Full guidance on what your BRIA should contain can be found here.

Final Business and Regulatory Impact Assessment

Title of Proposal

The National Health Service (Scotland) Act 1978 (Independent Clinic) Amendment Order 2016

Purpose and intended effect

- **Background**

Regulation of services provided by the independent health care sector in Scotland was set out in the National Health Service (Scotland) Act 1978 ("the 1978 Act") as amended.

Healthcare Improvement Scotland's functions in relation to the regulation of independent hospitals and private psychiatric hospitals were commenced in 2011 but functions in relation to independent clinics, independent medical agencies and independent ambulance services have not been commenced. Secondary legislation is therefore being brought forward to amend the definition of independent clinic in the 1978 Act and also to commence HIS' regulation functions in relation to those clinics.

Following the publication of the Keogh Review in England, the Chief Medical Officer of Scotland asked Mr Andrew Malyon in his role as expert advisor on plastic surgery to consider the report's implications for Scotland. Mr Malyon established the Scottish Cosmetic Interventions Expert Group (SCIEG) as a short-life working group on 4th March 2014 and published a report in April 2015. The report's recommendations were accepted by the Scottish Ministers and covered :

- Regulation
- Good practice
- Informed and empowered public
- Accessible redress and resolution
- Monitoring and evaluation

The first recommendation on regulation split the work into three phases:

1. First recommendation entails regulation of independent clinics where services are provided by a doctor, dentist, nurse, midwife or dental care professional. This recommendation is being brought forward through secondary legislation amending the 1978 Act and commencing relevant provisions of that Act. The need to start with regulation of independent clinics was two-fold: many of the most high risk cosmetic procedures are carried out by regulated health professionals and the legislation to regulate these clinics was never commenced. The use of the proposed amendment order would close a loophole in the regulation of the independent health sector in Scotland.

Independent clinics are currently defined in the 1978 Act as clinics that are not part of a hospital and from which a medical practitioner or dental practitioner provides a service, which is not part of the National Health Service. We consider that the term 'service' includes consultations, investigations and treatments.

To assure the safety and quality of healthcare delivered in Scotland is the same standard as NHS provision independent clinics require to be regulated. Current scoping has identified the following to be regulated:

- Cosmetic clinics
- Private GPs
- Private dentists
- Mobile clinics
- Travel clinics
- Occupational health clinics
- Dental professionals
- Nurse led clinics
- Independent midwives

2. Cosmetic procedures provided by non-healthcare regulated practitioners (beauty/cosmetic salons) will be covered by phase two. The regulation is still being scoped out but it may involve a licensing system within which a register is available and inspections can be carried out.

3. Healthcare provided by other allied health professionals, eg. Healthcare scientists will be looked at in phase three.

For over a decade, regulation providing some protection has been in place for those receiving cosmetic procedures in independent hospitals. Regulated health care professionals working in any setting are also responsible to their regulatory bodies for their practice and therefore need to adhere to guidance on consent, prescribing, clinical care and reporting adverse events. In non-health care settings there is a range of health and safety at work legislation applicable to beauty therapists, most of whom have trained for a minimum of three years.

The guidance on the delivery of botulinum toxin, a medicine that must be prescribed, has been regularly updated. In 2013, the General Medical Council (GMC) updated its guidance on remote prescribing, stating:

"You must undertake a physical examination of patients before prescribing non-surgical cosmetic medicinal products such as Botox, Dysport or Vistabel or other injectable cosmetic medicines. You must not therefore prescribe these medicines by telephone, video-link, or online". The Nursing and Midwifery Council and the General Dental Council have similar guidance on the delivery of botulinum toxin.

The gaps identified both in the 2011 consultation report and in the work of the SCIEG are any inspection of the premises and all staff in independent clinics; the definition of a clinic in terms of which regulated health care professional provides the services; and the lack of any regulation apart from health and safety legislation of

the provision of non-surgical procedures in any facility other than a hospital; the lack of an overseeing body to receive and act on complaints; a lack of a legislative enforcement options for an overseeing body.

In the UK the gaps include the use of dermal fillers, some of which are not subject to the EU's Medical Devices Directives and therefore only subject to General Product Safety Regulations. The proposal to replace the Directives with a Regulation currently going through the European Parliament process seeks to ensure that a range of currently unregulated cosmetic products are included by extending the scope to include "certain implantable or other invasive products without a medical purpose that are similar to medical devices in terms of characteristics and risk profile (e.g. non-corrective contact lenses, implants for aesthetic purposes);" The detail of the Regulation also contains proposals for a Unique Device Identifier system in the EU to allow for identification and traceability of devices. The outcome of the debates for new legislation will be known in 2016, and the SCIEG backs this development.

