The Regulation of Independent Clinics in Scotland

Health and Sport Committee meeting - 11 February 2016

1. Do you support the new regulations?

Save Face are in support of regulation that is based on the risks posed to public health outweighing the burden for treatment provider. We concur that for some treatment sets and for private hospitals regulation is a positive and essential step forward. However, having gained significant experience in the non-surgical cosmetic treatment industry including the challenges and issues faced by both the consumer and the registered healthcare practitioners who operate within it, we vehemently disagree with the inclusion of this treatment set within the new regulations.

Current legislation set out by the Department of Health states that the risk of harm must be sufficient to justify the burden of regulation and any regulated activity or treatment must meet the following criteria:

• there is a fair playing;
• the requirement to register must be based on risk to people who use services and the extent to which statutory system regulation of providers can mitigate that risk;
• all types of provider must meet the same requirements.

As previously highlighted to the Scottish Government within our response to their initial consultation, Save Face calls for providers of non-surgical cosmetic treatments to be exempt from the regulation of private clinics as it is in conflict with all of the rationale set out above.

In all other regulatory frameworks in place in the UK, Wales and Ireland non-surgical cosmetic treatments are defined as cosmetic treatments and are not classified as a regulated activity, the CQC for example deem the following cosmetic activities exempt from regulation:

• Purely cosmetic interventions.
• the piercing of any part of the human body
• tattooing
• subcutaneous injections of a substance(s) to enhance appearance
• removal of hair roots or small skin blemishes by application of heat using an electric current;

They classify any medical professional providing these services as ‘beauticians’ as they do not undertake service that treat disease, disorder or injury as per the following excerpt taken from the ‘CQC Scope of Registration March 2015’

*However, there may be occasions when the person providing treatment is not acting in the capacity of a listed health care professional, even if holding a professional qualification (for example, a beautician undertaking a cosmetic/aesthetic service who is also qualified as a nurse).*
Non-surgical cosmetic treatments are an anomaly amongst all other treatments that fall within the scope for regulation. It is the only set of treatments that are widely practiced by a wide range of other registered healthcare professionals e.g. Prescribing Pharmacists, Physiotherapists, Podiatrists, Optometrists etc. and an even wider range of non-healthcare practitioners including; beauty therapists, hairdressers and an unknown quantity of other layman’s from vast and varied professional backgrounds that have emerged and set themselves up as a treatment provider. Some of whom will have undergone some form of training and frighteningly others will have simply purchased products illicitly over the internet and are self-taught.

Therefore, by choosing only to regulate three types of service provider who present the lowest risk to public safety is absolutely nonsensical and defies the very definition of regulation as it does not capture ALL of the professions who currently offer this service. It is absolutely ludicrous that registered healthcare professionals who fall within the scope for regulation will be prosecuted for not registering their services with HIS whilst a beauty therapist or a self-taught novice can operate with impunity.

Save Face firmly believe that the proposal to implement a phased approach to regulation in this industry sector will pose a greater risk to the service user as it not inclusive of all treatment providers as outlined above. It will make an already complex landscape even more difficult for service users to be able to navigate their way to a safe pair of hands. It will leave the public prey to a two tier system: good practice by well qualified professionals on one level, which will almost certainly cost the consumer more; and on another level a cut-price, budget approach provided by untrained practitioners with little consideration of risk or redress if complications arise.

To further complicate matters, the Government/HIS will not be conveying a clear message to consumer seeking non-surgical cosmetic treatments based on the regulation which should only direct service uses to regulated practitioners by deeming all other providers unsafe and unregulated, but instead, because they will not be posing any sanctions on other providers whatsoever until Phase 2 of the project whereby other providers may be required to acquire a licence. Licensing is likely to be lighter touch and less expensive, placing an unfair burden on lower risk professional services. There is a risk of inconsistency of standards and how they are applied/enforced by local authorities. If a licenced premises is found to be in breach of the requirements it will not be enforceable by the Sherriff in the same way that the healthcare professionals would be held to account under the regulatory framework nor are these practitioners accountable to their statutory regulators in the same way as the regulated healthcare professionals.

