

Consultation response - Regulation of non-surgical cosmetic procedures

Regulation of non-surgical cosmetic procedures - Scottish Government consultations - Citizen Space

Proposal	Healthcare Improvement Scotland Response
The Scottish Government propose that private, non-surgical cosmetic procedures (NSCPs) should only take place either: • In an independent clinic, or other healthcare setting regulated by Healthcare Improvement Scotland (HIS): or • In a business premises that is licensed by the local authority.	In relation to the consultation on the amendments to the regulation of independent healthcare services, Healthcare Improvement Scotland (HIS) has been working closely with Scottish Government colleagues to drive improvement in the current regulatory arrangements. Having reviewed the proposals, we are pleased to see these changes coming forward and support them. In broad terms HIS supports further regulation of non-surgical cosmetic procedures (NCSPs) and that NSCPs should only take place in a registered independent healthcare service, or a business premises licenced by a local authority. However, it remains unclear if the intention is to specify the professionals that can oversee or carry out specific NSCPs or to prescribe that specific treatments must be carried out in a registered independent healthcare service.
	The consultation paper says "Because a premises will need to meet certain requirements and be subject to inspection whether by HIS or the local authority (LA), it will not be possible for procedures to be carried out by practitioners working in hospitality venues, a client's own home or any other location outwith a licensed

premises or HIS regulated clinic." However, the current regulations¹ provide for a service user to have choice in the way in which the service is provided to them. Based on this principal HIS allows some services to provide domiciliary visits for a range of healthcare, including some lower risk NSCPs. This should be borne in mind, when considering the level of restrictions on registered independent healthcare services.

We support the proposal that NSCPs are prohibited from hospitality venues, exhibition venues and any other *commercial* location outwith a licenced premises or registered independent health care service.

Proposals for grouping NSCPs

The Groups proposed are:

Proposal

1. We propose that Group 1 will contain those procedures which carry the lowest level of risk, are the least invasive, and which we propose can be safely carried out by a trained and licensed practitioner who is not a healthcare professional.

We propose that Group 1 procedures can be undertaken in either a licensed premises or a HIS regulated setting. These questions invite you to consider procedures that we propose to include in group

HIS Response

HIS has no comment on the procedures in Group 1. The definition of independent healthcare services focuses on the professional providing the treatment rather than a given treatment or procedure. Any healthcare professional cited in the definition of an independent clinic would be required to register regardless of the treatments offered.

Individuals, who are not healthcare professionals, and that offer Group 1 procedures will be able to obtain Local Authority licencing which is considerably less expensive than regulation by HIS. At present the law would not allow an HCP to access the LA licensing route. Allowing a route for HCPs offering Group 1 procedures to be regulated via a Local authority licence would ensure a parity of regulation. However, those HCP would still be personally responsible for operating to their professional registrations, including being aware of the need to register with HIS if the portfolio of

¹ The Healthcare Improvement Scotland (Requirements as to Independent Healthcare Services) regulations 2011 – Regulation 2

- 1. For each procedure you are invited to consider which group you believe the procedure belongs to, and whether:
 - the procedure can be carried out in a licensed premises or HIS regulated setting, (Group 1 - Our recommendation for these procedures)
 - only in a HIS regulated setting, (Group 2) or
 - in a HIS regulated setting and only by an appropriate healthcare professional. (Group 3)

Individual procedures are described in more detail in the glossary in Annex B of the background paper, but if you do not know what a procedure involves you may wish to select 'Don't know'.

We propose that group 1 procedures include:

- Microneedling
- Chemical peels that only affect the outermost level of skinpoo
- IPL/LED therapy
- Use of lasers for tattoo removal
- Laser hair removal

treatments changes. This would require an amendment of the current definitions of independent healthcare services.

HIS are mindful of rapid and ever-changing nature of cosmetic and beauty treatments. Has consideration been given to a mechanism which would allow Scottish Ministers to amend or update the lists in each of the groups without the need for a change to legislation?

In respect of lasers used for NSCPs, it would be helpful to specifically define the laser treatments under this category for absolute clarity about what can be done by a non-health care professional vs health care professional.