The Committees of Advertising Practice (CAP) provided updated guidance on marketing both surgical and non-surgical cosmetic interventions in 2011[1] and new guidance on the social responsibility of time-limited deals for cosmetic interventions[2]. SCIEG supports these guidance documents with non-confirmed reports of a reduction in unacceptable marketing campaigns but poor practice is still occurring. It is not clear whether the general public and relevant businesses know that these guidance documents exist.

- **Objective**
  Give a description of what the proposal is trying to achieve and how it fits with Scottish, UK and EU policy.

The proposal will ensure that independent health clinics where services are provided by a doctor, dentist, nurse, midwife or dental care professional will be regulated in Scotland for the first time. This means there will be a register of these types of clinics and they will be inspected. There will be a body who receives complaints and where necessary investigates and enforces the law regarding the regulation of the clinics. The clinics will be held to standards ultimately leading to an increase in the quality of care for patients and provision of public safety.
The regulations covers specific professionals providing services/procedures. It does not regulate types of services/ procedures. This means that a number of clinics which provide other services in areas other than cosmetic procedures will be covered by this legislation. The rational for this lies in the difficulty to define aesthetic practice/procedures and in the need to include in the regulation other independent clinics such as private dentists which have not been regulated in Scotland , despite their regulation in England for a number of years.

[1] http://www.cap.org.uk/Advice-Training-on-the-rules/Help-Notes/Cosmetics-interventions-marketing.aspx

[2] http://www.cap.org.uk/Advice-Training-on-the-rules/Advice-Online-Database/Cosmetic-Interventions-Social-Responsibility.aspx

This regulation is complementary to the NHS England model of regulation of services provided in the independent sector and the increasing interest in the EU on ensuring that cosmetic products, some of which do not need to be marketed as a medical device if they have no medical purpose, are regulated.

This regulation intends to provide greater oversight of the independent healthcare delivered in Scotland and an assurance that independent clinics are complying with the National Care Standards and legislation. Additionally, more information about the performance of independent clinics will be available so the public can make an informed choice.

- **Rationale for Government intervention**
  Explain why the SG is making this proposal and how it contributes to the objectives of the National Performance Framework (provide a list if necessary) and Purpose.

Over the last decade, the uptake of cosmetic procedures appears to have soared. According to market research data, cosmetic procedures were worth £2.3 billion in 2010 and up to £3.6 billion in 2015 (Keogh Review[3]). According to the British Association of Aesthetic Plastic Surgeons (BAAPS), the number of cosmetic surgical operations increased by an average of 17% between 2012 and 2013.

As cosmetic procedures have grown in popularity, the diversity of settings in which they are performed has increased. Historically, cosmetic surgery was almost exclusively performed within hospital settings. In contrast, the range of procedures currently available can be performed within many locations – including private clinics, dental surgeries, beauty parlours and client homes.

The literature suggests there has been a very rapid increase in the use and variety of non-surgical cosmetic procedures that are used in high-income countries, but little robust data are available. Use of procedures appears most common amongst middle-aged women. However, there are indications that the target demographic may be expanding, with one author arguing that there should be a shift from asking 'when is it too early [to start treatment]?' to 'when is it too late?' [1]. It is also reported that men are increasingly interested in this area.[4]

In general, serious adverse events were reported to be exceedingly rare for non-surgical procedures, with most complications being mild and self-limiting. However, the quality of the evidence base for many non-surgical procedures was found to be poor. A high proportion of the scientific literature declared financial conflicts of interest, with many authors receiving funding from the manufacturers of cosmetic treatments. Overall, most studies report people are generally happy with the outcome of cosmetic procedures, although again noting the considerable limitations in the evidence base [2].

