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

# **Financial Memorandum**

#### Introduction

- 1. As required under Rule 9.3.2 of the Parliament's Standing Orders, this Financial Memorandum is published to accompany the Non-surgical Procedures and Functions of Medical Reviewers (Scotland) Bill ("the Bill"), introduced in the Scottish Parliament on 8 October 2025.
- 2. The following other accompanying documents are published separately:
  - Explanatory Notes (SP Bill 77–EN);
  - a Policy 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 Financial Memorandum has been prepared by the Scottish Government to set out the costs associated with the measures introduced by 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.

# Background – Non-surgical procedures

- 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.
- 6. 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. Alongside the growth of this industry there has been increased concern about the

SP Bill 77–FM 1 Session 6 (2025)

safety of these procedures, especially but not only, where they take place outwith a safe, hygienic and regulated setting.

- 7. 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 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. Procedures carried out by the NHS are excluded from this definition as are procedures carried out by a health care provider such as an independent health care service or regulated health care professional in connection with the prevention, diagnosis or treatment of illness. Illness is given the same definition as the National Health Service (Scotland) Act 1978, which is inclusive of injury, and disability, and would encompass both physical and mental conditions.
- 8. The procedures regulated by the Bill are currently undertaken by different types of practitioners. They are sometimes carried out by regulated healthcare 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 a heightened risk of harm to clients.
- 9. Non-surgical procedures are performed across a wide variety of settings, ranging from regulated clinical environments to unregulated venues such as beauty salons, hotels, mobile vehicles, and private homes, many of which lack external standards or inspection. When complications arise, these can range from minor to severe, potentially causing permanent disfigurement and requiring NHS intervention. Stakeholder engagement highlighted a number of such cases, including serious outcomes like burns, infections, and vascular injuries, with some effects only appearing some time after the procedure.
- 10. The purpose of the Bill is to regulate specified non-surgical procedures, restricting the settings in which they may be carried out, and preventing them from being provided to under 18s. Separately the Scottish Government intends to lay an order under the Civic Government (Scotland) Act 1982 ("the Licensing Order") establishing a licensing scheme for procedures that are not included in the Bill. The Licensing Order is not included in the scope of this Financial Memorandum, but it is intended to complement the Bill and it is therefore relevant in considering costs on the Scottish Administration or other bodies. The Scottish Government intends to lay the Licensing Order by the end of the current parliamentary session.

- 11. The Bill will primarily have an impact on existing businesses delivering procedures regulated by the Bill, but which do not meet the definition provided in the Bill of a "permitted premises". A permitted premises is defined in relation either to:
  - Premises where services are provided under certain NHS contracts, or which are community pharmacies. For instance, mixed practice dental practices where NHS services are offered but a private service is also offered which may include procedures regulated by the Bill; or
  - The premises being part of an Independent Hospital regulated by Healthcare Improvement Scotland (HIS), or an Independent Clinic from which a medical practitioner, dentist, prescribing nurse or midwife or prescribing pharmacist is operating.
- 12. There is no comprehensive or formally collected information on the number of businesses that will be affected by the Bill due to the current unregulated nature of the sector. Healthcare Improvement Scotland reports that most of the approximately 550 independent services 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. In 2023, there were 3,955 hair and beauty services registered in Scotland in the Office of National Statistics' Inter-Departmental Business Register, but it is not possible to determine what proportion of these offer non-surgical procedures (and businesses may not be registered in this register).
- 13. Of respondents to the Scottish Government <u>public consultation</u> on the regulation of non-surgical cosmetic procedures (which also covered some 'lifestyle' procedures), 367 respondents reported that "I undertake or am an employee or representative of an organisation that undertakes non-surgical cosmetic procedures in an unregulated setting such as a beauty salon". A separate survey sent to businesses that had responded to the consultation received 415 responses. These were from respondents that either indicated that they were "A salon or clinic which is not currently regulated by Healthcare Improvement Scotland and is led by someone who is not a healthcare professional" or appeared from the comments they made to have been from such a business.
- 14. The Scottish Government has received consistent feedback (accepted by businesses themselves) that there are more businesses offering non-surgical procedures in the currently unregulated sector than the regulated one. Given the number of independent healthcare services is known, and the majority of these provide non-surgical procedures this provides an absolute lower bound for the number of businesses in this part of the sector as approximately 500. The Scottish Government estimates however that it is likely that there are twice as many businesses in the unregulated sector than the regulated one, so a more likely lower bound would be 1,000. The Scottish Government notes that the number of businesses offering hair and beauty services necessarily offers an upper bound to the estimation of businesses working in this sector. The ONS Inter-Departmental Business Register lists 3,955 businesses offering hair and beauty services. Even if 20% of such businesses are not registered, that would mean a maximum of 5,000 businesses. The Scottish Government

knows that not all businesses offering hair and beauty services are offering non-surgical procedures. The Scottish Government estimates that a likely proportion is that no more than 30% of businesses in the wider sector are providing non-surgical procedures and therefore a more likely upper bound of 1,500 businesses. Therefore, the Scottish Government estimates a likely core range of between 1,000-1,500 businesses in the unregulated sector. This would also mean that upwards of a quarter of all such businesses have responded to the Scottish Government through its consultation or survey of businesses. Please note that calculations in this paragraph are estimates which are provided for the purpose of a general reflection of the sector. The figures should not be considered exact and should be interpreted with caution.

