

Consultation on Amendments to the Regulation of Independent Health Care

February 2023

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1. Introduction

The providers of independent health care in Scotland and the UK are many and varied, and the complexity of this area of health care provision continues to increase. The Scottish Government wants all health care provided to people in Scotland to be safe, appropriate and carried out by those with the right qualifications.

To achieve this vision, we need to ensure that independent health care services provided in Scotland are effectively regulated. We want the regulation of independent health care in Scotland to reflect the current landscape of provision, which includes an increasing number of services provided online. It is also important that this regulation is self-funding.

We ran a consultation in 2020, which focused on non-surgical cosmetic procedures which pierce or penetrate the skin, such as lip enhancements and dermal fillers. This consultation also asked whether services provided by pharmacists who undertake independent health care practices (including non-surgical cosmetic procedures), outwith the terms of an NHS contract should be regulated by Healthcare Improvement Scotland.

As the independent health care landscape in Scotland continues to change, we believe this may mean that the way independent health care is regulated needs to be updated. We are taking this opportunity to run a new consultation to seek views as to whether further change is needed and how it should happen.

2. Proposals for reform

We are proposing to make three changes to the way independent health care in Scotland is regulated:

1. Enable Healthcare Improvement Scotland to regulate independent health care services provided by pharmacists and pharmacy technicians which are not provided under the terms of an NHS contract or from non-General Pharmaceutical Council (GPhC) registered premises;
2. Enable Healthcare Improvement Scotland to regulate independent medical agencies providing health care services which consist of or include the provision of services by a medical practitioner, dental practitioner, registered nurse, registered midwife, dental care professional, pharmacist, or pharmacy technician. This would include independent medical agencies operating entirely online. However, services provided by either a pharmacist or pharmacy technician in pharmacy premises registered with the GPhC or a

nurse agency regulated by the Care Inspectorate (officially known as Social Care and Social Work Improvement Scotland) would be exempt; and

3. Enable Healthcare Improvement Scotland to cancel the registration of any independent health care service where there has been a failure to pay continuation fees.

We would propose to make these changes by amending provisions in the National Health Service (Scotland) Act 1978 that cover Healthcare Improvement Scotland's regulation of independent health care services.

2.1 Regulation of independent health care services provided by pharmacists and pharmacy technicians

Independent clinics where services are provided by a doctor, nurse, dentist, dental care professional or midwife have been regulated by Healthcare Improvement Scotland since 2016. However, independent clinics where services are provided by pharmacists and pharmacy technicians are not currently regulated in Scotland.

In response to the consultation in 2020, 90% of respondents agreed that services provided by pharmacists who undertake independent health care services outwith the terms of an NHS contract should be regulated by Healthcare Improvement Scotland. We are aware that some pharmacy professionals are offering non-surgical cosmetic procedures and other services, such as travel advice or weight loss clinics, in premises other than registered pharmacies or those where pharmaceutical services are provided under an NHS contract. Our proposal is for independent health care services provided by pharmacists and pharmacy technicians to be regulated by Healthcare Improvement Scotland in the same way as other independent health care services.

Since the 2020 consultation, the landscape has grown considerably from 8 to potentially 26 independent health care services provided by pharmacy professionals. Therefore we are taking this opportunity to engage further and ask whether independent health care services provided by pharmacists and pharmacy technicians which are not provided from a registered pharmacy or under an NHS contract should also be regulated by Healthcare Improvement Scotland.

2.2 Regulation of independent medical agencies, including online-only services

Online health care services are often a one-off intervention where clinicians do not have access to the complete health care record of the patient and rely on the patient giving an honest medical history. They can potentially be used by vulnerable people to access medicine or quantities of medicine that would be hard to obtain from a physical premises with a face-to-face consultation.

Section 10F(2) of the National Health Service (Scotland) Act 1978 (which was inserted into that Act by section 108 of the Public Services Reform (Scotland) Act 2010) defines "independent medical agency" as:

“an undertaking which is neither an independent clinic nor an undertaking comprised in a hospital and which consists of or includes the provision of services, other than in pursuance of this Act, by a medical practitioner”.