[3] https://www.gov.uk/government/publications/review-of-the-regulation-of-cosmetic-interventions

[4] https://www.harleymedical.co.uk/cosmetic-surgery-for-men

An Omnibus survey undertaken as part of the research for the SCIEG group found that 4% of the adult Scottish population reported having had a private cosmetic procedure in their lifetime (varied between 3% in the 18-24 age group and 7% among the 25-34 age group), of which:

- 54% have had a cosmetic dental treatment
- 17% have had an injectable cosmetic treatment
- 16% have had a laser skin procedure

In the adult Scottish population:

- 1% had a cosmetic procedure in the last 12 months
- 4% plan to have one in the next 12 months

On reported health problems in the first month after a private cosmetic procedure more than a quarter (27%) of the Omnibus responders reported difficulties such as slow healing, bleeding or numbness.

On complaints, the Omnibus survey found the first point of contact if something went wrong would be the provider (40%) but with 22% saying their first point of contact would be the GP and 8% saying a solicitor. The view from the focus groups was that people did not always know where to go to complain. This seemed to be especially the case for some minority groups – Asians reported being less likely to complain as they had less knowledge of where to complain. This finding was echoed by the Omnibus survey, with 7% of adults belonging to minority ethnic groups saying they would turn to a hospital first, compared to 3% of white adults.

The Omnibus survey found that: 43% of people in Scotland believe cosmetic surgery is regulated, 39% believe cosmetic dentistry is regulated, 12% believe non-surgical cosmetic procedures are regulated.

The Scottish Government's purpose is to focus Government and public services on creating a more successful country, with opportunities for all of Scotland to flourish, through increasing sustainable economic growth. This is underpinned by five strategic objectives. The order amending the definition of independent clinic in the National Health Service (Scotland) Act 1978 (along with a commencement order to bring relevant provisions into force) will contribute positively to the following objectives:

WEALTHIER & FAIRER - Enable businesses and people to increase their wealth and more people to share fairly in that wealth.

SAFER & STRONGER - **Help local communities to flourish, becoming stronger, safer places to live, offering improved opportunities and a better quality of life.**

HEALTHIER - **Help people to sustain and improve their health, especially in disadvantaged communities, ensuring better, local and faster access to health care.**

SMARTER - Expand opportunities for people in Scotland to succeed from nurture through to lifelong learning, ensuring higher and more widely shared achievements.

The Strategic Objectives themselves are supported by 15 national outcomes which describe in more detail what the Scottish Government wants to achieve over the next ten years. Legislation to regulate independent clinics will make a positive contribution to delivering over half of our published national outcomes.

Consultation

Within Government
List the Government agencies, directorates and enforcement bodies that you have consulted and explain how their input supported the formulation of the policy proposals.

This legislation has been developed in a collaborative way, with extensive involvement from colleagues both across and out with the Scottish Government and from a wide range of interests.

Discussions have been on-going with colleagues across the Scottish Government to develop the SSIs including Chief Medical Officer, Chief Dental Officer, Chief Nursing Officer, Allied Health Professionals, Primary Care Division, Mental Health Division, Business and Innovation Division, Scottish Government Legal Division.

Public Consultation
Consultation throughout the development of the SCIEG report included focus groups with the public, the questionnaires to clients and healthcare professionals, professional bodies via representation of ENT, dermatology, maxillo-facial, plastic surgery on the SCIEG High Quality Care subgroup, public partners on the Informed and Empowered Public subgroup, and Healthcare Improvement Scotland (HIS). HIS were also represented on SCIEG and have undertaken a joint public consultation with the Scottish Government on the fees for the legislation and regulation.

Business
Scottish Government officials plan to hold face-to-face meetings with a variety of stakeholders, including representatives from:

Elanic clinic
Dermal clinic
Save Face
Optical Express
Private UK cosmetic clinic
Independent nurse practitioner
Cherrybank Dental
Private GP services

To date there have been a number of conversations with specific businesses and

with business organisations around the legislation of independent clinics.

Stakeholder Meeting 1st September 2015 in Saint Andrew's house, Edinburgh. Notes, available and minutes published.

Presentation and discussion at the Joint Regional Meeting of the British College of Aesthetic Medicine and British Association of Cosmetic Nurses on the 5 September 2015.

Teleconference with the Nursing Midwifery Council 15 September 2015

Survey Monkey Survey on impact of legislation was designed and distributed to main stakeholders to collect coordinated responses from main groups.

Teleconference with Directors of Save Face on the 22nd of October 2015

Meeting with Optical Express

HIS have held meetings with General Dental Council and dentists.

Options

Option 1 – Do nothing option

This option will mean the status quo where independent clinics provided by a doctor, dentist, dental care professional, nurse and midwife and in particular providers in the cosmetic industry will not have a framework for registration and inspection and will not have to pay the fee for this service.