# Background – Certification of death

- 15. The Bill includes two amendments to the Certification of Death (Scotland) Act 2011. These amendments are straightforward and brief and would not normally merit their own primary legislation. It has been agreed to include them in this Bill as an appropriate vehicle, following standard procedures.
- 16. The Certification of Death (Scotland) Act 2011 was introduced to improve the quality and accuracy of death certification in Scotland. The 2011 Act confers functions on medical reviewers (MRs), employed by HIS. The service is the Death Certification Review Service (DCRS).
- 17. National Records of Scotland randomly selects 12% of Medical Certificate Cause of Death (MCCDs) each year for review by MRs. These reviews are designed to check the quality and accuracy of MCCDs and to improve how information about the cause of death is recorded.
- 18. There are two types of review: Level 1 and Level 2. Level 1 reviews consist of a review of the MCCD and a discussion with the certifying doctors. Level 2 reviews consist of a review of the MCCD and the patient medical records, and a discussion with the certifying doctors.
- 19. In Scotland, a death must be registered before a body can be buried or cremated. In the rest of the UK a coroner may release a body for burial or cremation before the death is registered. DCRS are required to consider and approve applications for cremation when a body is repatriated from abroad. The amendment at section 17 of the Bill to the Certification of Death (Scotland) Act 2011 will ensure that DCRS do not need to do the same for repatriations from other UK nations for cremation in Scotland.

# Costs on the Scottish Administration – Non-surgical procedures

20. There are no anticipated direct costs on the Scottish Government, beyond the usual administrative burden associated with officials' time spent in supporting

implementation of the Bill, including undertaking appropriate secondary legislation and drafting guidance where required. There will be some administrative costs borne if changes are made using enabling powers in the Bill, in particular in setting training and qualification standards and in restricting some procedures to appropriate healthcare professionals. Matters concerning the regulation of independent healthcare are currently a responsibility of a policy team within the Directorate for the Chief Operating Officer, NHS Scotland, who are leading on the current legislative programme and can be expected to lead on matters of implementation and any of the future activity referred to here. The team responsible also works on other Scottish Government priorities and will continue to do so. Future activity would therefore be delivered from within this existing staff complement and is not expected to lead to an increase in activity. The cost of this work would depend on the degree of staff time required, and the grades at which work is delivered. Based on illustrative scenarios included in Annex A the range of costs is estimated as being between £70,000 and £185,000 p.a. for as long as such activity is required, probably for two to three years. Details of how these scenarios are arrived at are included in Annex A. Publication of materials through the Scottish Government contract may cost approximately £1,000 per document, depending on length and complexity. These costs would be met from within existing directorate resource.

The key impact to the Scottish Administration and its bodies will be on the work of HIS, as the main body that will be responsible for enforcing the provisions of the Bill. and registering additional services. It may be deemed necessary that the Scottish Government develops marketing activity to provide public information about the new licensing and regulatory regime for procedures. The budget required to develop and run marketing activity is dependent on a number of factors, including the budget available, the key objective of any communications, the audience(s) identified, and the most appropriate channels to be used to reach and engage the audience(s). No decision has yet been taken about the necessity of marketing activity; this will be a matter for Officials to determine, and any proposed activity and associated budget, if deemed essential, will require approval from relevant Ministers and the First Minister The cost of a public information campaign is largely dependent on the budget that can be made available. The Scottish Government publishes the costs of marketing activity<sup>1</sup> and possible costs of a campaign can be estimated from these published costs. Based on recent campaign activity for cervical cancer, menopause and organ donation a lower cost campaign could cost between £20,000-£50,000 per year to run. Higher cost campaigns may cost multiple hundreds of thousands of pounds to run, especially where TV advertising costs are included. The total campaign spend for Scottish Government in 2024-25 was £2.26m. No decision has been taken about the appropriateness of campaign activity, and that would be a matter for Scottish Ministers to determine alongside commencement and implementation of this legislation. It is unlikely that a higher cost campaign would be considered proportionate. An alternative approach would be the use of social media to share key messages around the new licensing and regulatory regime the cost of which would be absorbed within the staff resource for implementation as outlined in paragraph 20.