Furthermore, there has been no budget set aside for the marketing or promotion of this new service to the consumer, nor will there be an accessible register of regulated providers for each specific service leaving the consumer vulnerable and in the same position as they are now with no other option but to take practitioners at face value and entrust that what they are saying is true and the qualifications they claim are genuine.

Therefore the question must be raised as to what reasonable and justifiable rationale is there for incorporating such providers under the umbrella of regulation? As I have previously stated non-surgical cosmetic treatments are the ONLY set of treatments that would fall within the scope of regulation proposed by HIS that may be and are frequently provided by non-healthcare professionals. In addition to that, unlike other private services that are provided by the medical professionals that fall within the
scope, non-surgical cosmetic treatments carry no regulation or legislation that dictates who should and who should not be able to administer them and therefore can be provided by ANYONE and ANYWHERE.

We are therefore calling on the Scottish Government to make non-surgical cosmetic treatments exempt from the definition of an independent clinic by acting upon the plans set out within the Consultation Feedback Report where it states ‘The Scottish Government is considering a number of service types to exempt from the definition of an independent clinic. This would reduce the number of services to be regulated and so should reduce the number of staff required and therefore, the registration fee.’

2. Do you believe that further regulation is needed?

We concur that for some treatment sets and for private hospitals regulation is a positive and essential step forward. However, having gained significant experience in the non-surgical cosmetic treatment industry including the challenges and issues faced by both the consumer and the registered healthcare practitioners who operate within it, we vehemently disagree with the inclusion of this treatment set within the new regulations. We propose that Scotland should maintain the same position as the rest of the UK and encourage self-regulation for healthcare providers and implement a licencing scheme for non-healthcare providers.

3. Do you agree with basing the definition of ‘independent clinic’ on the healthcare professional providing the service rather than basing it on a specific procedure or specific ‘cosmetic’ treatments and do you agree with the range of healthcare professionals identified?

Having a blanket set of standards that do not define a minimum standard of practice or specific set of requirements for each treatment set deems the regulation completely ineffective and serves no purpose. All it will mean is that the environment in which the treatments take place are suitable but it will do nothing to assess the suitability and qualifications of the practitioner providing the service. Nor will it act as a benchmark to ensure that standards for each treatments set are improved year on year. It will also limit the collection of data to determine whether or not the implementation of the regulations has been successful and effective in reducing the risk to public safety. Furthermore, how can a service user establish what level of standard of care and service they should expect to receive from a treatment provider and how can complaints be managed effectively if investigators have not got a specific set of standards and protocols to assess whether or not the practitioner has breached the regulations? How can it be enforceable, if there are no standards in place how is a practitioner supposed to know what is required of them? It offers no more protection to public safety than what exists currently, the service user will still be in a vulnerable position with nowhere to turn when something goes wrong.

4. Will the regulations result in a lowering of risk to members of the public who have treatments carried out?

Our response to this question is combined with our response to Question 5 detailed below.

5. Could the legislation and the new requirement to register (including costs associated with registration) have any unintended consequences (such as on smaller one premise businesses, or unintentionally divert people to those businesses who are not registered such as salons (and which don't have to accommodate the additional costs for registration)?
Save Face

Save Face believe that should the Government proceed with the plans to include non-surgical cosmetic within the definition of an ‘independent clinic’ would have several detrimental unintended consequences not only for those who are required to register but also for HIS and the tax payer. The unintended consensus will unfold like a domino effect as one consequence leads to another and another if the decision to include non-surgical cosmetic treatments within the scope of regulation goes ahead.