Refer to the section above for a more detail presentation on the background and evidence of the independent clinic regulatory framework and market.

Sectors and Groups affected

The public, consumers, independent clinics, businesses in the cosmetic interventions industry and government plus government agencies will be affected by this option.

Benefits & Costs

This option will leave the current market unchanged meaning that consumers and the public will remained uninformed and unpowered to make informed choices.

Providers will benefit from not having to pay the fee and accommodate the inspection and registration but they will not benefit from the lack of a level playing field or the accreditation that will come with the inspection regime raising their profile and public confidence in their services. Patient safety will remain at risk and Healthcare Improvement Scotland will be unable to regulate independent clinics.

Option 2 – Amendment of the definition of 'independent clinic' in section 10F of the National Health Service (Scotland) Act of 1978 ("the 1978 Act") to add registered nurses, registered midwives and dental care professionals to the existing health professionals (medical practitioners and dental practitioners) and to commence regulation of independent clinics .

The legislation is made under the 1978 Act and sets out requirements which must be complied with by providers of independent healthcare services. The requirements include a requirement to register and the payment of a fee . It also make provision concerning inspections of independent clinics by persons authorised to do so by HIS. This is the preferred option.

Sectors and groups affected

The public, consumers, independent clinics, businesses in the cosmetic interventions industry and government plus government agencies will be affected by this legislation.

Benefits

Benefits to providers

Providers will directly benefit from this legislation as it will standardise the level of quality and safety that it is provided in this market. It may have the effect of driving out of the market those providers who do not comply with the level of safety and quality providing a 'level playing field' for this market.

There will also be unquantifiable benefits for providers in terms of increase reputation of the cosmetic market provided by regulated independent clinics overall therefore increasing confidence in their services and potentially increasing their customer base and turnover.

The introduction of inspections will provide an incentives for provider to improve their services possibly leading to an increase in the quality of care and outcomes of their services.

Benefits to consumers

A direct benefit resulting from the inspection of independent clinics will be the availability of more and better information about the performance of a range of independent clinics for consumers. This will increase the degree of confidence when choosing a particular provider empowering and informing consumers in their decision making process.

Poorly performing clinics will be more easily identifiable and will either have to improve the quality and safety of their services or will have to stop providing them. This will have a significant impact on the quality and safety of services that consumers will experience.

All the above benefits should lead to a reduction in the number of adverse outcomes resulting from treatments at independent clinics and a reduction in the number of complaints
Additionally, consumers that feel that they have received a poor service or had a bad outcome as a result of undergoing treatment at an independent clinic will now have a clear root to register a complaint and to get help and advice on how to get a satisfactory response to their complaint.

Benefits to public and society

The measures introduced by this legislation will increase the quality of care and level of safety that it is provided in this market leading to an overall reduction in the risk to public health.

They will also increase trust and confidence for the general population when it comes to assessing risks and opportunities within this sector. The initiation of this regulation and accompanying social marketing will also increase the knowledge of the public on what is regulated and what is not.

Benefits to government and agencies

The measures introduced will have unquantifiable benefits for the NHS as the reduction in adverse episodes resulting from procedures provided by unregulated and substandard clinics will mean that there will be less cases where the NHS will have to carry out remedial treatment as provider of last resort and of emergency care for these patients. This will also free up resources to deal with patients.

There will also be some indirect benefits to government as this legislation aid its objectives by providing greater oversight of the healthcare delivered in Scotland. Additionally the assurance that independent clinics are complying with the National Care Standards and legislation.

Costs

Cost to providers

Providers will incur costs in relation to regulation. These costs can be separated into two groups:

Firstly, the costs in order to comply with the regulation regime set out in the 1978 Act and in regulations made under the Act. In our discussions with independent clinics during consultation, these stated that the processes and equipment required to comply with legislation are already in place and so we expect these costs to be minimal. They foresee some small unquantifiable costs in terms of investment in equipment in the first year and training of staff in the first year and then on-going for staff turnover.

There could be some independent clinics whose costs could be high if they don't already have in place the processes and equipment require to comply with the regulation. We expect these costs to vary depending on the range of treatments that

these clinics offer.

There might be additional costs for those businesses who fail the inspection as they will have to act upon any enforcement action and costs of re-inspection.