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<sup>&</sup>lt;sup>1</sup> Marketing spend - gov.scot

## Healthcare Improvement Scotland (HIS)

- 22. The main burden of enforcing the provisions of the Bill is likely to fall on HIS. HIS are already responsible for the regulation of independent health care. Independent health care services are required to register with HIS under the terms of the National Health Service (Scotland) Act 1978 ("the 1978 Act"), and HIS have powers to undertake inspections and, where relevant, require improvement action.
- 23. If the provisions of the Bill lead to an increase in businesses seeking registration as independent health care services, this will have an impact on HIS. HIS have confirmed that they do not believe that it is possible to reasonably estimate the number of additional registrations the Bill is likely to lead to. The Scottish Government agrees that there is no robust evidence on which to base an estimate, but information is included below on possible behaviour and the costs to which this might lead.
- 24. The estimate of between 1,000 to 1,500 existing businesses in the unregulated sector provides an absolute upper bound for the total number of businesses that might seek to register with HIS. However, the Scottish Government does not consider this upper bound to be a reasonable higher estimate for this activity, as not all existing businesses currently provide procedures regulated by the Bill for which registration will be required. The options for those businesses which do currently provide procedures for which registration will be required are set out in paragraphs 46-47, but in short such businesses may either cease offering such procedures, cease operation, or seek registration with HIS. Based on responses to the business survey, and discussions with businesses, the Scottish Government expects that it is reasonable to assume that around a third of existing businesses do not offer procedures regulated by the Bill, a further third of the total may change their business model so that they are not required to register and the remaining third will be composed of those businesses that will need to either register with HIS, or cease operation because they are unable to do so. This presents a more likely higher estimate of 500 new registrations over the first few years of the legislation being commenced. This figure remains an estimate however and should be treated with caution.
- 25. The largest obstacle to registration with HIS appears, from survey feedback, to be the requirement for an appropriate healthcare professional to operate from a business's premises. Many practitioners responding to the Scottish Government survey to businesses indicated that such professionals may not be available, or that their services may not be affordable. Taking this into account it may be that while 500 businesses may wish to seek registration, a significantly smaller number of businesses will be able to do so. This number could be smaller or equivalent to the general increase in the number of registered independent healthcare services in recent years. For example in 2024/25 HIS registered 63 services and the total number of registered services increased from 540 in 2023/24 to 554. If 10 settings in the currently unregulated sector sought registration with HIS this would not represent a significant change given the current annual fluctuations in the number of services.

- 26. This range from 10-500 businesses still represents a wide range of possible new registrations. Once the Bill has passed, including any changes, further work may be required to understand the number of potential registrants including further engagement with, or surveys of, businesses about their intentions (carried out within the Scottish Government resource identified at paragraph 20 and Annex A). Further planning will take place with HIS on this basis to prepare for any increase in the number of registrations.
- 27. The cost of new registrations will be a function of the total number of additional registrations combined with the costs of regulatory activity connected to inspection, registration of premises, and responding to complaints or notifications. HIS have provided a table of costs for regulatory activity which is included an Annex B, Annex B also includes published information on the volume of some of these activities in a given year, on the basis of these potential costs new registrations could lead to increased fee income of between approximate £8,000 to £18,000 over a five year period and the known average costs of an initial registration and on inspection in that time are £7,000. The Scottish Government does not consider it likely that the combination of additional costs due to complaints and notifications, or any other costs relating to additional registrations are likely to be such that they would exceed the total increase in income. The Scottish Government intends to continue working with HIS to further consider the impact of additional registrations on HIS.
- 28. The cost of regulating this sector is intended to be borne by the businesses themselves. This is why fees are charged by HIS in connection with registration, continuation and other matters. HIS set their fees following consultation with the sector, within legislative maxima set by Scottish Ministers in legislation. The current fees are available publicly on their website. The maximum fees were last set in regulations made in 2024. Tables of current fees and the legislative maxima are also included in Annex B. In addition to fee income, funding is provided by Scottish Government in their baseline funding to support general activity in relation to independent healthcare.
- 29. The total income from, and costs of, regulatory activity are highlighted in HIS' Annual Report and Accounts, the most recent of which is available for the year end 31 March 2025.<sup>4</sup> The expenditure on independent healthcare in 2024-25, including 554 registered services, is reported as £1,636,000, of which £1,382,000 is raised from fees charged for regulatory income. The expenditure on independent healthcare includes activity in relation to public safety work, such as addressing concerns raised about services that are not registered independent healthcare services. HIS note, within their Annual Report and Account, their need to review functions to ensure effective and efficient regulation.
- 30. The Bill will add a new function of identifying where the procedures regulated by the Bill are undertaken outwith a permitted premises, which will also be an offence. HIS

<sup>&</sup>lt;sup>2</sup> Marketing spend - gov.scot

<sup>&</sup>lt;sup>3</sup> The Healthcare Improvement Scotland (Fees) Regulations 2024