As outlined above there is no obvious logic as to why the decision has been made for cosmetic treatments to be included within the new regulation all other regulatory bodies have chosen not to incorporate these treatments on the justification that by doing so seriously conflicts with the rationale for imposing regulations as set out by the Department of Health which states that the risk of harm must be sufficient to justify the burden of regulation and any regulated activity or treatment must meet the following criteria:

• There is a fair playing;

There certainly is not fair playing for providers who are required to register, neither within the regulatory framework nor in comparison to those who will still be able to operate with impunity simply because they have a different qualification, many of which pose a far greater risk to public safety. Amongst the 3 professions included there are a number of unfair and disproportionate disadvantages for example, a dental practice who offers both private and NHS treatments will not be required to register (even though they are not regulated in any other way) but a nurse who operates some private services, in whatever shape or form that may be outside of the NHS will be required to register. This puts nurses at a serious disadvantage to both Doctors and Dental professionals who will be able to side-step the requirement to register under the loophole that they offer some NHS treatments alongside their private endeavours.

• The requirement to register must be based on risk to people who use services and the extent to which statutory system regulation of providers can mitigate that risk;

Save Face firmly believe that the proposal to implement a phased approach to regulation in this industry sector will pose a greater risk to the service user as it not inclusive of all treatment providers as outlined above. It will make an already complex landscape even more difficult for service users to be able to navigate their way to a safe pair of hands. It will leave the public prey to a two tier system: good practice by well qualified professionals on one level, which will almost certainly cost the consumer more; and on another level a cut-price, budget approach provided by untrained practitioners with little consideration of risk or redress if complications arise. To further complicate matters, the Government/ HIS will not be conveying a clear message to consumer seeking non-surgical cosmetic treatments based on the regulation which should only direct service uses to regulated practitioners by deeming all other providers unsafe and unregulated, but instead, because they will not be posing any sanctions on other providers whatsoever until Phase 2 of the project whereby other providers may be required to acquire a licence. Licensing is likely to be lighter touch and less expensive, placing an unfair burden on lower risk professional services. There is a risk of inconsistency of standards and how they are applied/enforced by local authorities. If a licenced premises is found to be in breach of the requirements it will not be enforceable by the Sherriff in the same way that the healthcare professionals would be held to account under the regulatory framework nor are these practitioners accountable to their statutory regulators in the same way as the regulated healthcare professionals.
Furthermore, there has been no budget set aside for the marketing or promotion of this new service to the consumer, nor will there be an accessible register of regulated providers for each specific service leaving the consumer vulnerable and in the same position as they are now with no other option but to take practitioners at face value and entrust that what they are saying is true and the qualifications they claim are genuine.

- All types of provider must meet the same requirements;

As stated above this quite simply is not the case with the plans set out by HIS, in fact it only captures 3 types of provider out of an endless pool of providers.

Unintended Consequences - Service Providers

An overwhelming majority (73%) of respondents' who responded to the consultation were not in favour of the plans to regulate ‘Independent Clinics' and feedback that the fees were too high and disproportionate.

As outlined above the planned regulations will have a detrimental impact on Nurses in particular who provide these services outside of the NHS who are required to register which presents a number of unfair and disproportionate disadvantages in comparison to the requirements set out for Doctors and Dentists who are more likely to also operate NHS services from an independent clinic. For example, a dental practice who offers both private and NHS treatments will not be required to register (even though they are not regulated in any other way and provide the exact same service as those who are required to register) but a nurse who operates some private services, in whatever shape or form that may be outside of the NHS will be required to register. This puts nurses at a serious disadvantage to both Doctors and Dental professionals who will be able to side-step the requirement to register under the loophole that they offer some NHS treatments alongside their private endeavours.

It will also have a serious impact on practitioners who provide their services from a number of locations. As the requirements stipulate that each location where private services take place are required to register poses a significant and unrealistic financial burden on practitioners. It is unrealistic to assume that the providers will be able to pay to have each location assessed. The possibility of the premises/salon owner contributing to the fee is highly unlikely especially when there are so many other types practitioners (as outlined above) who offer these services who would not have to register with HIS that could fill the position of the Doctor, Nurse or Dental Professional which will result in the practitioner losing a client base they have worked very hard to build up. In consideration of these points the practitioner will more than likely have to significantly reduce the amount of treatments they provide by only operating from one location or will have to stop providing treatments altogether.

