

Consultation on the Regulation of Non-Surgical Cosmetic Procedures in Scotland

January 2020

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Introduction

The number of non-surgical cosmetic treatments being carried out across Scotland and the UK has risen considerably over the years and continues to do so. In Scotland, independent clinics run by a doctor, nurse, dentist, dental nurse, midwife or dental care professional and who provide these procedures are regulated by Healthcare Improvement Scotland (HIS). However non-surgical cosmetic procedures themselves, such as lip enhancement or dermal fillers, are not currently regulated and anyone is currently able to administer such procedures.

The Scottish Government's vision is for a safer Scotland and we want to ensure that anyone providing non-surgical cosmetic procedures does so safely and is competent and appropriately trained to do so. Our commitment to public safety must be maintained with assurance for people who choose to have non-surgical procedures carried out by individuals who are not healthcare professionals in non-healthcare premises. This consultation seeks your views on the regulation of such individuals and premises.

Thank you for taking the time to consider this consultation paper. Please read the background to why we are consulting on specific actions. We would welcome your views on the further regulation of independent clinics and non-surgical cosmetic procedures.

The consultation seeks your views on the following questions:

- 1. Do you agree that further regulation of non-surgical cosmetic procedures is needed?**
- 2. Do you agree that the carrying out of non-surgical cosmetic procedures (that pierce/penetrate the skin) by individuals who are not qualified healthcare professionals should be licenced under Part 1 of the Civic Government (Scotland) Act 1982?**
- 3. Do you agree that services provided by pharmacists who undertake independent healthcare practices (including non-surgical cosmetic procedures), outwith the terms of an NHS contract should be regulated by Healthcare Improvement Scotland?**
- 4. Do you have any other comments?**

For additional information please refer to:

Keogh Review Final Report

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/192028/Review_of_the_Regulation_of_Cosmetic_Interventions.pdf

The Scottish Cosmetic Interventions Expert Group report

<https://www2.gov.scot/Topics/Health/Quality-Improvement-Performance/HealthCareImprovementScotland/Cosmetic-Interventions-Expert-Report>

Section 10F of the National Health Service (Scotland) Act 1978 (as amended).

<http://www.legislation.gov.uk/ukpga/1978/29/section/10F>

The National Health Service (Scotland) Act 1978 (Independent Clinic) Amendment Order 2016, SSI 2016/148

<http://www.legislation.gov.uk/ssi/2016/148/contents/made>

The National Health Service (Scotland) Act 1978 (Independent Clinic) Amendment Order 2017, SSI 2017/67.

<http://www.legislation.gov.uk/ssi/2017/67/introduction/made>

Healthcare Improvement Scotland

http://www.healthcareimprovementscotland.org/our_work/inspecting_and_regulating_care/independent_healthcare/regulation_of_clinics/regulation_of_clinics_faqs.aspx

How do I respond to the consultation?

You are invited to respond to this consultation by 30 April 2020. Please respond to the consultation using the Scottish Government's consultation hub, Citizen Space (<http://consult.gov.scot>). You can access and respond to this consultation online at <https://consult.gov.scot/healthcare-quality-and-improvement/regulation-of-independent-healthcare>

Further details on how to respond can be found at Appendices A & B.

Overview

The Scottish Cosmetic Interventions Expert Group (SCIEG) was set up in January 2014 to explore the need to regulate cosmetic procedures. This followed the publication of the UK-wide Keogh Review in April 2013 which, amongst other things, identified that little regulation already existed, and there was a call from all groups, professions and experts for a new legislative framework.

SCIEG's 2015 report recommended a phased approach to regulation. The first phase addressed the regulation of independent clinics run by certain healthcare professionals. Independent clinics where services are provided by a doctor, nurse, dentist, dental nurse, midwife or dental technician were brought within the regulation of Healthcare Improvement Scotland (HIS) through a series of Scottish Statutory Instruments (SSIs) which came into force on 1 April 2016¹. These SSIs amended the National Health Service (Scotland) Act 1978 (the 1978 Act), which is the primary legislation from which Healthcare Improvement Scotland's statutory powers are taken. It also provides for the regulation of independent healthcare services.

The policy is to ensure that where healthcare professionals are working independently from the NHS, they do so in a clinic that is registered with HIS who will inspect the premises to ensure that they meet cleanliness and hygiene standards, that the business is viable and suitably indemnified, and that they have paid their registration fee.

