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Dear Conveners

Re: Non-surgical Procedures and Functions of Medical Reviews (Scotland) Bill Financial Memorandum

This letter provides further information in addition to the <u>financial memorandum</u> for the above bill ("the Bill") published on 8 October and should be considered an addition to that memorandum. This information is provided in relation to the parts of the memorandum that consider Part 1 of the Bill (and its relevant schedules) relating to the regulation of non-surgical procedures.

The Financial Memorandum included the Scottish Government's best estimates of the costs, savings and changes to revenues to which the provisions of the Bill would give rise at the time at which it was introduced to the Parliament for consideration alongside the Bill. However, the memorandum noted that consideration of these matters was ongoing, in particular relating to the financial implications for the Scottish Government and its agencies.

The Scottish Government has worked in particular with Healthcare Improvement Scotland (HIS) in relation to the costs to HIS of enforcing the offences to be created under the Bill and the costs arising from any increase in registrations that result from the Bill. The Scottish Government is now able to provide supplementary information which may be useful to your committees in considering the Bill, and in understanding the cost of enforcement this is contained in the annex below.

The Scottish Government has also been made aware that the average cost to the Scottish Legal Aid Board of a sheriff court summary criminal case in 2024/25 was £814, and this should replace the figure of £321 quoted for legal aid in Annex C of the financial

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memorandum. The total cost of the prosecution for a summary case should therefore be £1,501 instead of £1,008. The costs provided in the Financial Memorandum were based on the latest available published information, but I acknowledge that this is based on datasets for the year 2016/17, and as such, the court costs and prosecution cost can also be expected to increase. I would also like to take this opportunity to highlight that although the figures for a summary case are included, and although they are considered to be the most appropriate indication of the cost of prosecuting a case under the Bill, a case may also be brought under the solemn procedure. The costs of such procedure are included in the dataset linked to from the financial memorandum.

Yours sincerely,

Jenni Minto MSP





Annex: Costs to Healthcare Improvement Scotland

- 1. As highlighted in the Financial Memorandum¹ the main cost to Healthcare Improvement Scotland (HIS) will be that associated with the requirement to register additional settings as independent clinics. The ability to estimate the impact of this on HIS was impaired by uncertainty around these factors:
 - The cost/impact of additional registrations on HIS,
 - The cost potentially recovered as a result of such registrations,
 - The likely volume of new registrations resulting from the Bill,
 - The cost/impact of enforcement activity (and therefore the cost/impact of enforcing new offences in the bill.)
- 2. On the first and second bullets points of Paragraph 1 above some information was provided in the original financial memorandum. Further information provided about current registered clinics since the Scottish Government submitted the financial memorandum means more information that may be helpful in considering the overall impact of the Bill can be shared, and this is included in paragraphs 10-16 below. This information is not intended to replace, but rather to supplement the potential costs highlighted in the financial memorandum. New information has also been provided about certain aspects of enforcement activity, which may support the Parliament's consideration of the Bill. This has been included in paragraphs 17-24 below alongside some more detailed consideration by the Scottish Government on this issue. We continue to acknowledge that there is uncertainty around the cost of enforcement activity, but trust that the additional information and consideration will be helpful.
- 3. On the third bullet point, a broad range of between 10 and 500 new registrations over the first years of the Bill coming into force was suggested². The Scottish Government does not have any new information that would allow this estimate to be refined further, but figures within that range are used to provide a range of potential costs based on the new information that has been obtained.
- 4. For the purposes of considering the impact of additional registrations this supplemental note uses illustrative low/medium/high scenarios of 50, 100 or 500 additional registrations that may result from the Bill. The financial memorandum highlighted that it was possible that the number of new registrations would be extremely low, and in fact would not be particularly visible amongst the existing variation in new and total registrations.³ In the last four years between 50 and 100 services have been registered in each year, but the overall number of services has only increased from 519 in 2021/22 to 554 in 2024/25. As such, 50 was chosen as the lowest reasonable illustrative figure, as this is a level at which it can be expected that an increase in registrations will have an identifiable impact on HIS.