As further unintended consequence which will occur from the scenario described above will lead to an emersion of a mass of practitioners from non-regulated professions entering the market place to fulfil the demand and void left behind by those who have been forced out of the industry by the burden of the regulations. This will undoubtedly result in an increase in unscrupulous practice within the industry. Currently there are a number of non-healthcare practitioners who operate within the industry by sourcing prescription from Doctors and Nurse prescribers, it is unlikely that that the medical professionals will want to continue to offer this service to those who are unregulated which could lead to practitioners sourcing products illegitimately over the internet or via medical practitioners across the border from neighbouring countries. It could also result in the rise in other professionals such as Prescribing
Pharmacists, Physiotherapists and other prescribing professionals and non-prescribing healthcare professionals entering the industry and further muddying the waters for both the regulators and consumers alike all of whom would fall out of the current scope for regulation and would be able to offer prescription services to beauty therapists etc. with impunity.

Current regulations and legislation requires all patients seeking Botulinum Toxin (Botox) treatments to be consulted by the prescriber of the prescription only medicine by a registered prescriber, as mentioned above this does include the professions included within the proposed regulations set out by the Scottish Government but also includes several other healthcare professionals who are also able to prescribe. After the patient has been consulted with by the prescriber ANYONE, regardless of their qualification may administer the drug. The person administering the treatment does not have to be supervised by the prescriber nor any other healthcare professional. Once a prescriber has seen the patient once there are NO rules or regulations in place to dictate how frequently the patient has to be seen by the prescriber and therefore, in almost all cases the prescriber consults the patient once and continues to supply the product to the person administering it without seeing them again regardless of the amount of times they are treated with the drug. This also raises several concerns such as;

- What if the patients' medical condition has changed since first seeing the prescriber?

- What if the person ordering the medicine i.e. the beauty therapist who is administering the treatment is dishonest and tells the prescriber it is for a person they have already seen when in actual fact it could be for someone entirely different? Doctors and Dentists are able to order Botox on mass without the requirement to state who the product is for and who will be administering the treatment.

Therefore the issue of non-healthcare professionals administering Botox treatments will not be addressed or minimised by the proposed regulation. Save Face also has considerable evidence to demonstrate that non-healthcare professionals, namely beauty therapists are sourcing Botox illegally and with ease via the internet or via other illicit means such as via prescribers who are willing to provide the product without seeing the patient beforehand.

The proposed regulation will also not prevent beauty therapists from being able to source and administer dermal fillers, to do so would require a change in the law. Dermal fillers present a greater and more long term risk than Botox. In the 2013 report ‘Review of the Regulation of Cosmetic Interventions’ by Sir Bruce Keogh dermal fillers were described as ‘a crisis waiting to happen’. Complications include: Infection, scarring, persistent inflammatory response (redness), thickening, pain, infection, asymmetry, tissue loss, poor aesthetic outcome, visual disturbance, blindness.

A further unintended consequence might be that regulated healthcare providers choose not to use their qualification in order to avoid HIS regulations and may relinquish their registration with their respective statutory body in order to avoid being required to register.

Unintended Consequences HIS/ Government/ Public Resources
Save Face

Save Face are deeply concerned that HIS and the Government have seriously underestimated the task at hand and have not taken on board any of the lessons learned from historic attempts to regulate this industry sector, nor does it seem to have taken any guidance from the recently published HEE report. Following the Keogh report published in 2012 Health Education England were appointed with the task of creating a suitable framework for the qualifications to determine the suitability of treatment providers within the industry, the final report which was published in January 2016 clearly states that in addition to Doctors, Dentists and Nurses it recognises Prescribing Pharmacists, Dental Hygienists and Physiotherapists as suitable professions to administer these treatments as well as Beauty Therapists who obtain the necessary qualifications. It also supports self-regulation amongst the aforementioned providers as a suitable means of regulating the industry without placing unnecessary and inappropriate burden on public resources.