<sup>&</sup>lt;sup>4</sup> HIS Annual Report and Accounts for year ended March 2023

will also take on responsibility for identifying whether, either in registered or unregistered premises, services are being offered to under 18s. Additional enforcement powers are provided in the Bill to support the additional functions. No change is anticipated to the funding available to support these roles and so this activity will have to be undertaken within the current funding envelope as noted above, or supported from any increase in fee revenue. HIS have not provided figures for the cost of enforcement activity they undertake and confirmed that they do not have the information they would require to make an informed calculation or estimate on future activity. Such activity falls within the overall expenditure on independent healthcare. HIS's current enforcement approach focuses on supporting compliance, and very rarely leads to prosecution. Whilst the Scottish Government expects that HIS will continue this approach, this does not provide evidence or a baseline against which potential new enforcement activity may be forecast, or the potential costs calculated. HIS will be expected to consider their existing enforcement activity against the enforcement of new offences in the Bill and prioritise appropriately. These costs of enforcement activity will be considered alongside wider factors in considering the setting of fees in future years, but this will be a matter for future consideration and consultation. The enforcement required to support implementation of the Bill may extend the scope of existing regulatory activity for registered services, and HIS may need to develop processes to support this activity. The Scottish Government is unable to provide estimates of the cost of this at this time but will be urgently considering this question and will provide further information once available.

- 31. HIS is also responsible for providing guidance and advice to the sector. HIS currently has guidance suitable for the delivery of the procedures regulated by the Bill in a registered setting and has confirmed that they do not think there is any immediate need for this to be reviewed or changed, over and above the ongoing work to do so. The Scottish Government will support HIS with any requirements in this respect that do occur, and expects the administrative burden on HIS to be manageable within current overall funding, by existing staff. The Scottish Government will continue to consider if there is substantial initial administrative activity to implement the Bill in terms of, for instance establishing any new processes etc. (although this is not currently anticipated). The Scottish Government does not have costs for such activities, but will continue to consider and provide further information once available.
- 32. On the basis of the above the Scottish Government acknowledges extra costs of additional registration, and increased activity in relation to identifying businesses committing new offences under the Bill. The Scottish Government regrets that no more information can be provided on the likely full scale of this activity and therefore the costs associated with it. However the Scottish Government does not consider that the Bill will lead to additional costs that need to be met by the Scottish Administration, as these costs will be met from within existing resources or through increased fee income with the increased number of registrations leading to an increase in both expenditure on regulatory activity and fee income.
- 33. Decisions on future fees will be made by HIS. If, contrary to the Scottish Government's expectations, additional income from increased registrations is not

sufficient to meet increased expenditure on independent healthcare, HIS retains the ability to increase fees up to the legislative maxima. The Scottish Government acknowledges that HIS has historically managed fee levels and increases to ensure that they do not become a barrier to positive engagement, but considers that proportionate increases in continuation fees, registrations fees and the levying of fees for variation or removal of conditions could raise substantial funds. This is not the current intention, but remains a means by which the regulation of independent healthcare could continue to be funded by businesses in the sector. Modelling has not been undertaken on potential increases on the current services regulated by HIS. As an illustration the impact of average increases can be projected. These impacts assume that those already paying higher fees see a commensurately greater increase. Under such a model increases of £250, £500 and £1,000 across continuation fees could raise £125,000, £250,000 or £500,000 respectively.

34. Powers in the Bill provide for the delivery of non-surgical procedures to be further regulated in the future. The Scottish Government intends to use this power to establish training requirements and to restrict the supervision of/carrying out of some procedures to appropriate healthcare professionals. It is not possible for such requirements to be imposed at this time, as further consideration must be given to the effects of the UK Internal Market Act 2020 and whether any of its provisions restrict the ability of such restrictions to be made. Any such regulations are not expected within the current parliamentary session. By taking an enabling power approach in this regard the Scottish Ministers can respond once these issues have been considered in more detail, and any issues resolved. Further detail is available in the associated Delegated Powers Memorandum. Additional regulation has the potential to further impact on the work of HIS. In considering this impact however the Scottish Government has considered HIS's existing role. Insofar as further regulation may set training standards or impose supervision or other requirements about healthcare professionals undertaking procedures, or set additional requirements or restrictions related to procedures then these would be matters similar to the existing requirements on healthcare services as set out in existing regulation<sup>5</sup> and in some cases set out in existing HIS guidance. As such the enforcement of any new requirements is not considered by the Scottish Government as a matter which would create an additional ongoing burden, but the Scottish Government acknowledges a requirement to provide guidance to HIS or support HIS in any changes required to HIS guidance, this activity would form part of the implementation work set out in paragraph 20 as part of the role of staff within the Directorate for the Chief Operating Office, NHS Scotland.