There could also be costs associated with facilitation of the inspection in terms of time taken with inspectors, supplying requested information to HIS as part of the inspection process. We would expect these costs to occur mostly in the first year and to reduce considerably in consequent years as providers put in place the system required to collect and report information. There could also be some administrative and training costs in relation to inspections.

The costs to cover the administrative requirement of completing the registration will be minimal. The availability of web based registration and advice provided to businesses will mitigate the burden.

Secondly, there will be a fixed yearly cost to providers resulting from the initial registration fee and an annual continuation fee. HIS have run an initial consultation on registration and maximum fee levels. Responses to the consultation shows that a large proportion of respondents have concerns regarding the impact that the fees could have on small businesses, single practitioners and occupational health services. Some of these impacts will be mitigated by the complete removal of fees due to the exemptions for certain clinics within the clinic definition. Other impacts will be mitigated by the review and likely stratification of the annual continuation fees. There will be a full consultation on the annual continuation fees in 2016.

Fees and a discussion about this and the fees are presented below:

Table 1 – Costs of registration and continuation fees

Service	Application for Registration	Annual Continuation	Variation or Removal of Condition	Cancellation of Registration
Maximum Fees for Independent clinic	£3,500	£3,500	£100	£100

Our best estimation indicates that around 400 independent clinics will have to register with HIS as a result of this legislation. The maximum level of fees that HIS can charge independent clinics is contained within a separate Scottish Statutory Instrument and sets the level at £3,500 for registration and £3,500 as an annual continuation fee. Based on this level of fees the total cost of registration for independent clinics in Scotland will be in the region of £1.4 million in the first year. After that only new to the market clinics will have to register as this is a once only procedure. In terms of continuation fee it is estimated maximum total costs of approximately £1.4 million a year.

However, registration and continuation fees are likely to differ from these maximum fees. HIS propose to charge the actual registration and continuation fees on a cost recovery basis and so these will be set up once they know the exact number of clinics in the registration list. At the moment HIS best estimate is to charge a registration fee of £2,165 to all clinics, this will add to a total cost for the independent clinics industry of £974,250 in the first year. The continuation fee will be set up in 2016 after a full consultation. The continuation fee structure will take into account the size of the clinic and this will be developed after consultation.

Fees for variation or removal of condition and cancellation of registration

The maximum fee to be set in respect of issuing a new certificate of registration is £100. However, HIS has indicated that they do not propose to charge fees for new certificates or cancellations.

Loss of income

There could also be some costs to a British commercial organisation that currently runs a register of cosmetic clinics. During consultation they declared 28 customers in Scotland paying an annual fee £699 plus VAT. It is possible that some of these clinics might choose to no longer pay a fee to this organisation once the legislation is in place leading to financial losses for this commercial company.

Table 2 — Total costs on business and individuals

Costs associated with:	Cost of Implementation	Costs in year 2	Costs of in
Costs of registrations	£1.4 m	£1.4 m	£1.4 r
Total*	£1.4 m	£1.4 m	£1.4 r

*These calculations are based on the maximum fees that are to be set through Regulations. HIS is intending to charge a lower registration fee and to designed a continuation fee structure that takes into account the size of the business.

Cost to consumers

There could potentially be a cost to consumers resulting from this legislation if the providers decided to pass the costs of the registration fees on to the consumer. However, in a competitive market this is unlikely given the fact that providers will be competing for customers and since the service will be at level playing field, they will probably be competing on price.

Cost to Government and Government Agencies

Costs to the Scottish Government

There will be initial set up costs for the Scottish Government in the order of

£195,500. These funds will be provided to HIS to upgrade their IT system and pay for the recruitment of staff who will work in the new regulatory regime. THIS will also fund the salary costs of the new staff until the regulatory regime becomes self-funding.

Costs to Health Improvement Scotland

HIS will undertake the inspections of independent clinics. The inspection system is to be self-funded by means of registration and continuation fees charged to independent clinics. The fees will have to cover the costs of registration, inspection, complaints, enforcement, notifications, quality assurance, training and development, project management, corporate support and finance as a result of IS inspection regime. We would expect that a degree of efficiency in the inspection process would be realised over time decreasing the resources and therefore costs required to carry out the inspections.

HIS estimate the need for 19.15 whole time equivalent (WTE) staff in 2016/17; 20.54 and 17.74 in the years 2017/18 and 2018/19 respectively. The details are shown in table 3, 4 and 5.

