

Amendments to the Regulation of Independent Health Care: Consultation Analysis

September 2023

About this report

This report provides an analysis of responses to the Scottish Government's consultation on Amendments to the Regulation of Independent Health Care, which ran from 1 Feb 2023 to 26 April 2023. We are grateful to everyone who took the time to respond.

[The full consultation paper can be accessed on gov.scot](#)

It is worth noting that, throughout the analysis, time has been taken to identify trends in the responses where possible and appropriate.

Chapter 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 wishes to ensure that independent health care services provided in Scotland are effectively regulated. We want this to reflect the current landscape of provision, which includes a number of services provided online. It is also important that this regulation is self-funding. The way independent health care is regulated needs to be updated and we ran a new consultation to seek views as to whether further change is needed and how it should happen.

We made the following three proposals, which would be actioned by amending provisions in the National Health Service (Scotland) Act 1978 that cover Healthcare Improvement Scotland's regulation of independent health care services:

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.
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.

Chapter 2: Overview of responses

A total of 71 responses were received. Of these, 20 were from organisations and 51 were from individuals.

Responding organisations included NHS Boards, health professional bodies, and independent healthcare organisations.

A full list of the organisations that responded can be found at Annex A.

Four responses were removed from the consultation entirely. All 4 removed responses were from respondents who submitted 2 responses. In line with Scottish Government guidelines, the original response was removed while the most recent one was included in the analysis.

Of this total of 67 eligible responses, [58 have been published on gov.scot](#). The remaining respondents did not want their responses to be published, however all responses have been considered in this analysis, irrespective of whether or not they have been published.

The consultation paper included 9 questions. Numbers 1-5 were closed, offering specific response options, followed by a free text box for further comments. The remainder of the questions (6-9) were open, for free text responses only. The full set of questions can be found at Annex B.

Chapter 3: Responses on further regulation for independent healthcare services

There were five questions in the consultation document that related to further regulation of independent healthcare services in Scotland.

This analysis follows the layout of the consultation document.

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

Answer	Organisations	Individuals	Total
Yes	15	36	51
No	1	9	10
Don't Know	2	2	4
Not Answered	2	0	2

The majority of those who responded to this question (76%) believed that further regulation of independent healthcare services in Scotland was required. Over 50% of the responses felt that all independent healthcare providers should be regulated and 36% believed regulation improves safety and can improve outcomes for patients. The respondents that were not of this view (15%) had varying reasons for not being supportive of further regulation, including the belief that all services are regulated already, that regulation does not improve service, and the Scottish Government should be focussing on regulating aesthetic services.

Four respondents chose “don’t know” but none provided reasoning. Out of those that did not select a particular option, one provided comments nonetheless, stating that they are “keen for these changes to come into force as soon as possible as they will have a positive effect on the overall quality of healthcare provided in the independent sector”.

Question 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?

Answer	Organisations	Individuals	Total
Yes	17	38	55
No	0	6	6
Don't Know	1	3	4
Not Answered	2	0	2

A significant majority of those who responded to this question (82%) agreed with the proposal 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”.

Reasons given for this view included the firm belief that everyone should be regulated and that regulation improves patient safety. The few respondents that were not of this view generally thought that regulation is not required whatsoever, and one suggested that regulation by the GPhC already provides sufficient regulation.

Some respondents answered “don't know” to question 2, questioning whether Healthcare Improvement Scotland is the best organisation for managing the regulations, and whether other options were considered.

Question 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?

Answer	Organisations	Individuals	Total
Yes	16	35	51
No	2	8	10
Don't Know	1	4	5
Not Answered	1	0	1

Again, a majority of those who responded to this question (76%) believed 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”.

As with responses to the first two questions, the majority of individuals who responded in the affirmative offered views that everyone should be regulated, and that regulation would improve safety for patients and service users. A small number of respondents felt the amendments would close a legislative loophole.

15% of respondents disagreed with this proposal, with the majority of comments centred on the belief that the professional bodies already regulate these professions, and further regulation is not required.

Five respondents answered “don't know” to question 3, and all provided varying reasons. One felt that “allowing non-medical people to carry out treatments that can cause significant harm unregulated is massively hypocritical”. Another felt that HIS is not the right organisation to be the regulator for independent healthcare providers and others should be considered. As with many of the responses who answered “no” to this question, one respondent believed that the professional bodies already regulate these professions, and further regulation is not required.