# Police, Crown Office and Court Service

35. Most businesses and practitioners whose practice is made illegal by the Bill can be expected to either adjust their business model or cease operation. In the first instance, where businesses do continue to operate, the Scottish Government expects

<sup>5</sup> The Healthcare Improvement Scotland (Requirements as to Independent Health Care Services) Regulations 2011

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that HIS will seek to encourage compliance with the new legislation and will not necessarily need to resort to the prosecution of the new offences.

- 36. Despite the approach outlined above it may be necessary in some cases for HIS to seek to proceed with a prosecution. The Scottish Government cannot exclude the possibility that HIS may require some support from Police Scotland in gathering the evidence to support such a case, and a prosecution will lead to costs to the Crown Office and Procurator Fiscal Service and to the Scottish Courts and Tribunal Service. In other cases, Police Scotland may become aware of an offence independently, especially if it is connected to other offences or activity under investigation. Given the core expectation that the police are unlikely to be acting in relation to these offences, the Scottish Government considers it reasonable not to provide a potential estimate for such activity.
- 37. The average costs of certain aspects of criminal procedures have been estimated, and such estimates are provided in Annex C. These would lead to an average cost of £1,008 for a prosecution of the offences in the Bill. Such prosecutions would be a last resort for HIS and Scottish Government expect that their number would be extremely low, and unlikely to exceed five in a given year. This gives a possible anticipated cost of £5,040 for criminal procedures.

# Costs on the Scottish Administration – Certification of death

#### Medical reviewers to authorise cremation

- 38. Medical reviewers have a function under the 2011 Act to review applications for repatriation where the deceased died outwith Scotland but is to be cremated in Scotland (section 18). Section 17 of the Bill amends section 18 of the 2011 Act. If the amendment is not made this will impact on costs going forward and therefore the amendment will result in a saving as costs would otherwise require to be incurred. In order for the duty on DCRS to process all repatriations from outwith Scotland to be fully met, there would be cost implications for DCRS due to the number of cases they are required to review. If section 18 were not amended, and the requirement continued to apply in respect of deaths in England, Wales and Northern Ireland, significant costs would require to be incurred in order for these reviews to be carried out.
- 39. Medical reviewers processed 181 repatriations for the year 2024-2025. Until the 2011 Act is amended, medical reviewers must also review repatriations from within the UK, estimated at around 2,000 cases per year. Each repatriation case takes around four clinical hours to process and is estimated to cost approximately £376 per case (four hours of work at £94 per hour). For 2,000 cases, this is 8,000 hours of clinical work per year.

40. Given the required allowances for medical reviewer leave, this equates to 200 working weeks per year, requiring 4.8 full time equivalent medical reviewers to cover the workload. Based on 2,000 cases at £376 per Level 2 review (4 hours of clinical work per case), the costs of this are £752,000 per year, if the amendment is not made to the 2011 Act. The amendment proposed therefore would result in a saving. This cost does not include the additional administrative support required, as administration costs are minimal and are part of the HIS budget. There would be a need to appoint additional medical reviewers to enable those applications to be processed in an appropriate time frame. As well as costs to DCRS, the time it would take to appoint and train additional medical reviewers would result in initial delays to the bereaved being able to arrange funerals.

#### Interested persons review

- 41. Section 16 of the Bill amends sections 4 and 8 of the 2011 Act. The 2011 Act confers functions on medical reviewers (working in the DCRS). One of the key functions is to review a random selection of MCCDs to check the quality and accuracy of the MCCD and improve the way that information about deaths is recorded. In addition to random reviews, section 4 of the 2011 Act provides for interested person reviews. Section 16 of the Bill amends the provision to allow for an interested person review in cases where a random review has been previously undertaken.
- 42. There are no financial costs from the amendment to section 4 of the 2011 Act. The legislative change allowing a Level 2 review of a MCCD that has already undergone a Level 1 review will occur rarely and is likely to have a minimal impact in terms of any extra resource required for DCRS. There are few requests for interested person reviews, and it is not anticipated that this amendment will lead to an increase in requests. The DCRS annual report for 2024-25 shows that only six interested person reviews were carried out and in 2023-24 there was one. The cost for clinical time is approximately £376 per interested person review (four hours of work at £94 per hour). There would also be some additional administration time associated with the review, which is likely to be small given the minimal anticipated increase in workload based on the small numbers in previous years.