Notwithstanding the rationale deployed by the Department of Health as outlined above, it seems that no measures have been put in place to gain a thorough understanding of the industry sectors and treatment sets that fall within the scope for regulation. It also seems that no measures have been put in place to prevent the issues that other regulatory bodies have faced when previous attempts to regulate have been made.

The CQC, who tried to regulate this industry and failed. The decision came to deregulate in 2010 because of the vast amount of professional backgrounds of the practitioners operating within the industry and the inconsistent standard of service. The CQC were not able to deliver the service on a cost neutral basis the assessments were charged fees upwards of £1,500 and relied on tax payer’s contributions from the government to cover the deficit. Therefore the feasibility of HIS being able to deliver the service effectively without posing an additional cost to the tax payer to regulate an elective set of treatments in such times of disparity is ludicrous especially in consideration of the underestimated figures listed in the anticipated number of ‘Independent Clinics’ in Scotland that will need to register and the amount of complaints and subsequent investigations that will need to be carried out.

Anticipated figures set out by HIS:

- 450 registrations
- 22 independent hospital inspections
- 400 complaints enquiries and 100 complaints investigations
- 10 enforcements, and
- 1,500 notifications, of which 20 will be serious enough to be escalated to a senior inspector.

The aforementioned figure of circa 450 clinics that are estimated to be required to register as an independent clinic seems frighteningly low, particularly as it has been confirmed by HIS that any private service provided by a Doctor, Nurse, Midwife or Dental Professional will be resgisterable. Save Face have a database of over 350 clinics that only provide non-surgical cosmetic treatments that would fall within the requirements to register.

As stated above it seems highly unfair that practitioners, predominantly Dentists who offer a both private and NHS services out of the same practice will not be required to register (even though they are not regulated in any other way) whilst any other
practitioner providing private services away from the NHS will have to even though they are offering the exact same services as those who are required to register. It needs to be clarified and defined as to what constitutes a private clinic. Save Face suggest that if a practice if providing in excess of 50% private services it is in the interest of fairness and equality that they too should be required to register.

Currently HIS anticipate (clarified in a recent email enquiry) that there are only 50 dental practices in Scotland that are required to register as they are wholly private, this figure seems extremely low. But based on the scenario outlined above whereby mixed practices who offer private and NHS services are required to register then the estimated figure could quadruple.

This lack of consideration and foresight to define service providers and practices who are required to register poses serious question marks as to the depth of research, knowledge and suitability of the proposed legislative infrastructure. As part of our response I have attached a list of all dental practices/ professionals in Scotland and there are 4,324. A report commissioned by the British Dental Council in 2013, detailed below, estimated that over 39% which equates to at least 1,686 of the figure above of dental practices were completely private and a further 90% offered a wide selection of private treatments. The report details the exponential growth of the private market which suggests that these figures should now be much higher.


These figures are notwithstanding the other private service areas that are provided by the other professions listed within the proposed regulation framework. Worryingly, I have serious concerns, which I have raised previously with Scottish Government that, as it includes ALL services provided by these professionals could pose serious burdens on those who offer non-healthcare services such as massage, reflexology, acupuncture, holistic services, hairdressing and beauty therapy.

Save Face also believe that the number of complaints that are anticipated have also been seriously underestimated. Logic would suggested that in any scenario where the overwhelming majority (73%) of respondents’ who responded to the consultation were not in favour of the plans to regulate ‘Independent Clinics’ will be extremely keen to make reports of bad practice and actively seek out to report those who have not registered all of which will need to be investigated. In addition to that there is an existing resentment between medical practitioners who believe that non-healthcare professionals should not be able to operate within the industry due to the level of risk involved for the consumer if a complication was to occur. Applying regulation in one area without the other will create further animosity which will result in a significant number of complaints being reported by the healthcare professionals who are operating in line with the regulations whilst a competitor in the same area is not and is able to continue to do so without breaking the law.