2. We propose that Group 2 will contain procedures which carry a higher level of risk,

We support the proposal that procedures that carry a higher level of risk and are more invasive should be supervised by an appropriate healthcare professional. However, it

and are more invasive than those in Group 1. We propose that Group 2 procedures should only be undertaken in a HIS regulated premises. We propose they can be safely carried out by a trained practitioner who is not a healthcare professional, but such practitioners should be supervised by an appropriate healthcare professional.

These questions invite you to consider procedures that we propose to include in group 2. For each procedure you are invited to consider which group you believe the procedure belongs to, and therefore whether:

- the procedure can be carried out in a licensed premises or HIS regulated setting,
- only in a HIS regulated setting, or
- in a HIS regulated setting and only by an appropriate healthcare professional.

Individual procedures are described in more detail in the glossary in Annex B of the background paper but if you do not know what a procedure involves you may wish to select 'Don't know'.

Listed below are procedures which we propose belong in Group 2. For each procedure please select which group you think is most appropriate.

should be clearer if the intent is to prescribe that these treatments are supervised by an appropriate healthcare professional or prescribe that group two procedures can only take place in a registered independent healthcare service. We remain cognisant the proposed list will create demand on HIS that may require additional resource, over and above any additional fee revenue and, should be considered accordingly for timelines with any implementation plans.

In addition, a definition and additional guidance will be required to support the interpretation of 'supervised' and 'appropriate healthcare professional'.

The consultation states "Under this proposal Group 2 procedures must be undertaken either by an appropriate healthcare professional or by a trained practitioner who is being supervised by a healthcare professional who will remain responsible for the procedure. The healthcare professional would be responsible for ensuring that the practitioner's training and competence is appropriate to the procedure. HIS would consider the training and competence of both healthcare professionals and non-healthcare practitioners as part of their inspection."

To support any supervising HCP to make decisions on the competence of practitioners they are supervising, there needs to be detailed guidance on the training required for non-healthcare professionals as well as for those healthcare professionals supervising treatments. If the HCP deems the non-HCP competent, it would be extremely difficult for HIS to then demonstrate they are not competent without clear guidance on the training requirement for each procedure. Further it is the responsibility of the provider to ensure they are compliant with the regulations and to demonstrate to HIS that "at all times suitably qualified and competent persons are working in the independent health care service in such numbers as are appropriate for the health, welfare and safety of service users."

- Mesotherapy (injection of certain drugs, or other products into the middle layer of the skin)
- Injections of toxins (e.g. Botox®) for cosmetic purposes
- Injections of drugs for cosmetic purposes
- Injections of semi permanent dermal fillers in small quantities (<2ml - e.g. to reduce wrinkles, or plump lips)
- Any other injections of a product, even if it is not a drug or toxin, for lifestyle or cosmetic purposes. (not including tattooing which is already licenced)
- Medium depth peels (that penetrate and destroy the outer layer of skin fully and penetrate into the next layer or upper dermis)
- Photo rejuvenation
- Radiofrequency treatments
- HIFU (high frequency ultrasound)
- Cryolipolisis (the use of cold to destroy pockets of fat under the skin)

This proposal may result in the supervising practitioner undertaking a face-to-face consultation with a client and then prescribing a course of treatment or medication to be administered by a trained non-HCP practitioner. Some professional regulators will impose additional limitations and expectations on registrants which restricts this practice, for example the GPhC have issued guidance to registrants about which restricts delegating responsibility for administration of medicines to non-healthcare practitioners. The NMC are currently consulting on prescribing practices for registered nurses and midwives.

We note that the background papers have set out what in meant by supervision in the is context. This interpretation of supervision is beyond the scope of clinical supervision as understood in the nursing profession. In the NHS. it means 'Clinical supervision is a formal process of professional support, reflection and learning that contributes to individual development'.

Citation: Butterworth T (2022) What is clinical supervision and how can it be delivered in practice? Nursing Times [online]; 118: 2, 20-22.

In the proposal supervision is "the healthcare professional would be responsible for ensuring that the practitioner's training and competence is appropriate to the procedure. By supervision we mean that an appropriate healthcare professional must be present on site and undertake an initial face to face consultation for each procedure, including prescribing any prescription-only medicine for the procedure. The supervising professional will remain responsible for the safety of the procedure, satisfying themselves that the client is an appropriate candidate, is able to consent and understands any risks that may be associated with the procedure. They will also be required to be on site and available to answer any questions, or in the event of complications which require medical management, or if the practitioner undertaking the procedure requires support".

