

POLICY NOTE

THE NATIONAL HEALTH SERVICE (SCOTLAND) ACT 1978 (INDEPENDENT CLINIC) AMENDMENT ORDER 2016

SSI 2016/148

The above instrument was made in exercise of the powers conferred by sections 10G and 105(7) of the National Health Service (Scotland) Act 1978. The instrument is subject to affirmative procedure.

Policy Objectives

1. The policy (achieved through this instrument and a related instrument which commences certain provisions within the National Health Service (Scotland) Act 1978) will bring independent health clinics, where services are provided by a medical practitioner, a dental practitioner, a registered nurse, a registered midwife or a dental care professional, into regulation by Healthcare Improvement Scotland. The regulation regime is set out in the National Health Service (Scotland) Act 1978 (“the 1978 Act”) and regulations made using powers in that Act and covers registration, inspection, enforcement and complaints.
2. The aim is to provide the legal framework to enhance the safety of the public using these services and to close the gap in the regulation of independent healthcare. Independent hospitals have been regulated by Healthcare improvement Scotland since April 2011 but the legislation to regulate clinics was not commenced at that time.

Background

3. The background to the development of the policy is to action the recommendation accepted by the Scottish Ministers from the Scottish Cosmetic Interventions Expert Group to regulate independent clinics. The Scottish Cosmetic Interventions Expert Group recommended regulating all independent health clinics as opposed to just cosmetic interventions since the range of services are changing rapidly and there was a need to ensure independent dentists and all high risk services were included as swiftly as possible.
4. The effect of regulation is to include matters such as the inspection of premises and the management processes; a system for complaints to be referred to an external body and a set of enforcement methods where standards are not met.

Exemptions

5. The Order substitutes a new definition of “independent clinic” into the 1978 Act and also sets out certain exceptions to that definition to ensure proportionality in the new regulatory burden. The policy behind the exceptions is to cover clinics that are providing advisory or ancillary services to the main business of an organisation or which provide other services that are already regulated by the NHS. The list of exceptions is :
 - Independent health clinics in schools, colleges and universities
 - Occupational health clinics provided by employers for the sole use of employees

- Independent clinics providing first aid or talking therapies
- Independent clinics which also provide NHS primary dental and general medical services (both of which are already inspected by the NHS).

Consultation

6. To comply with the requirements of section 10G of the 1978 Act the following bodies have been consulted and a series of focus groups representing stakeholders were held in the autumn of 2015.

- General stakeholder meeting September 2015 in St Andrew's House, Edinburgh (attended by representatives from the industry, Transgender Alliance, Treatments You Can Trust, Save Face, HIS and the Scottish Government).
- Joint Regional Meeting of the British College of Aesthetic Medicine and British Association of Cosmetic Nurses September 2015
- The Royal Environmental Health Institute of Scotland's Health and Safety Update course September 2015
- Teleconference with the Nursing and Midwifery Council September 2015
- Teleconference with the Directors of Save Face October 2015
- Stakeholder meeting with Optical Express November 2015
- Visit to Independent dentist Cherrybank December 2015

7. The reviews with stakeholders main emerging theme was the approval for regulation. Specific points from the reviews were the need to ensure certain exceptions were considered (as above) and phase two regulation actioned. Phase two, which is being scoped, is intended to regulate certain services provided by practitioners such as beauticians and hairdressers. In addition the stakeholder engagement noted that duplication of regulation should be reduced where possible so primary dental and general medical (GP) services that were also providing NHS services and inspected by the NHS, should be exempt from the new regulation.

8. A full list of those consulted and who agreed to the release of this information is published on the Scottish Government website, it includes:

- NHS Boards
- Local Authorities
- Regulatory & Professional Bodies
- Independent HealthCare Providers

Impact Assessments

9. An Equality Impact Assessment screening workshop and literature review have been completed on the policy of regulation of independent health clinics and the summary attached. The literature review found one paper on the topic which was the completed impact assessment on the implementation of the regulation which showed no impact. Our assessment has been that the main impact is on knowledge of the public and the potential issue of changes to the fee structure to the clinics (given that regulation means that clinics will be required to register and hence pay a fee) which may cause a pricing differential to emerge, affecting consumers and businesses in lower socio-economic groups unequally. The fee impact is considered unlikely to be significant as the regulation will be equal and thus competition will be on price and businesses are unlikely to pass costs onto the consumers and risk losing their customers. To reduce

the information gap a social marketing campaign on cosmetic interventions will be provided for young women aged 18 -29 to understand and source information. The market will be monitored by the regulator.

10. A screening review for the Child Rights and Wellbeing Impact Assessment (CRWIA) was undertaken. This concluded that no CRWIA is necessary.

Financial Effects

11. A Business and Regulatory Impact Assessment (BRIA) has been completed and is attached. The impact of this policy on businesses is that, through clinics being brought within the regulatory regime, they will be required to register with Healthcare Improvement Scotland and pay a registration fee and annual continuation fee set at full cost recovery levels. There may be costs to bring services to the standards being set.

Scottish Government
Healthcare Quality and Strategy Directorate

13 January 2016