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

Answer	Organisations	Individuals	Total
Yes	16	34	50
No	1	7	8
Don't Know	2	6	8
Not Answered	1	0	1

A majority (75%) of respondents felt that currently unregulated independent medical agencies operating entirely online and headquartered in Scotland should be regulated by Healthcare Improvement Scotland. Reasons provided included improving safety for service users and “if independent medical agencies are to be regulated, then those that operate entirely online should be included in that regulation. The distinction between the physical and the online presence of a service is no longer meaningful in terms of the protection of the public”. Eight respondents specifically mentioned that they felt it important that all four nations should have a joined up approach when regulating online independent medical agencies.

Following a similar theme to responses from previous questions, there is an overriding belief from some people who responded “no” that regulation from professional bodies is sufficient and further regulation is not required. One respondent felt online businesses providing medical services should be banned altogether.

A small number of respondents who answered “don’t know” to this question and provided comments highlighted a lack of clarity around the question, specifically on how the regulations will impact online businesses headquartered outside of Scotland but providing services to Scottish people.

Question 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?

Answer	Organisations	Individuals	Total
Yes	15	31	46
No	2	12	14
Don't Know	1	4	5
Not Answered	2	0	2

Over two thirds of respondents (69%) agreed 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”. They felt this would improve equality, protect people from bad business practices, and that it would be an important step to ensuring HIS can self-fund. Caveats to this included the idea that fees should be proportionate to the size of the business and cancellation should only occur after a warning or payment scheme was offered.

From those who disagreed with the proposal, cancellation was felt to be too extreme a response, and could lead to an abuse of power. A few respondents suggested that there should be no fees and regulation should be funded entirely by the taxpayer.

One respondent who answered “don’t know” and provided comments worried about such an extreme consequence if a genuine mistake was made – what if someone just forgot to pay their fee?

Chapter 4: Responses on impact assessments

The remaining questions related to the impact assessments to be carried out on the amendments to independent healthcare regulations. All were open questions inviting free text responses.

Question 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?

42 respondents answered this question (14 organisations and 28 individuals). 15 responses were generally of the view that the amendments would have a positive impact on protected characteristics and 10 did not believe it would have a negative impact. Five responses indicated they did not know how it would affect people with protected characteristics. Three of the respondents view was that the changes in regulation would have a negative impact due to increasing cost, with one citing it would result in “non-viable business”. The remaining respondents did not give clear reasoning on whether the changes would impact people with protected characteristics.

Question 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?

43 respondents answered this question (13 organisations and 30 individuals). There was no consensus between respondents to this question. Nine felt the amendments would have a positive impact, 8 felt there would be no impact or at least not have a negative impact, and 9 felt there might be a possibility of some disadvantage based on increasing fees being “passed on to the users/patients”.

Question 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?

40 respondents answered this question (13 organisations and 27 individuals). There was specific mention by 14 respondents that healthcare access should be equal across the entirety of Scotland. Nine respondents believed the amendments will improve safety, with one stating that “regulation will provide the necessary accountability to ensure that services available to consumers in remote, rural and island communities are safe and of high quality, with an appropriate complaints system in place”. Ten respondents did not believe the amendments would impact island communities at all, and only 3 felt it would impact them negatively. Those that believed it would have a negative impact cited HIS’ high costs limiting access to services for remote communities, online GPs pushing physically-based GPs away from islands, and “further regulation would just make it more difficult to access healthcare in island communities”.

Question 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?

37 respondents answered this question (12 organisations and 25 individuals). Of those who responded, 26 were of the view that the amendments would have a positive impact on the rights of children and young people or no negative impact. Other respondents were unsure if there would be any impact.

Annex A

List of organisations that responded

Aesthetics

APIL

Azimuth Healthcare Solutions Ltd

BMA Scotland

Christopher Sale Dentistry Ltd

Consumer Scotland

Directors of Pharmacy Scotland

General Medical Council

Health and Social Care Alliance Scotland (the ALLIANCE)

Healthcare Improvement Scotland

Independent Healthcare Providers Network (after consulting our members)

Law Society of Scotland

NHS Fife Pharmacy and Medicines Directorate

NHS Greater Glasgow & Clyde

NHS National Services Scotland

Oxford Online Pharmacy

RCN Scotland

Royal College of General Practitioners Scotland

Royal Pharmaceutical Society

The British Association of Cosmetic Nurses

Annex B

List of questions asked

1. Do you agree that further regulation of independent health care services in Scotland is needed?
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?
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?
4. Do you agree that unregulated independent medical agencies operating entirely online and headquartered in Scotland, should be regulated by Healthcare Improvement Scotland?
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?
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?
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?
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?
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?



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