

Information for Services

Clarification of the interpretation of Regulation 12 of *The Healthcare Improvement Scotland (Requirements as to Independent Health Care Services) Regulations 2011*

1. Background

Regulation 12(a) and (b) of The Healthcare Improvement Scotland (Requirements as to Independent Healthcare Services) Regulations 2011 (the 2011 regulations) state:

A provider must, having regard to the size and nature of the service, and the number and needs of service users—

‘(a) ensure 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;

(b) ensure that at all times a suitably qualified health care professional is working within the independent health care service whilst service users are present;’.

[The Healthcare Improvement Scotland \(Requirements as to Independent Health Care Services\) Regulations 2011 \(legislation.gov.uk\)](https://www.legislation.gov.uk)

Currently ‘suitably qualified’ and ‘competent’ are not defined further in legislation for independent healthcare services providing a range of different services, treatments and procedures.

2. Why do we think we need to clarify the interpretation of Regulation 12?

The application of the staffing regulation in independent healthcare services has recently become a renewed focus of concern for Healthcare Improvement Scotland, given the following:

- A recent increase in applications for registration from newly qualified healthcare professionals setting up aesthetic clinics, where healthcare experience is very limited.
- A recent increase in service providers offering training to healthcare and non-healthcare professionals in non-surgical aesthetic treatments and procedures.
- A recent increase of service providers offering remote prescribing services/online consultations due to COVID-19.

This has led Healthcare Improvement Scotland to develop advice and guidance in order to provide further clarity on the meanings of ‘suitably qualified’ and ‘competent’, so services can meet the requirements of Regulation 12(a) and (b) of the 2011 regulations. This also links to the general arrangements that providers of independent healthcare services have for emergency situations.

3. What we considered?

Regulation 12 of the 2011 regulations states:

‘Staffing

12. A provider must, having regard to the size and nature of the service, and the number and needs of service users—

*(a) ensure 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;*

*(b) ensure that **at all times a suitably qualified health care professional** is working within the independent health care service whilst service users are present;’*

A ‘healthcare professional’ is defined in Regulation 1 of the 2011 regulations:

‘ “health care professional” means—

(a) a registered medical practitioner;

*(b) a registered dentist, or dental practitioner registered with the General Dental Council;**

(c) a registered pharmacist as defined in section 108(1) of the Act(1);

(d) an ophthalmic optician, as defined in section 108(1) of the Act but excluding a body corporate enrolled in the list kept under section 9 of the Opticians Act 1989(2);

(e) a registered nurse, midwife or health visitor (being a person registered in the register maintained under article 5 of the Nurses and Midwives Order 2001(3));

(f) a person who is registered as a member of a profession to which the Health Professions Order 2001(4) extends;

(g) a registered chiropractor as defined in section 43 of the Chiropractors Act 1994(5);
or

(h) a registered osteopath as defined in section 41 of the Osteopaths Act 1993(6)’.

* Healthcare Improvement Scotland considers dental care professionals to be dental practitioners as they are registered with the General Dental Council and are included in the definition of an independent clinic. Dental care professionals are clinical dental technicians, dental hygienists, dental nurses, dental technicians, dental therapists and orthodontic therapists.

In order to clarify ‘suitably qualified health care professional’ and ‘suitably qualified and competent persons’ the following were reviewed.

1. Recommendations from the Keogh Review in terms of minimum qualifications for independent healthcare providers.
2. The professional regulator statements of ‘Work undertaken is within scope of practice of their professional registration’.
3. Stance from indemnity providers regarding the standard of training required before granting indemnity.
4. The range of different training that can be undertaken by healthcare professionals, for example accredited training (SQA), half day course, full day course, Master’s degree. Relevant clinical specialties – plastic surgeon, GP

5. The additional training requirements such as basic or advanced life support, anaphylaxis and managing complications.
6. Information relating to qualifications and training from the following regulation of independent stakeholder group members up to the end of 2021.
 - <https://bcam.ac.uk/>
 - <https://www.bapras.org.uk/>
 - <https://baaps.org.uk/>
 - <https://www.bacn.org.uk/>
 - <https://www.jccp.org.uk/Home/> - not a stakeholder group member, but key player

4. What this means for services?

We would expect all new services registering to meet this interpretation of Regulation 12(a) and (b) below.

