

Health, Social Care and Sport Committee
21 May 2024
16th Meeting, 2024 (Session 6)

Subordinate legislation

Background

1. At this meeting the Committee will scrutinise a package of related Scottish Statutory Instruments (SSIs). The Committee will consider the following—

Instruments subject to affirmative procedure

- [National Health Service \(Scotland\) Act 1978 \(Independent Health Care\) Modification Order 2024](#)
- [The Healthcare Improvement Scotland \(Inspections\) Amendment Regulations 2024](#)

Instruments subject to negative procedure

- [The Healthcare Improvement Scotland \(Fees\) Regulations 2024](#)

Instruments not subject to any parliamentary procedure

- [The Public Services Reform \(Scotland\) Act 2010 \(Commencement No. 8\) Order 2024](#)

National Health Service (Scotland) Act 1978 (Independent Health Care) Modification Order 2024 [draft]

Overview

2. At this meeting, the Committee will take evidence from the Cabinet Secretary for Health and Social Care and officials on the National Health Service (Scotland) Act 1978 (Independent Health Care) Modification Order 2024 before debating a motion in the name of the Minister for Social Care, Mental Wellbeing and Sport inviting the Committee to recommend approval of the instrument.
3. This is a draft Scottish Statutory Instrument (SSI), which requires approval by resolution of the Parliament before it can become law. More information about the instrument is summarised below:

Title of instrument: [National Health Service \(Scotland\) Act 1978 \(Independent Health Care\) Modification Order 2024](#) [draft]

Laid under: [National Health Service \(Scotland\) Act 1978](#)

Laid on: 26 April 2024

Procedure: Affirmative

Lead committee to report by: 4 June 2024

Commencement: If approved, the instrument comes into force on 19 June 2024

Procedure

4. Under the affirmative procedure, an instrument must be laid in draft and cannot be made (or come into force) unless it is approved by resolution of the Parliament.
5. Once laid, the instrument is referred to:
 - the Delegated Powers and Law Reform (DPLR) Committee, for scrutiny on various technical grounds, and
 - a lead committee, whose remit includes the subject-matter of the instrument, for scrutiny on policy grounds.
6. The lead committee, taking account of any recommendations made by the DPLR Committee (or any other committee), must report within 40 days of the instrument being laid.
7. The normal practice is to have two agenda items when an affirmative instrument is considered by the lead committee:

- an evidence session with the Minister and officials, followed by
 - a formal debate on a motion, lodged by the Minister, inviting the lead committee to recommend approval of the instrument.
8. Only MSPs may participate in the debate, which may not last for more than 90 minutes. If there is a division on the motion, only committee members may vote. If the motion is agreed to, it is for the Chamber to decide, at a later date, whether to approve the instrument

Delegated Powers and Law Reform Committee consideration

9. The DPLR Committee considered the instrument on 7 May 2024 and reported on it in its [32nd Report, 2024](#). The DPLR Committee made no recommendations in relation to the instrument [*or summarise any points/recommendations made*].

Purpose of the instrument

10. The Policy Note states that the purpose of the instrument is to:
- enable Healthcare Improvement Scotland (“HIS”) to regulate independent clinics where services are provided by pharmacists and pharmacy technicians;
 - 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
 - enable HIS to cancel the registration of independent health care services that fail to pay their continuation fees.
11. The Policy Note accompanying the instrument is included in **annexe A**. It includes a summary of consultation undertaken on the instrument, impact assessments carried out, and the anticipated financial effects.

Report

12. A draft report has been pre-prepared and is circulated separately, as a private paper, for consideration later in the meeting.

The Healthcare Improvement Scotland (Inspections) Amendment Regulations 2024 [draft]

Overview

13. At this meeting, the Committee will take evidence from the Cabinet Secretary for Health and Social Care and officials on the National Health Service (Scotland) Act 1978 (Independent Health Care) Modification Order 2024 before debating a motion in the name of the Cabinet Secretary inviting the Committee to recommend approval of the instrument.
14. This is a draft Scottish Statutory Instrument (SSI), which requires approval by resolution of the Parliament before it can become law. More information about the instrument is summarised below:

Title of instrument: [The Healthcare Improvement Scotland \(Inspections\) Amendment Regulations 2024](#) [draft]

Laid under: [National Health Service \(Scotland\) Act 1978](#)

