

## POLICY NOTE

### THE NATIONAL HEALTH SERVICE (SCOTLAND) ACT 1978 (INDEPENDENT HEALTH CARE) MODIFICATION ORDER 2024

**SSI 2024/XXX**

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.

#### Summary Box

The purpose of the instrument is to

1. enable Healthcare Improvement Scotland (“HIS”) to regulate independent clinics where services are provided by pharmacists and pharmacy technicians;
2. amend the definition of Independent Medical Agency (“IMA”) to cover services provided by dental practitioners, registered nurses, registered midwives, dental care professionals, pharmacists and pharmacy technicians which will include wholly online services based in Scotland; and
3. enable HIS to cancel the registration of independent health care services that fail to pay their continuation fees.

#### Policy Objectives

The instrument aims to increase public safety and avoid situations where pharmacists and pharmacy technicians provide services from unregulated clinics (services provided in registered pharmacies and/or under an NHS contract are excluded) and where wholly online providers are able to provide services to patients in Scotland without being regulated.

The changes regarding IMAs, including online services, are particularly urgent. Online healthcare services do not currently fall within regulation by HIS. This is considered to pose a public health risk.

In relation to cancellation of registration, the changes made by this instrument will provide HIS with a meaningful sanction against registered providers who fail to pay their continuation fees. We assess that this deterrent is likely to have a positive impact on the willingness of providers to pay the fees they owe, and is intended to be used as a last resort.

#### Transitional measures

Pharmacists and pharmacy technicians that wish to provide an independent clinic will be required to register with HIS. However this instrument gives a grace period of 1 year where it will not be an offence for a clinic to be provided by a pharmacist or pharmacy technician without being registered. This, then, allows time for applications to be made to HIS by any pharmacists or pharmacy technicians currently providing clinics. A similar result is achieved for IMAs through the operation of the Public Services Reform (Scotland) Act 2010 (Commencement No.8) Order 2024 which commences HIS’ function in relation to IMAs and is being laid along with this instrument.

**EU Alignment Consideration**

This instrument is not relevant to the Scottish Government's policy to maintain alignment with the EU.

**Consultation**

To comply with the requirements of section 10G of the National Health Service (Scotland) Act 1978 a public consultation took place from 1 February 2023 to 26 April 2023.

As a result of that consultation the following general themes emerged; the majority of respondents agreed with the proposed amendments, as a result it was decided to proceed with the proposals.

A full list of those consulted and who agreed to the release of this information is attached to the consultation report published on the Scottish Government website, it includes responses from BMA Scotland, Directors of Pharmacy Scotland, General Medical Council, Royal Pharmaceutical Society, and the British Association of Cosmetic Nurses

**Impact Assessments**

A Child Rights and Wellbeing, Equality, Fairer Duty Scotland, and Island Communities impact assessment have been completed in relation to the instrument and are attached. There are no foreseen impact issues and no action is being taken.

**Financial Effects**

A Business and Regulatory Impact Assessment (BRIA) has been completed and is attached. The impact of this policy on business will be an additional business expenses for all IMAs and any independent clinics where services are provided by pharmacists and pharmacy technicians. For businesses who fail to pay their fees, their registration will be cancelled and the business will require to make good any unpaid fees should they wish to re-register.

Scottish Government  
Chief Operating Officer, NHS Scotland Directorate

April 2024