Would the HCP require additional indemnity to supervise a non-HCP as it states they remain responsible for the non-HCP? Under the NMC code a nurse is responsible for her own actions, the patient and public safety? In point 11 of NMC code: 11 Be accountable for your decisions to delegate tasks and duties to other people. To achieve this, you must: 11.1 only delegate tasks and duties that are within the other person's scope of competence, making sure that they fully understand your instructions 11.2 make sure that everyone you delegate tasks to is adequately supervised and supported so they can provide safe and compassionate care 11.3 confirm that the outcome of any task you have delegated to someone else meets the required standard NES have published a framework about delegated responsibilities from healthcare professionals and this may well be useful to consider in supervision in this context. https://www.nes.scot.nhs.uk/nes-current/making-delegation-safe-and-effective/ As part of any final proposal, it should be clear when staff are being supervised and when responsibilities are being delegated. In general, we do not object to the list of treatments included in group 2, but would query if IPL and Laser treatments are included in Group 1 then radiofrequency treatments, photo rejuvenation and HIFU may also be group 1 as they appear to us to carry similar risks. 3. We propose that Group 3 will contain the HIS has no comment on the procedures included in Group 3. However, we support procedures which carry the highest levels of the proposal that procedures that carry the highest level of risk are only carried out by risk and which are more invasive than Group 1 an appropriate healthcare professional. However, it should be clearer if the intent is

or 2 procedures. We propose that, as well as being undertaken in a HIS regulated premises, these procedures should always be undertaken by an appropriate healthcare professional.

These questions invite you to consider procedures that we propose to include in group 3. For each procedure you are invited to consider which group you believe the procedure belongs to, and therefore whether:

- the procedure can be carried out in a licensed premises or HIS regulated setting,
- only in a HIS regulated setting, or
- in a HIS regulated setting and only by an appropriate healthcare professional.

Individual procedures are described in more detail in the glossary in Annex B of the background paper, but if you do not know what a procedure involves you may wish to select 'Don't know'.

Listed below are procedures which we propose belong in Group 3. For each procedure please select which group you think is most appropriate.

to prescribe the practitioners that can carry out these treatments or prescribe that group three procedures can only take place in a registered independent healthcare service.

In the consultation it states "The setting meets HIS' wider standards for the condition of the premises and any equipment or materials to be used". This should be expanded to include meeting the wider requirements of the regulation of independent healthcare services, beyond the environmental requirements, Further, in order to clarify expectations for any service that will become a registered independent healthcare service as a result of these changes, additional guidance is required to support them in understanding the regulatory requirements. Registering an IHC service with HIS is about much more than what your environment looks like.

In respect of lasers used for NSCPs, it would be helpful to specifically define the laser treatments under this category for absolute clarity about what can be done by a non-health care professional vs health care professional. This would further assist when thinking about age limits on any NSCP carried with a laser, in particular hair removal.

- Platelet rich plasma, biotherapy or injections of any products derived from the patient's blood
- Injection microsclerotherapy (use of injections to treat visible spider veins)
- Injection lipolysis or injections of fat dissolving agents
- Dermal micro coring (removal of small amounts of skin to reduce visible signs of aging)
- Hay fever injections
- Any procedure involving intravenous fluids or drawing and processing bloods for cosmetic or lifestyle purposes, for instance provision of intra venous vitamins and minerals, or intra venous blood oxygenation.
- Use of dermal fillers for the purpose of augmentation of e.g. the breasts and buttocks
- Deeper chemical peels such as phenol peels
- All laser treatments not specified above, including lasers which target the deeper layers of the dermis.
- Carboxytherapy (the injection of CO2 under the skin to promote collagen production)

- Cellulite subcision (making small incisions to reduce appearance of cellulite)
- Electrocautery (removal of skin tags through electricity)
- Cryotherapy and cryocautery (use of extreme cold to remove e.g. skin tags)
- Thread lifting and cogs (placement of dissolvable material under skin to tighten appearance and promote collagen)
- All group 1 or 2 procedures where procedures are carried out in an intimate area (except hair removal and not including procedures such as tattooing and skin piercing which are already licenced)

4. Please provide any comments you have in relation to the grouping of procedures and the level of regulation required.

There should be a consistent level of regulation across the groups of regulation, to ensure there is no incentive to mask the provision of Group 2 and Group 3 treatments.