The second phase, which the Scottish Government is currently taking forward, is to look at non-surgical cosmetic procedures that pierce/penetrate the skin (such as dermal, lip fillers, wrinkle smoothers) provided by people who are not qualified healthcare professionals and who work from non-regulated premises, for instance beauty or hairdressing salons. SCIEG recommended compulsory licensing by local authorities for all cosmetic practitioners delivering cosmetic procedures as indicated above, as well as an effective ban on these procedures being carried out by non healthcare professionals.

Why We are Consulting

There is evidence from social and traditional media of individuals who are not regulated healthcare professionals providing unregulated lip enhancing injections, or dermal fillers or injections for facial wrinkles. Similarly, there is anecdotal evidence from healthcare professionals and media coverage that there is an increase in such procedures going wrong: causing discomfort, harm, or permanent damage in severe cases.

There is also growing potential for risk posed by an increase in unregulated premises carrying out non-surgical cosmetic procedures that pierce/penetrate the skin. The Scottish Government's commitment to patient safety must be maintained with the

¹ The National Health Service (Scotland) Act 1978 (Independent Clinic) Amendment Order 2016, SSI 2016/148 and the National Health Service (Scotland) Act 1978 (Independent Clinic) Amendment Order 2017, SSI 2017/67.

same level of assurance for people who choose to have procedures carried out by individuals who are not healthcare professionals in non-healthcare premises.

In addition, a number of pharmacists have now entered the cosmetics procedure field and are providing injectable procedures within premises which are not currently classified as independent clinics under the 1978 Act. This means that they do not need to be registered with HIS.

SCIEG recommended that regulation should be extended to ensure that non-surgical procedures (including dermal fillers) which pierce/penetrate the skin should only be provided by or on behalf of regulated healthcare professionals by individuals who have an appropriate level of expertise. When these procedures are provided on behalf of a regulated healthcare professional, that professional should have overall responsibility for the quality of care delivered.

We are not averse to this SCIEG recommendation in principle and recognise that the safety of everyone that chooses to have a cosmetic intervention carried out is of paramount importance, regardless of provider or location. However, there is currently a lack of evidence of harm from all activities and therefore we do not want to cause undue financial difficulties for reputable small businesses, if this can be avoided by the introduction of other appropriate regulation. We consider that a blanket ban on non-medical professionals carrying out non-surgical cosmetic procedures could be difficult to enforce and might drive unregulated providers underground.

We therefore offer, in this consultation, a way forward that ensures the visibility of all services and licensing backed with rigorous implementation guides (specific conditions) to ensure best practice in all circumstances. Conditions could include that services are provided in a clean and safe environment; individuals would be 18 years of age or older; cooling off periods would be offered and sharps etc. would be disposed of appropriately.

The National Health Service (Scotland) Act 1978 provides HIS with powers to regulate independent clinics. At present only clinics in, or from which, services are provided by specified healthcare professionals (including doctor, nurse, dentist, dental nurse, midwife or dental care professional) are captured within the definition of an independent clinic in section 10F of the 1978 Act (as amended). Where services are provided by a person who is not a healthcare professional and they operate from premises which do not fall within the definition of "independent clinic" then they are currently unregulated.

Further statutory, as opposed to voluntary, regulation would ensure that providers of non-surgical cosmetic procedures that pierce/penetrate the skin and who are not qualified healthcare professionals are regulated with the aim of ensuring that both they and their premises meet required standards.

Fundamentally, we want to ensure that anyone providing non-surgical cosmetic procedures that pierce/penetrate the skin is competent and appropriately trained to do so. We are therefore seeking views on the need for further statutory regulation to ensure the safety of end users.

Proposals for Reform

Licensing of non-surgical cosmetic procedures that pierce/penetrate the skin provided by non-health professionals

The Scottish Government propose that those who are not qualified healthcare professionals and who provide higher risk, non-surgical cosmetic procedures that pierce/penetrate the skin are regulated by licence under Part 1 of the Civic Government (Scotland) Act 1982.

We propose to introduce an Order under section 44 of the 1982 Act that would ensure that a licence is required for carrying on a business which provides non-surgical cosmetic procedures through piercing or penetrating the skin e.g. providing dermal fillers, lip enhancements. The intention would be to include a similar requirement regarding inspection of premises as currently applies to tattoo parlours and skin piercing, so that local authority Environmental Health Officers (EHOs) would visit the premises and assess them against the specified conditions before a licence is granted.