However, the provisions which establish Healthcare Improvement Scotland’s functions, in respect of independent medical agencies, have not yet been commenced. This means that services which fall into the definition of independent medical agency are currently not regulated by Healthcare Improvement Scotland. We therefore propose to commence Healthcare Improvement Scotland’s functions in relation to independent medical agencies to allow oversight of health services falling in this definition.

In addition, there has been a small but increasing proportion of independent health care services who are now operating solely online, with no physical premises. While the majority of online providers headquartered in England are regulated by the UK Government through the Care Quality Commission, online-only health care services headquartered in Scotland are currently unregulated.

The proposed regulation of online health care under independent medical agencies will be consistent with the approach taken by regulators in Wales and Northern Ireland, which have similar regulatory framework to Scotland. The 4 UK home nations will work cooperatively to regulate and inspect the services based in their jurisdiction.

We are proposing to enable Healthcare Improvement Scotland to regulate these services. We would do this by amending the definition of an independent medical agency in section 10F(2) of National Health Service (Scotland) Act 1978 (as detailed above). The definition would be widened to include not just independent health care services provided by a medical practitioner, but also those provided by a dental practitioner, registered nurse, registered midwife, dental care professional, pharmacist or pharmacy technician. This would mean that any health care service provided in Scotland (whether online or otherwise) by any of these individuals would be regulated by Healthcare Improvement Scotland.

However, we propose that the definition of independent medical agency would not extend to (and therefore Healthcare Improvement Scotland would not regulate) services provided by:

- pharmacist or pharmacy technician in pharmacy premises registered with the GPhC
- premises where pharmaceutical services are provided under an NHS contract, or
- a nurse agency regulated by the Care Inspectorate (known officially as Social Care and Social Work Improvement Scotland (SCSWIS), and defined in schedule 12 paragraph 4 of the Public Services Reform (Scotland) Act 2010).

This is due to the fact that these services would already be regulated.

2.3 Non-payment of continuation fees

Healthcare Improvement Scotland's regulation of independent health care is intended to be funded by fees paid by its regulated independent health care services. To legally operate in Scotland, a service must be registered which includes paying a fee to Healthcare Improvement Scotland, and services are then charged continuation fees to maintain their registration. The money from the fees funds Healthcare Improvement Scotland's regulation activities, such as inspections.

Although being registered with Healthcare Improvement Scotland is intended to be conditional upon each service paying their continuation fees, services that fail to pay their fees cannot currently be removed from the register. This undermines Healthcare Improvement Scotland's ability to self-fund its regulatory activities and means that services that repeatedly fail to pay their fees can continue to operate in Scotland.

We are proposing to allow Healthcare Improvement Scotland to cancel the registration of any independent health care service that fails to pay its continuation fees within a certain notice period.

3. Responding to this Consultation

We are inviting responses to this consultation by 26 April 2023.

Please respond to this consultation using the Scottish Government's consultation hub, [Citizen Space](#). Access and [respond to this consultation](#) online. You can save and return to your responses while the consultation is still open. Please ensure that consultation responses are submitted before the closing date of 26 April 2023.

If you are unable to respond using our consultation hub, please complete the Respondent Information Form to:

Directorate for Healthcare Quality and Improvement
Scottish Government
GER
St Andrews House
Edinburgh, EH1 3DG

4. Handling your response

If you respond using the consultation hub, you will be directed to the About You page before submitting your response. Please indicate how you wish your response to be handled and, in particular, whether you are content for your response to be published. If you ask for your response not to be published, we will regard it as confidential, and we will treat it accordingly.

All respondents should be aware that the Scottish Government is subject to the provisions of the Freedom of Information (Scotland) Act 2002 and would therefore have to consider any request made to it under the Act for information relating to responses made to this consultation exercise.

If you are unable to respond via Citizen Space, please complete and return the Respondent Information Form included in this document.

To find out how we handle your personal data, please see our [privacy policy](#).

5. Next steps in the process

Where respondents have given permission for their response to be made public, and after we have checked that they contain no potentially defamatory material, responses will be made available to the public on [Citizen Space](#). If you use the consultation hub to respond, you will receive a copy of your response via email.