¹ Para 23, footnote references are made in this note to paragraph numbers, or named tables in the Annexes, within the Financial Memorandum introduced to the Scottish Parliament on 8 October 2025. This is available at the Scottish Parliament website.

² Para 26

³ Para 25

- 5. The high scenario used here is 500. As set out in the financial memorandum this would imply that between half and a third of all businesses currently in the unregulated sector would seek to register with HIS.⁴ For this scenario to occur, it would require all of such businesses to be:
 - Undertaking non-surgical procedures that are to be regulated under the Bill;
 - Undertaking those procedures in such volumes or as such a proportion of the current business's services, that it is financially worth seeking registration (given the additional costs);
 - Able financially to meet the costs of registration (including the cost of employing or working with an appropriate healthcare professional);
 - Able to identify such a healthcare professional; and
 - Able to meet all other requirements of HIS registration.
- The Scottish Government does not consider that there are likely to be sufficient numbers of appropriate healthcare professionals for this level of new registrations. This is in keeping with the feedback from businesses that such professionals are going to be hard to access. Nonetheless, such a figure is useful as an illustrative upper bound for possible costs. Between these lower and upper illustrative figures the Scottish Government continues to have no information to allow the likely volumes of registrations to be more closely estimated. The Scottish Government acknowledges the need to provide best estimates of regulatory costs, but also the importance of not providing false certainty, especially where multiple assumptions must be made. The Scottish Government's best estimate for the financial impacts of the Bill flow from the estimate of the number of new registrations. The best estimate for that number of registrations is that it will fall somewhere between 50 and 500 registrations, and this estimate is provided with a reasonable degree of confidence. Exercising best professional judgement the Scottish Government has provided a figure of 100 additional registrations as a reasonable medium scenario, the Scottish Government considers that the actual number of registrations is as likely to fall above this figure (so between 100 and 500 registrations) as below (between 50 and 100 registrations) but much less confidence is attached to this figure.
- 7. HIS have also reported, that existing trends are leading, or may lead in coming years, to changes in the number of registrations, or other demands on their services. Figures from recent years show that the number of registrations has increased over time, and this is expected to be a consequence of the growth of the sector. It is also possible that reflects changing patterns of compliance. HIS have recently reported an increase in the number of reports made to them of potentially unregistered services, and in the number of initial inquiries for services who may wish to register. This may be linked to the greater awareness of HIS registration requirements given public discussion of this Bill and the wider regulatory framework. The increase may also be related to recent changes in the guidance of the Nursing and Midwifery Council which now states that cosmetic prescriptions for the purposes of cosmetic procedures cannot be made without a face-to-face consultation. This may have led to an increase in the number of nurses undertaking consultations for prescriptions in the premises of beauty or other settings, thus bringing them into the definition of an independent healthcare service under section 10F of the National

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⁴ Para 24

Health Service (Scotland) Act 1978. It is yet to be seen whether these changes will lead to a permanent increase in registrations, but it is entirely possible that such an increase will take place in coming years, and could be seen even if this Bill were not to proceed. To the extent that businesses register with HIS in advance of provisions of the Bill coming into force this may reduce the pool of businesses that could register with HIS after and as a result of the Bill, because they will be businesses currently operating in the same pool.

8. Alongside these increasing trends for independent healthcare service registrations, HIS are also registering Independent Medical Agencies for the first time. The numbers of such registrations are currently low. It is estimated that fewer than 20 IMAs will be registered in the current year.