For existing services, we would expect to see that existing members of staff work towards this over a timescale agreed with the service provider and any new members of staff meet this interpretation of Regulation 12(a) and (b) below.

- 4.1. As a minimum, we would expect that all clinical staff working in the service, with the exception of those in training and under supervision, meet all of the following requirements to demonstrate they are suitably qualified and competent:
 - (a) Suitable post registration experience as a registered healthcare professional.
 - (b) Evidence of a post registration education and training in the relevant clinical specialty/area of study.
 - (c) Evidence of supervised practice by an experienced practitioner in the relevant specialty/area of study.
 - (d) Evidence of ongoing professional development in the relevant specialty/area of study.
 - (e) Evidence of training to recognise and manage complications.
- 4.2. In addition to the requirements in 4.1 for all clinical staff working in the service, we would expect as a minimum that the service provider must ensure that all of the following requirements are met immediately:
 - (a) There is a responsible healthcare professional present in the service while service users are present.
 - (b) The responsible healthcare professional must have oversight of all treatments and be able to demonstrate they are suitably qualified and competent to deal with emergency situations if they arise.
 - (c) In particular, the service provider must ensure that the responsible healthcare professional is able to prescribe and administer prescription-only medicines as part of a response to complications and/or an emergency situation, if required.

5. **Practically, how might this affect services?**

Practically, there will be little or no change for a large number of services already registered with us, as all clinical staff working in services meet or are working towards the requirements in 4.1.

In relation to 4.2(a) and (b), again there will be little or no change for a large number of services already registered with us. However, in relation to 4.2(c), for some services, where a prescriber does not work in the service at all times, for some treatments where prescription-only medicines, not part of the emergency kit, require to be prescribed the service will now have to consider how they will meet this requirement.

It will no longer be an option for the service to use a prescriber who is not physically present in the service where it may be necessary to prescribe and administer prescription only medicines, which are not part of the emergency kit, as part of a response to complications and/or an emergency situation. For example, if a practitioner administers dermal fillers and a complication of this procedure arises, this would require the use of hyaluronidase to dissolve the dermal filler. Hyaluronidase is a prescription-only medicine, which cannot be kept in the emergency kit and requires to be prescribed following a face-to-face consultation. Therefore, a service should not administer dermal fillers unless a prescriber is present to prescribe hyaluronidase, if required.

6. **Why do beauticians and beauty therapists that provide aesthetic treatments not need to register with Healthcare Improvement Scotland?**

Beauticians and beauty therapists that provide aesthetic treatments are not included in the definition of an independent clinic and therefore will not be required to register with Healthcare Improvement Scotland.

Following the Scottish Government's consultation on the regulation of non-surgical cosmetic procedures, it will now consider legislation, which would restrict who can administer dermal fillers. The Scottish Government will also consider other treatments and whether they require regulation.

7. **What happens next?**

In relation to new services registering with Healthcare Improvement Scotland, we would expect Regulation 12 to be met in full.

In relation to existing services, we expect services to be able to demonstrate to us on inspection how they are meeting Regulation 12. Services who are unable to demonstrate this may be subject to enforcement action in line with our enforcement policy (see link below).

<https://www.healthcareimprovementscotland.org/his/idoc.ashx?docid=eeaa87d7-432d-4db0-917c-ec346a62c2c8&version=-1>

8. What do I do, if I need more information and/or advice?

If you wish to speak to a member of staff, please call our Independent Healthcare Enquiry Line on 0131 623 4342.

If you do not need to speak to a member of staff, but have a query you would like answered, please email his.ihtregulation@nhs.scot