#### Costs on local authorities

43. Local Authorities will not have any new responsibilities or functions under the Bill, so no direct costs are expected. Environmental Health Officers (EHOs) currently report that responding to reports of unsafe activity in inappropriate premises, and using their existing powers under health and safety legislation to manage the risks of unsafe procedures being carried out, is a burden on resources, however details of the costs of this that fall to Local Authorities have not been shared with the Scottish Government, and the Scottish Government does not have information available on the total cost of supporting environmental health functions. It is expected that these will vary between local authorities, depending both on how services are structured and the nature of the work carried out under this function. The Bill will lead to fewer unregulated premises

undertaking such procedures. Some businesses may register with HIS in order to undertake these procedures legally, others may adapt by ceasing to offer such procedures. Otherwise, a provider commits an offence if they continue to carry out procedures regulated by the Bill without registering the service with HIS and meeting any other requirements. As HIS is considered to be the main body expected to enforce regulation under the Bill, the role of Local Authorities in responding to unsafe activity may therefore be reduced, which may have a positive impact on their capacity.

- 44. The Licensing Order mentioned above at paragraph 10 above will create new functions for Local Authorities. This is likely to result in an increase in the demand on Local Authority licensing functions, and additional work for EHOs in conducting inspections of these premises. However, Local Authorities will be responsible for setting fees, and can consider the expected additional costs against this requirement. These costs are not a direct cost of the Bill but are relevant to the wider proposal and approach.
- 45. Local Authorities and HIS will have complementary regulatory and enforcement roles in relation to the procedures regulated by the Bill and which the Scottish Government proposes will be included in a licensing scheme. As such the Scottish Government expects that Local Authorities and HIS will need to work together: for instance Local Authorities' licensing officials or EHOs may be made aware of procedures regulated by the Bill being undertaken and need to report this to HIS. This cooperation is expected to build on existing relationships and arrangements and not represent an additional cost to Local Authorities which would require additional staffing or the allocation of additional staff time.

## Costs on other bodies, individuals and businesses

- 46. In addition to the costs outlined above, costs will be borne by businesses (including sole trading practitioners) that are required to comply with the requirements of the new legislation. The costs faced will depend on the approach they take to the new legislation and the adaptation they may choose to make to their business model(s). The impact on businesses has been considered in the Business and Regulatory Impact Assessment, which will be published after the Bill is introduced.
- 47. A business currently delivering procedures regulated by the Bill will have three broad options to adapt their business model (this is not intended as a comprehensive list of options: businesses are likely to take different approaches depending on a range of factors):
  - Option 1: Adjust the business to deliver procedures that are proposed as licensable activities so that the business can operate under Local Authority licence. This will involve stopping the delivery of any procedures regulated by the Bill.
  - Option 2: Register with HIS so the business can operate from a permitted premises, including the associated costs of working with an appropriate

- healthcare professional. This will allow the business to continue operating procedures regulated by the Bill.
- Option 3: Cease operating business on current model and premises, and practitioners seek to work within existing independent healthcare setting.
- 48. Direct costs of options 1 and 2 are shown in the table below, with figures provided as reported or estimated by businesses, but these have not been verified by the Scottish Government. Where potential costs are not provided the Scottish Government is not aware of any estimates of these costs available. The costs of option 3 will depend on how a business or current business model is wound down, and the basis on which any practitioners are employed by or work within existing settings. There may in addition be indirect costs in loss of business, as businesses change their operating model. This cannot be directly estimated.

	Initial / adaptation costs	Ongoing costs
Option 1	Possible training and equipment requirements for different range of procedures. Businesses quoted between £2,000 to £15,000 for such costs.  Marketing costs for new services. Loss of earnings from procedures that are discontinued.	Cost of participation in Local Authority licensing scheme, subject to the Licensing Order mentioned in paragraph 10 above. These will be set by the Local Authorities individually and are likely to be at a similar scale to the costs of licences for skin piercing and tattooing, which in most cases are under £500.
Option 2	Initial registration fees (see annex B).  Possible need to adapt premises to meet HIS requirements and prepare for the incorporation of new workers in a business setting. Businesses quoted £4,000 to £15,000 for these costs.	Cost of ongoing registration with HIS. (See annex B)  Cost of an appropriate healthcare professional supervising procedures. Businesses have estimated this potential cost in feedback to the Scottish Government, and depending on the assumptions made these estimates range from c. £20,000 to c. £70,000 per annum.

49. As set out in paragraph 34, powers in the Bill provide for the delivery of non-surgical procedures to be further regulated in the future. Additional regulation may have a further impact on businesses. This impact may include the cost of additional training to meet any new standard, the need to employ different/further healthcare professionals to undertake some procedures, or the cost of complying with further requirements or restrictions on the carrying out of procedures. The scale of this impact will be subject to decisions made at the time. Illustrative scenarios for the impact of possible changes are

included below, but these are not to be considered indications of future plans as decisions in relation to these matters have not been made. When the use of these powers is contemplated, account will be taken on the financial impact of the changes on businesses.