The fee structure and costs need to be considered to ensure a consistent cost of regulation. The cost of regulation for Group 1 treatments should not be disproportionately lower than Group 2 or 3 treatments as this may be an incentive to mask the provision of Group 2 and Group 3 procedures.

The minimum level of training for NSCPs should be defined in legislation for both health care professionals and non-healthcare professionals or it should be set out in

	a guidance document that is clearly linked to the legislation like an approved code of practice. Any Enforcement powers that are added to ensure compliance with the new arrangements should be consistent across HIS and Local Authorities. This would promote a consistent approach to regulation of the sector in Scotland.
5. Do you support or oppose the proposal that the practitioner of a Group 1 procedure operating in a licensed premises should also require a licence? Strongly support Somewhat support Neutral Somewhat oppose Strongly oppose	Support
6. Do you support or oppose the proposal that the practitioner of a Group 1 procedure operating in a HIS regulated setting should not require a licence? Strongly support Somewhat support Neutral Somewhat oppose Strongly oppose	Support
7. Please provide any comments about the answers you have given to questions 5 and 6 about the proposals for the establishment of licensing arrangements for Group 1 procedures:	If the service is already regulated by HIS, there is no need for additional local authority licensing.
8. To what extent do you agree or disagree that the Scottish Government should establish	HIS strongly supports the proposal that Scottish Government develops standards for hygiene and safety, standards of training and qualifications for practitioners of NSCPs

	and mandatory insurance for both licenced practitioners, for licensed premises and
 Standards of hygiene and health and 	services that are regulated by HIS.
safety for licensed premises?	
 Standards of training and qualification 	These standards for training and qualifications could be based on standards of
for licensed practitioners?	proficiencies documents that NMC produce.
 Mandatory insurance and indemnity to 	
compensate clients who suffer harm as	
a result of negligence or malpractice?	
9. To what extent do you agree or disagree that	HIS supports these proposed powers and suggests that both Local Authorities and
local authority officers should have powers of	HIS also have the power to impose sanctions on services that are providing Group 2
inspection and enforcement, including	NSCPs but do not have an appropriate health care professional present or continue
	to use remote consultations or digital services to obtain prescriptions.
- The removing of a licence from	
premises or practitioners who cannot	Consideration will need to be given as to how HIS and the Local Authorities will work
demonstrate compliance with	together to report services to each other and what powers both agencies then have in
standards established by the Scottish	relation to pursuing unregistered services, in particular services that use hospitality
Government?	and exhibition settings
- Barring individuals from holding a	
licence if they are associated with	
serious or repeated non-compliance	
with the standards established by the	
Scottish Government?	
10. Which of the following statements do you	There are precedents for healthcare to be delivered in a range of vehicles, including
agree with in relation to whether a vehicle can	breast screening, blood donation and dental care. It is possible that an appropriately
receive a licence as a premises?	designed vehicle could achieve the same standard as a fixed premises.
- Local authorities should have discretion	
to decide whether a vehicle can receive	
a licence as a premises	

 Vehicles should be eligible for a licence in all local authorities Vehicles should not be eligible for a licence in any local authority I don't know 	
 11. To what extent do you agree or disagree that the Scottish Government should establish Standards of training and qualification for non-healthcare and healthcare professionals undertaking procedures in HIS regulated services? Mandatory insurance and indemnity to compensate clients who suffer harm as a result of negligence or malpractice? 	HIS strongly supports the proposal that Scottish Government develops standards for hygiene and safety, standards of training and qualifications for practitioners of NSCPs and mandatory insurance for both licenced practitioners, for licensed premises and independent healthcare services that are regulated by HIS.
12. Do you agree or disagree that the healthcare professional supervising a group 2 procedure should - Conduct the / any initial consultation(s) with the client? - Prescribe any medications (e.g. Botox TM, lidocaine) required during the procedure, or required for the management of any complications that arise - Remain available on site for the duration of any procedure?	HIS strongly supports this proposal. However, it is important to note that it may not be possible for every healthcare professional that is cited in the definition of the relevant independent healthcare services to meet this requirement due to additional expectations of their professional body regarding delegation of responsibility.