Following the closing date, all responses will be analysed and considered along with any other available evidence to help us. Responses will be published where we have been given permission to do so. An analysis report will also be made available.

6. Comments and complaints

If you have any comments about how this consultation exercise has been conducted, please send them to the contact address above or [email the Independent Healthcare team directly](#).

7. Scottish Government consultation process

Consultation is an essential part of the policymaking process. It gives us the opportunity to consider your opinion and expertise on a proposed area of work.

You can find all our consultations online at [Citizen Space](#). Each consultation details the issues under consideration, as well as a way for you to give us your views, either online, by email or by post.

Responses will be analysed and used as part of the decision making process, along with a range of other available information and evidence. We will publish a report of this analysis for every consultation. Depending on the nature of the consultation exercise the responses received may:

- indicate the need for policy development or review
- inform the development of a particular policy
- help decisions to be made between alternative policy proposals
- be used to finalise legislation before it is implemented

While details of particular circumstances described in a response to a consultation exercise may usefully inform the policy process, consultation exercises cannot address individual concerns and comments, which should be directed to the relevant public body.

8. Questions

We are seeking views on the following 9 questions to be returned by 26 April 2023:

1. Do you agree that further regulation of independent health care services in Scotland is needed?

Yes
No
Don't know

Please give reasons for your response. Please be as specific as you can, and include any resources or references to evidence on this topic that we should consider.

2. Do you agree that independent health care services provided by pharmacists and pharmacy technicians which are not provided from a registered pharmacy or under the terms of an NHS contract should be regulated by Healthcare Improvement Scotland?

Yes
No
Don't know

Please give reasons for your response. Please be as specific as you can, and include any resources or references to evidence on this topic that we should consider.

3. Do you agree that independent medical agencies where services are provided by a medical practitioner, dental practitioner, registered nurse, registered midwife, dental care professional, pharmacist or pharmacy technician should be regulated by Healthcare Improvement Scotland?

Yes
No
Don't know

Please give reasons for your response. Please be as specific as you can, and include any resources or references to evidence on this topic that we should consider.

4. Do you agree that unregulated independent medical agencies operating entirely online and headquartered in Scotland, should be regulated by Healthcare Improvement Scotland?

Yes
No
Don't know

Please give reasons for your response. Please be as specific as you can, and include any resources or references to evidence on this topic that we should consider.

5. Do you agree that Healthcare Improvement Scotland should be able to cancel the registration of any independent health care service that fails to pay its continuation fees after a certain period of time?

Yes
No
Don't know

Please give reasons for your response. Please be as specific as you can, and include any resources or references to evidence on this topic that we should consider.

6. What are your views on how further regulation of independent health care in Scotland might affect the protected characteristics of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, and sex?

Please be as specific as you can, and include any resources or references to evidence on this topic that we should consider.

7. The Fairer Scotland Duty places a legal responsibility on certain public bodies in Scotland to actively consider how they can reduce inequalities caused mainly by people's financial situation. What are your views on how further regulation of independent health care in Scotland might affect this inequality?

Please be as specific as you can, and include any resources or references to evidence on this topic that we should consider.

8. What are your views on how further regulation of independent health care in Scotland might affect access to safe, high-quality public services in island communities?

Please be as specific as you can, and include any resources or references to evidence on this topic that we should consider.

9. What are your views on how further regulation of independent health care in Scotland might affect respecting, protecting and fulfilling the rights of children and young people as set out in the UN Convention on the Rights of the Child?

Please be as specific as you can, and include any resources or references to evidence on this topic that we should consider.

References

- Analysis of Consultation on the regulation of non-surgical cosmetic procedures – <https://www.gov.scot/ISBN/978-1-80004-339-8>
- Response to Consultation on Regulation of Non-surgical Cosmetic Procedures – <https://www.gov.scot/ISBN/978-1-80435-650-0>
- Citizen Space - <http://consult.gov.scot>
- Consultation - <https://consult.gov.scot/safety-openness-and-learning/amendments-regulation-independent-healthcare>
- Scottish Government Privacy policy - <https://www.gov.scot/privacy/>



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