Cost and impact of additional registrations

- 9. The financial memorandum uses estimates provided covering the costs of certain types of regulatory activity to estimate the potential impact of new registrations. A figure of £7,000 per registration over a five year period was estimated based on the cost of initial registration and the cost of one inspection in that period.⁵ HIS have since provided additional information about their target inspection model which places this estimate in context. HIS have confirmed that inspections are undertaken on the basis of risk and information or intelligence received, and inspection once in a five year period (as per this estimate) would be appropriate for a setting identified as lower risk. By contrast, highest risk settings would be inspected as much as twice a year. However, the higher rate of inspection would not be expected to be maintained long term.
- 10. The Scottish Government notes that in the most recent year HIS did not meet their key performance indicator relating to their target inspection model. Actual rates of inspection were used in drawing up the estimate of £7,000. **Table 1** below shows the actual number of completed inspections, including representing this as a percentage of registered services. N.b. the proportions cannot be directly compared against the KPI, as the KPI is not represented as inspections as a proportion of services given the intended level of inspection is risk based.

Table 1:

Year Number of Number of Inspections as % of registered services inspections registered services completed 2024-25 554 96 17.3% 2023-24 540 158 29.3% 2022-23 549 152 27.7% 2021-22 519 135 26.0%

⁵ Para 27, see also Table "Cost of HIS regulatory activity (2026/27)" in Annex B, which was provided based on estimates provided by HIS.

- 11. The Scottish Government has considered the information provided on *intended* rates of inspection activity. **Table 2**, below, is based on a low, medium and high estimated cost scenario per newly registered setting for a five-year period. In each case, the same estimated cost of £3,533 is used for the initial registration activity. However:
 - a. in the low-cost scenario, it is assumed that one additional inspection takes place per setting at an additional cost of £4,134. This would overall be a higher rate of inspection than the last financial year, but lower than the preceding years.
 - b. In the medium-cost scenario, it is assumed that a rate of 1.2 inspections per service per five-year period take place. This would assume that after their initial registration 30% of all settings are inspected in any given year which is closer to the inspection performance in 2023/24.
 - c. The high-cost scenario assumes 1.5 inspections per service in the fiveyear period, but this represents an inspection rate in excess of that achieved by HIS in recent years.

Table 2 below sets out these scenarios against the three illustrative scenarios for volume of registrations, thus providing one possible indication of additional costs for HIS.

Table 2:

Registrations	Regulatory cost (£ – 5 years) Low estimate	Regulatory cost (£ – 5 years) Medium estimate	Regulatory cost (£ – 5 years) High estimate
50	383,350	424,690	486,700
100	766,700	849,380	973,400
500	3,533,500	4,246,900	4,867,000

Consideration based on known costs of specific activity may not capture the 12. full impact on HIS of registered services. These costs do not include any cost related to enforcement activity against unregistered settings. As such HIS have also provided additional information about staffing for the current regulation of independent healthcare. This provides additional information through which the impact of additional registrations can be considered, although this is caveated that HIS staffing requirements are likely to change over time. Specifically, HIS have highlighted that they have commissioned an independent review of their regulatory functions, including Independent Healthcare and the Ionising Radiation (Medical Exposure) Regulations (IRMER). This review, alongside internal consideration of their staffing and processes are likely to lead to changes in their operating model which may in turn lead to reductions in the staffing requirement for regulatory functions. Scottish Government will work with HIS on the outcome of the review and any internal consideration and is prepared to support HIS in consideration of ensuring the most effective, and financially sustainable long-term regulation of independent healthcare.

13. Currently HIS estimate a ratio of 1 whole time equivalent member of staff, including Head of Function, Chief Inspector and subject matter experts, to every 19 registered services. This provides a basis on which projections can be made if a linear increase in staffing is expected as registrations increase. Such a linear increase is unlikely given the natural efficiencies that may emerge from increased scale, and this also assumes no impact of the current review of functions. As such the projections set out below should again be considered an extreme upper bound for additional costs. These projections assume for every 19 additional registrations an additional member of staff or whole time equivalent, would be hired. It is further assumed that additional staff are Band 7 and so attract a staffing cost of £80,500 (pay and additional staffing costs), but does not include other fixed costs such as equipment expenses etc. **Table 3** below sets this out.