 Be responsible for ensuring the practitioner is suitably trained for the procedure? Be responsible for ensuring the procedure will be undertaken safely? Be themselves suitably trained and 	
qualified in the procedure being undertaken?	
13. Thinking about the healthcare professional undertaking a group 3 procedure, which statement below do you agree with:	HIS has no preference to the approach taken, however for either option it is essential that there is clear guidance on the meaning of 'suitably trained' for each procedure. Regardless of the professional background.
These procedures should be undertaken by a suitably trained and qualified healthcare professional working within their scope of practice, but not otherwise be limited. These procedures should only be undertaken by certain healthcare professionals please see list in next question and tick all that apply;	It is noted for the practitioner licence there will have to be an NVQ qualification as "CPD courses will not be an appropriate form of qualification in themselves". This is true for HCPs as well and appropriate formal qualifications should be mandated for all NSCPs.
14. If your answer to the last question was that these procedures should only be undertaken by certain healthcare professionals, please tick all the healthcare professionals to which they should apply:	N/A
 - Medical practitioners (Doctors) - Dental practitioners - Dental care professionals - Registered nurses 	

- Registered midwives	
- Registered pharmacists	
- Registered pharmacy technicians	
15. Do you agree or disagree that the following settings should be required to register with Healthcare Improvement Scotland if they are offering non-surgical cosmetic procedures?	The National Health Service (Scotland) Act 1978 details exemptions that already apply to the definition of an independent clinic. This includes where NHS services and treatments are provided as part of the business of a GP practice, dental practice or community pharmacy.
GP practicesDental practicesCommunity pharmacies	HIS already regulates services that are provided from these locations, if the proposed service provider meets the definition of an independent clinic.
	If the intention is to remove the existing exemptions for NHS services and GPhC regulated pharmacies from the definition of independent clinic and independent medical agency, this will significantly increase the number of services that are required to register as independent healthcare services.
	We are aware that the majority of dental practices that offer both private and NHS dentistry also offer NSCPs. This would increase the number of services that would become an independent healthcare service by approximately 1000. We do not have the same level of intelligence about NSCPs offered in NHS GP practices or GPhC registered pharmacies, but it is possible that this would increase the number still further.
	HIS would require significant additional resources, in addition to any increased fee income, to be able to take forward this proposal in an effective way.
16. Do you agree or disagree that Healthcare	In order to ensure that regulation is effective and fair, Healthcare Improvement
Improvement Scotland should have powers of	Scotland requires these additional powers in order to build an effective case against
inspection, including powers of entry and	those avoiding regulation. HIS also requires appropriate powers to use information available on social media and evidence gathered by mystery shoppers to be used as

inspection of unregistered settings where there evidence against unregistered services. The Scottish Government should consider is reason to believe registration is required? sanctions in addition to a criminal offence that can be processed in a timely manner. However, there would be an additional resource requirement as a result of more effective enforcement powers. Agree Disagree I don't know 17. Which of the following statements is In general, HIS restricts the provision on NSCPs to those aged over 18. closest to your view? (please select only one option) HIS grants registrations with conditions of registration in place, which includes the age range of service users. The age range proposed depends on the range of services There should be a lower age limit under and treatments provided. For example, service providers request a lower age range to provide advanced skin care treatments for the treatment of acne in teenage which clients should not be allowed to undertake an NSCPs (different ages are children. considered in Question 18) There should be no lower age limit For Category 2 and Category 3, these should only be provided to adults aged 18 and under which clients should not be over. allowed to undertake an NSCPs, but all procedures for under 18s should be treated as a group 3 procedure and be required to be carried out by an appropriate healthcare professional - I don't know. 18. Regardless of your answer to question 17, if HIS grants registrations with conditions of registration in place, which includes the an age limit is to be put in place please indicate age range of service users. The age range proposed depends on the range of services for each procedure group what you think is the and treatments provided. For example, service providers request a lower age range to provide advanced skin care treatments for the treatment of acne in teenage appropriate age to be set for the procedures in that group. children. Please note that this question was revised on 6 For Category 2 and Category 3, these should only be provided to adults aged 18 and January 2025 to correct an error in the over.

