sovereign. As the Bill is drafted on introduction, it is the Scottish Government's view that it does not require Crown consent.

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

Policy Memorandum

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SP Bill 77–PM Session 6 (2025)