The total costs indicated in tables 3, 4 and 5 are best estimate and will amount to £1.15 million in year the first year, £1.34 million in the second year and £1.20 million in the third year.

Taking into account uncertainty in the number of complaints that HIS might have to deal with in the first three years of operation the range of costs we can anticipate is the region of between £1.12 and £1.18 million in the first year, £1.31 and £1.37 million in the second year and £1.17 and £1.22 million in the third year.

Table 3 - Total Pay and Non-Pay costs estimated by Healthcare Improvement Scotland for the financial year 2016-17.

	WTE	Band	Costs
Senior Inspector	1.76	8a	£93,387
Inspector	10.10	7	£401,055
Programme Manager	0.74	7	£33,432
Project Officer	0.51	5	£13,305
Project Administrator	4.21	4	£101,987
Comms Officer	0.03	5	£745
HR Advisor	0.15	6	£5,764
HR Assistant	0.15	4	£3,510
IT Assistant	0.06	4	£1,404
IT Analyst	0.03	6	£1,153
Sessional Costs			£175,000
Finance	1.42		£96,724
Non Pay Costs			£222,111
Total	19.15		£1,149,576

Table 4 - Total Pay and Non-Pay costs estimated by Healthcare Improvement Scotland for the financial year 2017-18.

	WTE	Band	Cost
Senior Inspector	1.67	8a	£89,598
Inspector	12.30	7	£493,713
Programme Manager	0.97	0	£44,352
Project Officer	2.19	5	£58,252
Project Administrator	1.89	4	£46,415
Comms Support	0.31	5	£8,966
HR Advisor	0.03	6	£1,153
HR Assistant	0.03	4	£702
IT Assistant	0.06	4	£1,404
IT Analyst	0.03	6	£1,153
Sessional Costs			£252,500
Finance	1.05		£84,108
Non Pay			£259,276
Total	20.54		£1,341,593

Table 5 - Total Pay and Non-Pay costs estimated by Healthcare Improvement Scotland for the financial year 2018-19.

	WTE	Band	Cost
Senior Inspector	1.41	8a	£76,132
Inspector	10.53	7	£426,861
Programme Manager	0.97	0	£44,810
Project Officer	1.64	5	£43,957
Project Administrator	1.67	4	£41,410
Comms Support	0.27	5	£8,105
HR Advisor	0.03	6	£1,153
HR Assistant	0.03	4	£702
IT Assistant	0.06	4	£1,404
IT Analyst	0.03	6	£1,153
Sessional Cost			£252,500
Finance	1.10		£80,624
Non Pay			£216,714
Total	17.74		£1,195,525

Costs to Health Improvement Scotland of raising awareness of legislation

HIS started raising business awareness activity in October 2015. This was in the form of mailings. There will be a further mailing after Christmas with a letter addressed to each provider proving contact information. In that pack will be an invite to registration events for providers in March, in Glasgow, Edinburgh and Aberdeen. The cost of these events is of approx. £2500 and it includes staff travel to Aberdeen and overnight accommodation. The postage costs are minimal.

Table 6 — Total costs on Health Improvement Scotland

Costs associated with:	**Cost of Implementation**	**Costs in year 2**	**Costs of in year 3**
Costs of inspections and registrations	£1,149,576	£1,247,376.	£1,195,525
Costs of raising awareness of legislation	£2500	£0	£0
Total	**£1,152,076**	**£1,247,376.**	**£1,195,525**

Costs of enforcement

HIS current enforcement practices for independent hospitals is minimal and relates to the need for a response to a point of fact or issue in the inspection report. For the new regulation of independent clinics, HIS has estimated they will require up to 8 enforcement activities a year including follow-up on complaints, other actions to those registered in year one and from year two, informing the Procurator Fiscal of clinics that are not registered. Enforcement activities in the subsequent years will include improvement notices; condition notices and follow-up; cancelation of registration etc.

There is a degree of uncertainty on the number of cases which will end up in a court proceeding. However, it is expected that the number will be small considering that HIS haven't had to undertake any court proceedings since they started regulating independent healthcare services in Scotland.

However, given the large number of clinics estimated at 400 and the variety and nature of the procedures undertaken at these clinics, HIS have estimated that up to 8 cases a year might end up in a court proceeding.