Laid on: 26 April 2024

Procedure: Affirmative

Lead committee to report by: 3 June 2024

Commencement: If approved, the instrument comes into force on 19 June 2024

Procedure

15. Under the affirmative procedure, an instrument must be laid in draft and cannot be made (or come into force) unless it is approved by resolution of the Parliament.
16. Once laid, the instrument is referred to:
 - the Delegated Powers and Law Reform (DPLR) Committee, for scrutiny on various technical grounds, and
 - a lead committee, whose remit includes the subject-matter of the instrument, for scrutiny on policy grounds.
17. The lead committee, taking account of any recommendations made by the DPLR Committee (or any other committee), must report within 40 days of the instrument being laid.
18. The normal practice is to have two agenda items when an affirmative instrument is considered by the lead committee:
 - an evidence session with the Minister and officials, followed by

- a formal debate on a motion, lodged by the Minister, inviting the lead committee to recommend approval of the instrument.

19. Only MSPs may participate in the debate, which may not last for more than 90 minutes. If there is a division on the motion, only committee members may vote. If the motion is agreed to, it is for the Chamber to decide, at a later date, whether to approve the instrument

Delegated Powers and Law Reform Committee consideration

20. The DPLR Committee considered the instrument on 7 May 2024 and reported on it in its [32nd Report, 2024](#). The DPLR Committee made no recommendations in relation to the instrument.

Purpose of the instrument

21. The Policy Note states that the purpose of the instrument is to allow inspectors, authorised by HIS under section 10K of the National Health Services (Scotland) Act 1978, to inspect medical records.

22. It further states that “the current list of professions restricts who HIS is able to draw upon to inspect medical records as part of their inspections. Currently, the ability to inspect medical records as part of inspections undertaken by HIS is restricted to medical practitioners, registered nurses, pharmacists, and registered dentists”.

23. The Policy Note accompanying the instrument is included in **annexe B**. It includes a summary of consultation undertaken on the instrument, impact assessments carried out, and the anticipated financial effects.

Report

24. A draft report has been pre-prepared and is circulated separately, as a private paper, for consideration later in the meeting.

The Healthcare Improvement Scotland (Fees) Regulations 2024 (SSI 2024/130)

Overview

25. At this meeting, the Committee will consider the following Scottish Statutory Instrument (SSI), which is subject to annulment by resolution of the Parliament until 4 June 2024. The Committee is invited to consider the instrument and decide what, if any, recommendations to make.

26. More information about the instrument is summarised below:

Title of instrument: [The Healthcare Improvement Scotland \(Fees\) Regulations 2024](#) (SSI 2024/130)

Laid under: [National Health Service \(Scotland\) Act 1978](#)

Laid on: 26 April 2024

Procedure: Negative

Deadline for committee consideration: 3 June 2024

Deadline for Chamber consideration: 4 June 2024

Commencement: 19 June 2024

Procedure

27. Under the negative procedure, an instrument is laid after it is made, and is subject to annulment by resolution of the Parliament for a period of 40 days beginning on the day it is laid.

28. Once laid, the instrument is referred to:

- the Delegated Powers and Law Reform (DPLR) Committee, for scrutiny on various technical grounds, and
- a lead committee, whose remit includes the subject-matter of the instrument, for scrutiny on policy grounds.

29. Any MSP may propose, by motion, that the lead committee recommend annulment of the instrument. If such a motion is lodged, it must be debated at a meeting of the Committee, and the Committee must then report to the Parliament (by the advisory deadline referred to above).

30. If there is no motion recommending annulment, the lead committee is not required to report on the instrument.

Delegated Powers and Law Reform Committee consideration

31. The DPLR Committee considered the instrument on 7 May 2024 and reported on it in its [32nd Report, 2024](#). The DPLR Committee made no recommendations in relation to the instrument.

Purpose of the instrument

32. The Policy Note states that the purpose of the instrument is to enable HIS, under Section 10Z5 of the National Health Service (Scotland) Act 1978 (“the 1978 Act”), to be able to prescribe the maximum fees which HIS may impose in respect of Independent Medical Agencies “IMAs”; and raise the maximum fees which may be imposed by HIS on all independent healthcare services in respect of applications for registration or cancellation of registration of independent health care services; the annual continuation of any such registration; and applications for the variation or removal of a condition of registration.