When considering an application for a licence the relevant local authority would be required to refuse it if they think that the applicant is not a fit and proper person or is disqualified from holding a licence. We intend to make it a requirement that an applicant's knowledge, skill, training and experience is taken into account when determining whether they are a fit and proper person to hold a licence.

Tattoo parlours and skin piercing is subject to licensing under the 1982 Act by virtue of the Civic Government (Scotland) Act 1982 (Licensing of Skin Piercing and Tattooing) Order 2006 (as amended by Civic Government (Scotland) Act 1982 (Licensing of Skin Piercing and Tattooing) Amendment Order 2006), and we propose to make similar provision here.

Activities carried out by a member of a profession regulated by a body mentioned in section 25(3) of the National Health Service Reform and Health Care Professions Act 2002 (GMC, GDC etc.) would not require a licence. This is consistent with the skin piercing and tattooing regulations. The healthcare professionals in this group who provide cosmetic treatments continue to be regulated by Healthcare Improvement Scotland.

Regulation of independent clinics operated by registered pharmacy professionals

We also plan to regulate independent health care services provided by registered pharmacy professionals, including cosmetic procedures, within an independent healthcare setting where these professionals are not providing pharmaceutical services under a NHS contract.

We intend to address the current legislative gap by amending the definition of "independent clinic" in section 10F of the 1978 Act so that it covers pharmacy professionals (registered pharmacists and registered pharmacy technicians) alongside the other specified healthcare professionals already covered. This would

mean that independent healthcare services provided by pharmacy professionals (including cosmetic procedures) will be regulated by HIS in the same way as other independent healthcare services.

To avoid regulatory overlap with the General Pharmaceutical Council, the intention is that HIS will only regulate services provided by pharmacy professionals which are provided outwith a registered pharmacy and not under the terms of an NHS contract for the provision of pharmaceutical services.

We seek views on the following four questions to be returned by 30 April 2020:

- 1. Do you agree that further regulation of non-surgical cosmetic procedures is needed?**
- 2. Do you agree that the carrying out of non-surgical cosmetic procedures (that pierce/penetrate the skin) by individuals who are not qualified healthcare professionals should be licenced under Part 1 of the Civic Government (Scotland) Act 1982?**
- 3. Do you agree that services provided by pharmacists who undertake independent healthcare practices (including non-surgical cosmetic procedures), outwith the terms of an NHS contract should be regulated by Healthcare Improvement Scotland?**
- 4. Do you have any other comments?**

Acronyms

EHO	Environmental Health Officer
GDC	General Dental Council
GMC	General Medical Council
HIS	Healthcare Improvement Scotland
NHS	National Health Service
SCIEG	Scottish Cosmetic Interventions Expert Group
SSI	Scottish Statutory Instrument

Appendix A: How to respond to this consultation

We are inviting responses to this consultation by 30 April 2020.

Please respond to this consultation using the Scottish Government's consultation hub, Citizen Space (<http://consult.gov.scot>). Access and respond to this consultation online at

<https://consult.gov.scot/healthcare-quality-and-improvement/regulation-of-independent-healthcare>

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 30 April 2020.

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

Openness & Learning
Scottish Government
GER
St Andrew's House
Edinburgh
EH1 3DG

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: <https://beta.gov.scot/privacy/>

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 at <http://consult.gov.scot>. 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.

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 to:

cosmetics.consultation@gov.scot

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: <http://consult.gov.scot>. 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.

Appendix B

CONSULTATION ON THE REGULATION OF NON-SURGICAL COSMETIC PROCEDURES

RESPONDENT INFORMATION FORM

Please Note this form **must** be completed and returned with your response.

To find out how we handle your personal data, please see our privacy policy:
<https://beta.gov.scot/privacy/>

Are you responding as an individual or an organisation?

- Individual
 Organisation

Full name or organisation's name

Phone number

Address

Postcode

Email

The Scottish Government would like your permission to publish your consultation response. Please indicate your publishing preference:

- Publish response with name
 Publish response only (without name)
 Do not publish response

Information for organisations:

The option 'Publish response only (without name)' is available for individual respondents only. If this option is selected, the organisation name will still be published.

If you choose the option 'Do not publish response', your organisation name may still be listed as having responded to the consultation in, for example, the analysis report.

We will share your response internally with other Scottish Government policy teams who may be addressing the issues you discuss. They may wish to contact you again in the future, but we require your permission to do so. Are you content for Scottish Government to contact you again in relation to this consultation exercise?

Yes

No



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