Table 3:

Registrations	Linear WTE increase	Additional Staff Cost (£ - annual)
50	2.6	209,500
100	5.2	419,000
500	26.0	2,095,000

Recovery of costs

- The financial memorandum also provided information on the fees payable by 14. different types of clinics. HIS have now provided additional information about the likely continuation fees payable by new registrants (who register as a result of business changes made in response to this Bill). The Scottish Government now considers that the majority of settings that register would pay the fees associated with an independent clinic carrying out non-surgical procedures with staff. This is in keeping with their current registration, whereby the largest group of existing registrants are registered as non-surgical clinics with staff followed by single handed non-surgical clinics. Currently these two groups make up a little under 80% of all registrants. Newly registered clinics will not be single handed organisations, as businesses registering with HIS as a result of the Bill proposals will be existing businesses, with non-healthcare practitioners who are now additionally working with a healthcare professional allowing them to register with HIS and become "permitted premises" for the purposes of the Bill. As such Table 4 below sets out the fee income over a five year period, based on an initial registration fee of £3,745 and an annual continuation fee of £1,787.
- 15. HIS have also provided information about the non-payment of fees. In 2024/25 HIS estimate bad debt to account for 13% of fees due, a loss of income of £209,000. An adjustment on this basis is also included in **Table 4**. This again does not assume any improvement in performance in recovering underpayments, however recovery of underpayment is another function that may benefit from increased scale, if increased volume of cases allows for greater experience or specialisation of staff in this role.

Table 4:

Registrations	Registration fee income (£)	Continuation fees (£ - 4 years)	Total (£ - 5 years)	Adjusted for bad debt (£)
50	187,250	357,400	544,650	473,846
100	374,500	714,800	1,089,300	947,691
500	1,872,500	3,574,000	5,446,500	4,738,455

Enforcement activity

- 16. HIS were not previously able to provide figures for the cost of enforcement activity i.e. activity directly related to addressing non-compliance with statutory requirements, for instance an independent healthcare clinic that has declined to register as required for the financial memorandum. HIS are a specialist reporting authority, with the ability to refer cases directly to the Crown Office for prosecution, and have existing powers in relation to entry, including entry to unregistered premises that are, or where there is reasonable cause to believe that independent health care services (premises where certain healthcare professionals are offering a service) are being provided. The new powers and responsibilities granted by the Bill are closely aligned with the current provision. HIS have reported however that they do not currently exercise their role as a specialist reporting agency nor do they exercise their powers to enter unregistered premises. Where HIS are made aware of a potential unregistered service they are generally able to address this through direct correspondence and supporting businesses to comply. What follows is based on the Scottish Governments interpretation of the information that is available.
- 17. Where encouraging compliance through correspondence is ineffective HIS have confirmed that they do prepare small numbers of cases to refer to Police Scotland, however this does not necessarily lead to police or other further action. HIS need to consider whether they can better use the powers available to them and would still be required to do so even if the Bill does not become law.
- 18. The Scottish Government considers that an approach that focuses on encouraging compliance is likely to continue to be appropriate in the majority of cases. Currently law-abiding businesses are not expected to deliberately flout new regulation at scale, and early non-compliance is likely to be inadvertent or based on a failure to understand the legislation. The Scottish Government does consider that, especially in the early years of the new legislation being in force, some stronger enforcement activity may be required, in line with what would be appropriate in current cases of non-compliance with registration requirements, even if this is not necessarily taking place at this time. Where a stronger approach is required the current costs associated with referrals to Police Scotland may be a starting point for the costs to be borne. Undertaking such a referral requires some or all of the following activity:
 - a. Engagement with Police Scotland,
 - b. Engagement with businesses, clients and members of the public,
 - d. Engagement with other regulators (e.g. professional regulators),