- A training standard may be put in place requiring practitioners of certain procedures to hold certain qualifications. As an example, the Scottish Government is currently aware of a number of qualifications equivalent to OFQUAL level 7 qualifications in Aesthetics offered by a number of providers. The cost of such courses appears to vary from £2,000-£15,000 depending on provider, existing experience and the way the course is delivered. The Scottish Government does not, at this time, make any judgement on the suitability of any particular training provider, but notes that the Joint Council of Cosmetic Practitioners, which operates a register for practitioners, accredits training providers which are available as a list of Approved Providers.
- The need to employ healthcare professionals in more circumstances than are currently required by the bill would lead to increased costs similar to those outlined above. This could fall to between approximately £20,000 to £70,000 per annum. A requirement that certain procedures be undertaken by e.g. a doctor or dentist, rather than a nurse or midwife would lead to costs, for those intending to continue to offer those procedures, at the higher end or in excess of this range.
- The imposition of a new requirement or restriction on procedures may require the purchase of different equipment to meet new hygiene protocols that may be required. The costs and impact of such restrictions would be considered at the point at which the restriction or requirement was put in place, equipment used in non-surgical procedures varies in price depending on procedure. As an illustration of the potential costs of clinical equipment a clinical fridge, which might be required to meet a new standard about handling products can cost c. £500, whereas a clinical autoclave which may be required to meet new standards for cleaning materials could cost £2,000 or more.
- 50. Where there are additional costs to businesses, or the number of businesses offering certain procedures is reduced, there may be second order impacts on businesses and individuals. Increased costs to businesses are likely to be passed on to consumers, and procedures may also be made more expensive due to the reduced competition for businesses offering them. The reduced competition may mean that businesses which are well placed to adapt to new requirements, or which are already delivering procedures in HIS registered premises may stand to benefit through increased demand and revenue, or an ability to set higher costs and increase profit margins on procedures. The decision to pass costs on to consumers or to increase the cost of procedures in response to wider changes in the market is one that will be made by businesses taking into account a number of factors including the degree to which the market is likely to meet such additional costs. This is not something that can be

predicted with any degree of accuracy. Knock-on impacts may also be felt by supplying businesses, insofar as the number of procedures undertaken reduces, or the types of procedures undertaken changes, and that has an impact on demand for materials that are used. The impact on training providers will be balanced between the reduced demand, if the industry is accessible to fewer people, and increased demand, if the standards of the industry are such that there is a greater degree of training required by those who are working in the industry. The impact on training providers will be largely subject to future decisions around levels of training required.

51. As noted above in paragraph 28 the cost of regulating the sector is intended to be borne by the sector itself, and HIS retain the ability to increase fee levels. If such a step were taken by HIS then this would have an additional financial impact on businesses in the sector, including businesses already in the regulated part of the sector. The level of impact would be dependent on future decisions. In considering the lower bound of such an increase the Scottish Government notes the highest fee charged for continuation of a clinic's registration went from £3,440 to £3,681, between 2023/24 and 2024/25 an increase of £241. Such routine increases should be considered the baseline, and an increase of an additional £200 would provide appreciable extra fee income. The upper bound would be an increase in fees to the legislative maxima for the services that currently attract the highest charge and a similar or proportionate increase to other fees, leading to increases of up to £1,319. No plans should be inferred from this possibility; these figures are included to provide information on the range of possible increases. HIS considers affordability and reasonable levels of increase when setting fees, which they do in consultation with the services registered with them. No decision has been made by the Scottish Government in relation to the setting of future maxima.

## Additional information

52. The Scottish Government is continuing to consider the costs and impact of its proposals, and of the Bill. The Scottish Government acknowledges that further work is required to consider fully the impact of implementation of the Bill on HIS, including: to model in more detail potential scenarios for additional registrations and the costs of this as well as the increase in fee income; to consider the full costs of new enforcement roles; and to consider the potential administrative burden of implementing and establishing new processes. The Scottish Government will continue to consider this, and work with HIS to derive new information to support consideration of the Bill and its likely impact. The Scottish Government will provide new information to parliament as soon as it is available.

#### Annex A

# Average staffing costs for Scottish Government core staff

Grade	Average employment cost
B1	£45,453
B2	£54,165
B3	£69,344
C1	£90,992
C2	£112,837

- 53. These are the gross staffing costs, including accruing superannuation liability charge (ASLC) and earnings related National Insurance contributions (ERNIC) estimates in February 2025, and subject to change related to pay and on costs.
- 54. Scenarios below are purely illustrative of possible costs assuming a lower and higher cost scenario.