In consideration of all of the points raised above Save Face have serious concerns regarding the suitability, resources and experience to implement and manage the proposed regulations efficiently and effectively. Currently the HIS are responsible for 23 private hospital facilities in Scotland and have sufficiently less resources and bandwidth than their English equivalent the CQC, who tried to regulate this industry and failed. The decision came to deregulate in 2010 because of the vast amount of professional backgrounds of the practitioners operating within the industry and the inconsistent standard of service.
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Unintended Consequences – Industry Sector

The proposed phased approach will also have a detrimental impact on the progression unity of the industry sector. This disparate and sporadic model will also make the collation of any cohesive, qualitative and quantitative data which would enable the measurement and evaluation of risk all but impossible. It will also mean that it will be impossible to determine levels of complaints, complications and breaches of standards amongst the two groups.

Questions

1. What rationale is there for choosing only to regulate Doctors, Nurses and Dentists?

2. Please can you clarify and define what constitutes a private clinic if it offers both private and NHS treatments? Save Face suggest that if a practice if providing in excess of 50% private services it is in the interest of fairness and equality that they too should be required to register.

3. Is it correct that practices who provide private services alongside their NHS services will not be required to register? This seems unfair and disproportionate that a NHS dental practice who offers private treatments will not be required to register but a nurse who operates some private services, in whatever shape or form that may be outside of the NHS will be required to register.

4. If a practitioner is exempt from being required to register because they offer NHS treatments alongside their private practice, does a Nurse or other profession listed within the scope who may rent a room in a practice that also offers NHS services still have to register?

5. Using the same rationale as above, does a dental professional who works in a Dental practice offering both NHS and Private treatments but only offers private services still have to register?

6. Is there scope for adding exemptions providing clinics can evidence that they have can meet certain criteria via a voluntary, self-regulatory model that has been approved by parliament?

For example, we recently formed part of a similar exercise put forward by the Welsh Assembly who ruled that (for acupuncturists) who were registered with the government led accreditation scheme ‘Professional Standards Authority’ had already satisfied that they had met the requirements set out by the Assembly and therefore were exempt from having to participate in the licensing scheme proposed by the Assembly.

It is our opinion that effective regulation would be more expensive and complicated than anticipated, therefore it would be more appropriate and cost effective for Scottish Government to encourage or enforce an existing and established model for this specifically for this treatment set. Save Face are Save Face is now the UK & Ireland’s leading accreditation scheme and have made significant strides in raising brand awareness. We are currently in the process of becoming PSA accredited. The Professional Standards Authority (PSA) is the Government accreditation scheme for voluntary accreditation schemes in non-regulated industries. The PSA also oversees statutory bodies that regulate health and social care professionals in the UK.
attaining PSA accreditation will place Save Face on the same level of standards and scrutiny as the three regulatory bodies to which our accredited practitioners are accountable. As the regulatory bodies do not regulate non-surgical cosmetic treatments, Save Face will become an extension of the regulators for the professionals who provide non-surgical cosmetic treatments. The government have made clear that they have no intention to regulate the industry nor are they willing to and a centralised register of treatment providers. The government also strongly supports self-regulation and states quite clearly within the Hampton report that there should be no duplication of regulatory activity where a fit for purpose model exists.

Save Face propose it is not in the public’s interest to allocate such a significant amount of public funding to such services. These are elective procedures and there are other forms of introducing more stringent standards across the board that would be cost neutral to the tax-payer. Save Face propose that it would be more appropriate cost effective and efficient to contract the ownership and management to a third party scheme. To Contract the development of standards, assessment model and audit to a third party organization who have specific knowledge and experience within the industry would enable the government to implement a higher and consistent level of standard within the industry more quickly and more cost effectively By adopting this method to encourage the lower risk clinics i.e. the medical professionals that currently site within the regulatory requirements to self-regulate would leave the government free to implement a licensing model to all other providers.

Save Face