- e. Collection and preparation of evidence,
- f. Provision of statements.
- 19. HIS advise that this work can involve the involvement of several members of staff, including input of more senior members of staff, and that the total time commitment for this work can range from 25-40 hours of activity. This activity is estimated to come at a cost of between £3,000 to £4,500. HIS emphasise that this can only be considered an approximate estimate, especially given this is not a regular activity. HIS have prepared cases on this basis on two occasions in the last year.
- 20. HIS are aware of this and will continue to consider how best to support such activity. The approach taken to this remains a matter for HIS. The Scottish Government has considered possible approaches, but these are set out purely as an illustrative indications of the potential financial impact of supporting this work.
- 21. To support enforcement requirements and develop of new processes HIS may choose to recruit specific additional staff. This may be permanent new staff, or may be taken on a contract basis. The cost for such resource would require further consideration, but on an interim basis it could be considered likely to be of a similar scale to an additional band 7 member of staff for up to one year (£80,500 as pay and additional staffing costs, but does not include other fixed costs such as equipment expenses etc). The expertise required for this work is likely to be reasonably available to HIS, given there are a number of other bodies currently acting as specialist reporting agencies and exercising various powers of entry. The Scottish Government acknowledges that this cost is not included in the financial memorandum.
- 22. In the short to medium term, HIS may choose to put in place dedicated resource to support other inspectors and staff and take a lead on any enforcement activity that requires stronger action than the existing approach. Given the low expected levels of non-compliance, this may only need to be a single staff member or WTE. It is acknowledged that the process of bringing a case to prosecution is relatively intensive and requires extensive staff time, and as such only a small number of prosecutions could be brought or prepared in a given year. Such a small number could nonetheless have a deterrent effect on the minority of businesses who may be prepared to break the law.
- 23. The potential staffing costs must be considered alongside the prospect of efficiencies and reduction in staffing requirement flowing from the changes to working practices highlighted earlier in this note, and against the potential for increased fee income. As highlighted in the financial memorandum, the Scottish Government does not intend to increase core funding to Healthcare Improvement Scotland considering that the regulation of independent healthcare should remain self-funding. If fee income is, or appears likely to be, insufficient to the costs of regulation it is expected that HIS will consider this in fee setting going forward.
- 24. This note provides multiple ways of considering the potential increase in costs for HIS, based on the increased in costed activity, based on linear increases in staffing and considering potential additional fixed costs (e.g. hiring of additional staff

to lead on enforcement activity.) These have themselves been considered on the basis of a range of potential scenarios for increases in registration. As such no single best estimate increase in costs to HIS can be provided with any confidence.

- 25. Consider only the potential ways of calculating costs based on the medium scenario of a 100 registrations the highest potential estimate (based on a linear whole time equivalent staffing increase) provided in this note is £419,000,(See table 3) to which one an extra £80,500 may be added to account for an additional WTE dedicated to specific enforcement activity (such as preparing cases for referral to prosecution) as discussed in paragraph 22. This would imply a full cost of £500,000 per annum to HIS, but the Scottish Government considers such a cost increase unlikely as it does not expect a linear staffing increase, this should be considered an extreme upper limit for the 100 registration scenario. On the other hand a lower estimate for the same scenario based on fixed cost activity, and assuming a low rate of inspection would provide a figure of £153,340, (see table 2, this figure is based on an average annual cost rather than the five year range provided in that table). The Scottish Government acknowledges that this figure probably does not adequately account for the full costs of additional registrations.
- 26. On this basis, and again using best judgement, if the rate of additional registrations is around 100, then it is likely that the increased cost to HIS will be between £200,000 and £400,000 per annum. Table 4 above estimates potential fee income based on existing fee levels (and making assumptions about the continuation rates payable). Although Table 4 provides fee income over a five year period that would average at £217,860 a year if there is no bad debt.