## Low cost staffing scenario

55. Assuming two members of staff working part time on implementation (alongside other priorities).

Grade	FTE	Cost
B2	0.5	£27,083
C1	0.5	£45,496
		£72,579

# High cost staffing scenario

56. Assuming full time team leader role with wider input from a number of other grades.

Grade	FTE	Cost
B1	0.2	£9,091
B2	0.5	£27,083
B3	0.5	£34,672
C1	1	£90,992
C2	0.2	£22,567
		£184,405

#### Annex B

# Cost of HIS regulatory activity (2026/27)

Activity	Cost
Registration	£3,533
Hospital Inspection	£8,566
Clinic Inspection	£4,134
Average per Complaint	£466
Average per Notification	£148

57. These are the current costs associated with specific regulatory activity, however there are additional costs associated with the running of the function such as enquiries, training, stakeholder engagement and regulatory development work.

# Volume of HIS regulatory activity (2025/26)

58. HIS published a <u>summary of complaints</u> received by their Independent Healthcare Regulation team in 2024/25.

Outcome	Number of Complaints
Used as intelligence to inform wider	45
regulatory work	
Signposted to the most appropriate	22
services to achieve best outcome	
Resulted in complaint investigation and	7
closed within the year	
Currently remain open	4
Total	78

59. HIS <u>Annual Report and Accounts</u> contained information on the number of inspections and registrations of independent healthcare. This notes that 96 inspections took place in the year 2024/25 and that this is a reduction on previous years, as can be seen in the table below.

	2024-25	2023-24	2022-23	2021-22
Number of registered	554	540	549	519
services				
Number of services	63	53	71	98
registered in year				
Number of inspections	96	158	152	135
completed				

#### Table of HIS fees

60. The fees charged for 25/26 are as set out in the <u>published fees booklet</u> on the HIS website and are also included below:

Туре	Fee
Application for registration – Independent Hospitals	£5,350
Application for registration – Independent Clinics	£3,745
Application for registration – Independent Medical Agencies (IMAs)	£3,745
Annual continuation – Independent Hospitals	£268 per surgical or inpatient place
Annual continuation – Independent Clinics carrying out surgical procedures	£3,681
Annual continuation – Independent Clinics carrying out weight loss using controlled drugs	£3,681
Annual continuation – Independent Clinics carrying out non-surgical procedures* (with staff, inc. practising privileges, additional directors, admin staff)	£1,787
Annual continuation – Independent Clinics carrying out non-surgical procedures* (single-handed practitioner)	£1,286
Annual continuation – Independent Clinics providing dental services (including dental hygiene services)	£3,681
Variation or removal of condition(s)	No charge
Cancellation of service	No charge
New certificate	No charge

<sup>\*</sup> N.B. Any non-surgical procedures, including healthcare procedures, and not necessarily procedures regulated by the Bill.

Projected future costs and income of additional registrations (All figures assuming no increase in costs and fees, based on most recent figures per tables above)

61. Over a five year period each additional registration of an independent clinic could lead to increased fee income of between £8,889 and £18,469. This is calculated on the basis of an initial registration fee and four annual continuation fees of either the minimum or maximum level for a clinic – which depends on the size of the clinic as set out in the table above. Data is not currently available to allow the projection of what the more likely fees are for any potential new registrations.

62. Each additional registration would also incur the cost of the initial registration, the average for which is £3,533 and over a five year period, if 20% of settings are inspected in a given year one inspection at a cost of £4,134. This total cost over a five year period would therefore be £7,667. This is less than the total income calculated above, but does not account for any increase in the volume of complaints, and assumes the current average costs reflects the cost of registering an inspecting new settings. This is provided for purely illustrative purposes, but demonstrates the rationale behind the assumption that additional fee income could meet additional costs of increased regulatory activity resulting from new registrations.

#### Maximum HIS fees

63. The maximum fees that may be imposed by HIS were set in the Healthcare Improvement Scotland (Fees) Regulations 2024, following consultation.

Service	Application for Registration	Annual Continuation	Variation or Removal of Condition	Cancellation of Registration
Independent hospital	£7,500	£500 per place	£1,000	£100
Private psychiatric hospital	£7,500	£500 per place	£1,000	£100
Independent clinic	£5,000	£5,000	£1,000	£100
Independent medical agency	£5,000	£5,000	£1,000	£100

#### Annex C

# Average estimated unit cost of criminal procedures

64. Costs of the criminal justice system in Scotland dataset: 2016-17 (published December 2019) provides the most recent estimates of the unit costs of criminal court procedures in relation to Prosecution, Court and Legal Aid costs. Certain relevant costs are as below, based on a prosecution of a Summary case brought to the Sherriff Court, for a unit average total of £1,008.

Part of procedure (Body)	Unit Cost
Prosecution cost (Crown Office and	£444
Procurator Fiscal Service)	
Court costs (Scottish Court and Tribunal	£243
Service)	
Legal Aid (Scottish Legal Aid Board)	£321
	£1,008

65. Court and Legal Aid costs are dependent on whether a guilty plea is entered and if so at what stage of the procedure, the costs above are average, further information on the calculation and meaning of these figures is available in the publication.

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



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