formatting that affected the interpretation of	
responses. This will be reflected in the final	
analysis of responses.	
(pick one of the ages below for each	
procedure)	
 Limited to clients aged 18 and over Limited to clients aged 16 and over Limited to clients aged 16 and 17 who have parental / guardian's consent, or otherwise to clients aged 18 and over No age limitations 	
Procedure Group 1	
Procedure Group 2	
Procedure Group 3	
19. Do you agree or disagree that procedures	HIS strongly agrees that any treatments on intimate areas should be limited to those
on intimate areas should only be available to	over the age of 18 and only after a complete face to face consultation with registered
clients of 18 years of age and over?	healthcare professional with the knowledge, education and competence to advise on
cultures of 10 years of age and ever.	such treatments. However further consideration is required specifically in relation to
Agree	laser hair removal.
Disagree	taser nan removat.
I don't know	
20. What are your views on how, if at all, the	Age: The proposal includes possible age restrictions for non-surgical cosmetic
introduction of licensing and regulation of the	procedures. This could help protect young people from risks but may also stop some
nonsurgical cosmetics sector in Scotland	from accessing treatments for medical/psychological reasons. Any rules should be
might affect anyone based on their protected	fair and not disadvantage those with this genuine need.
characteristics?	Tall and not disadvantage those with this genuine need.
Gildidotofistics:	Disability: Some people with medical conditions or disabilities may need/want these
	procedures for health or well-being (e.g. facial scaring, burns, clef lip etc). The new
	procedures for health or well-being (e.g. facial scaling, burns, clei lip etc). The flew

Protected characteristics include: age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, and sex, (Please provide any information in support to your answer in the box below)

Please give us your views.

licensing system should not create unnecessary difficulties for those who require treatment.

Sex: Women are more likely to have non-surgical cosmetic treatments than men, so any new rules should make sure they don't unfairly affect one sex more than the other.

Gender Reassignment: Regulations on treatments like fillers or laser procedures could affect transgender and non-binary people seeking gender-affirming care. The new system should ensure fair access (while keeping safety a priority).

Race and Ethnicity: Some treatments, such as skin care or hair removal are more commonly used by people from certain ethnic backgrounds. Training and licensing should properly ensure practitioners understand different skin types and how treatments affect them.

Pregnancy and Maternity: Some cosmetic procedures may carry extra risks during pregnancy. Regulations should make sure practitioners have the knowledge and give clear advice on risks.

Religion or Belief: Some people may prefer a practitioner of the same sex due to religious/cultural beliefs. Any new licensing should consider inclusivity along with keeping standards high.

21. What are your views on how the introduction of licensing and regulation of the non-surgical cosmetics sector in Scotland might affect people differently based on their financial situation?

Are there any plans for 'grandfathering' arrangements to allow services (non HCP and HCP) currently providing specific treatments to phase out/get appropriate training/staff etc to now be able to carry out the treatments as there are restrictions for both non HCP and HCP, which did not previously exist? Individuals will have built businesses, which provide them and their families with a livelihood, which in some instances could disappear overnight.

Please give us your views.	
Convention on the Rights of the Child?	
children and young people as set out in the UN	
respecting, protecting and fulfilling the rights of	absence of any restrictions, the aforesaid rights may be contravened.
the potential of age restrictions might affect	child) and Article 24, (every child has the right to the best possible health). In the
non-surgical cosmetics sector in Scotland and	procedure (i.e. over 18) will respect and uphold Article 3 (best interests of the
introduction of licensing and regulation of the	people aged 16 and 17 as children. Applying age restriction to non-surgical cosmetic
23. What are your views on how the	Article 1 of United Nations Convention on the Rights of the Child defines young
Please give us your views.	
your answer in the box below	
Please provide any information in support to	
services in island communities?	
might affect access to safe, high-quality	
non-surgical cosmetics sector in Scotland	
introduction of licensing and regulation of the	
22. What are your views on how the	
Please give us your views.	
your answer in the box below)	
(Please provide any information in support to your answer in the box below)	
(Diagon provide any information in support to	
financial situation.	
reduce inequalities caused mainly by people's	
Scotland to actively consider how they can	
responsibility on certain public bodies in	
The Fairer Scotland Duty places a legal	