HIS are meeting with the Crown Office and Procurator Fiscal Service in February to discuss costs. However, the table 7 below shows the costs from the criminal justice system database in 2013 which are used in table 8.

Table 7 — Unit cost of criminal procedures

	Average prosecution costs per procedure (COPFS)	Average court costs per procedure (SCTS)	TOTAL (excluding legal aid costs)	Average legal assistance costs per procedure (SLAB)	TOTAL (includi g legal aid costs)
heriff Court ummary rocedure	£342	£357	£699	£612	£1311

Source: Costs of the Criminal Justice System in Scotland Dataset (2013)

Table 8 – Total criminal justice costs*

Procedure	Number of cases	Cost per case	TOTAL*
Sheriff Court Summary Procedure	8	£699 - £1311	£5,592 -£10,488
		Average total each year	£8,040

*Ranges illustrate the differences in costs between 75% and 100% of defendants receiving legal aid

Fixed penalties and banning orders

HIS as a specialist reporting agency will be responsible for reporting cases to the Procurator Fiscal. They will not impose any fixed penalties or banning orders.

Scottish Firms Impact Test

The businesses that have been visited and involved in the run up to the introduction of this piece of legislation, have indicated that they support the proposal to regulate independent healthcare clinics. When asked about the financial implications, most indicated that whilst there would be set up costs and staff training, these would be minimal. Similarly, they had concerns around the setting of fees and in the main understand that whilst the regulations stipulate the maximum fee that can be charged by HIS, this will not be the norm and that the majority of fees will be set at a lower rate. Industry representation has been an integral part of the process to date with a number of business representatives being members of SCIEG and the subsequent focus groups.

Competition Assessment

Explain here whether your proposals will have an impact on competition ensuring you provide evidence to back up any statements you make.

The 4 Competition and Markets Authority (CMA) competition assessment questions given below should be used as an initial assessment of competition. If you answer 3 or more of the questions with a 'no' then it is unlikely your proposals will have an impact on competition. You should include the questions and your answers within your BRIA to provide evidence that your proposals do not have any impact on competition.

Will the proposal directly limit the number or range of suppliers?
Will the proposal indirectly limit the number or range of suppliers?
Will the proposal limit the ability of suppliers to compete?
Will the proposal reduce suppliers' incentives to compete vigorously?

If you answer yes to two or more questions then you will need to complete a full Competition Assessment.

Test run of business forms

As HIS currently regulate independent hospitals, It is likely that they will use or adapt current forms/paperwork

Enforcement, sanctions and monitoring

All independent clinics will be required to register with HIS before they can undertake their respective services. Failure to register with HIS and be fully inspected, will mean that they are in breach of the legislation and this will result in HIS as a specialist reporting agency informing the Procurator Fiscal that they are providing a service that is deemed to be illegal. Penalties include the possibility of fines and a limited custodial sentence.

Implementation and delivery plan

The requirement for providers to register with HIS will commence in April 2016. HIS will commence inspecting clinics from April 2017 at which time providers will be expected to meet the required standards.

- **Post-implementation review**
  HIS will review the process after the first year and amend fees as appropriate to ensure that they operate on a cost recovery basis only.

Summary and recommendation

Which option is being recommended and why? Refer to analysis of the costs and benefits in reaching the decision. Summarise, using the table below, the information gathered for each option.

- **Summary costs and benefits table**

Option	Total benefit per annum: - economic, environmental, social	Total cost per annu - economic, enviror social - policy and adminis
Regulate independent clinics where services provided by specified professionals		
Do nothing	Businesses Unquantifiable Scottish Government, NHS, Local	Unquantifiable

	Authorities Unquantifiable	
Regulation of independent clinics	Businesses Unquantifiable Scottish Government, NHS, Local Authorities Unquantifiable Consumers Unquantifiable	Scottish government £195,500 Judiciary £8,040 Healthcare Improvement Scotland £1.2 m Businesses maximum £1.4m New registration cost of maximum £3,500 per annum and maximum continuation fee of £3,500 Consumers Unquantifiable

Declaration and publication

The Cabinet Secretary or Minister responsible for the policy (or the Chief Executive of non departmental public bodies and other agencies if appropriate) is required to sign off all BRIAs prior to publication. Use appropriate text from choices below:

- Sign-off for Final BRIAs:

I have read the Business and Regulatory Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs. I am satisfied that business impact has been assessed with the support of businesses in Scotland.

Signed:

Date:

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