33. The Policy Note accompanying the instrument is included in Annexe C. It includes a summary of consultation undertaken on the instrument, impact assessments carried out, and the anticipated financial effects.

Committee consideration

34. So far, no motion recommending annulment has been lodged.

35. Members are invited to consider the instrument and decide whether there are any points they wish to raise. If there are, options include:

- seeking further information from the Scottish Government (and/or other stakeholders) through correspondence, and/or
- inviting the Minister (and/or other stakeholders) to attend the next meeting to give evidence on the instrument.

It would then be for the Committee, at the next meeting, to consider the additional information gathered and decide whether to make recommendations in relation to the instrument.

36. If members have no points to raise, the Committee should note the instrument (that is, agree that it has no recommendations to make).

37. However, should a motion recommending annulment be lodged later in the 40-day period, it may be necessary for the Committee to consider the instrument again.

The Public Services Reform (Scotland) Act 2010 (Commencement No. 8) Order 2024

38. This instrument has been laid as part of the package of SSIs to be considered, however, is not subject to any parliamentary procedure and included for information purposes only.

39. More information about the instrument is summarised below:

Title of instrument: [The Public Services Reform \(Scotland\) Act 2010 \(Commencement No. 8\) Order 2024](#)

Laid under: [Public Services Reform \(Scotland\) Act 2010](#)

Laid on: 26 April 2024

Procedure: Laid only

Deadline for committee consideration: 3 June 2024

Commencement: 19 June 2024

Purpose of the instrument

40. The Policy Note states that the instrument will commence the provisions which permit HIS to regulate independent medical agencies, which will include wholly online healthcare services based in Scotland.

41. It further states that the purpose of the instrument is to increase public safety and avoid situations where wholly online providers can provide services to patients in Scotland without being regulated.

42. The Policy Note accompanying the instrument is included in Annexe D.

Delegated Powers and Law Reform Committee consideration

43. The DPLR Committee considered the instrument on 7 May 2024 and reported on it in its [32nd Report, 2024](#). The DPLR Committee made no recommendations in relation to the instrument.

**Clerks to the Committee
May 2024**

Annexe A: Scottish Government 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

Annexe B: Scottish Government Policy Note

THE HEALTHCARE IMPROVEMENT SCOTLAND (INSPECTIONS) AMENDMENT REGULATIONS 2024

SSI 2024/XXX

The above instrument was made in exercise of the powers conferred by Section 100 of the National Health Service (Scotland) Act 1978. The instrument is subject to the affirmative procedure.

Summary Box

The purpose of the instrument is to allow inspectors, authorised by HIS under section 10K of the National Health Services (Scotland) Act 1978, to inspect medical records.

Policy Objectives

The instrument will amend regulation 5 of the Healthcare Improvement Scotland (Inspections) Regulations 2011 to allow 'a person authorised by HIS to carry out an inspection under section 10K (authorised persons)' to inspect medical records.

The current list of professions restricts who HIS is able to draw upon to inspect medical records as part of their inspections. Currently, the ability to inspect medical records as part of inspections undertaken by HIS is restricted to medical practitioners, registered nurses, pharmacists, and registered dentists.

EU Alignment Consideration

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

Consultation

No public consultation was required for this instrument.

Impact Assessments

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

Financial Effects

There are no foreseen impact issues and no action is being taken.

Scottish Government

Chief Operating Officer, NHS Scotland Directorate
10 April 2024

Annexe C: Scottish Government Policy Note

THE HEALTHCARE IMPROVEMENT SCOTLAND (FEES) REGULATIONS 2024

SSI 2024/130

The above instrument was made in exercise of the powers conferred by Section 10Z5 of the National Health Service (Scotland) Act 1978. The instrument is subject to the negative procedure.

Summary Box

The purpose of the instrument is to enable HIS, under Section 10Z5 of the National Health Service (Scotland) Act 1978 (“the 1978 Act”), to be able to prescribe the maximum fees which HIS may impose in respect of Independent Medical Agencies “IMAs”; and raise the maximum fees which may be imposed by HIS on all independent healthcare services in respect of applications for registration or cancellation of registration of independent health care services; the annual continuation of any such registration; and applications for the variation or removal of a condition of registration.

Policy Objectives

The instrument will revoke and replace the Healthcare Improvement Scotland (Fees) Regulations 2016 to;

1. prescribe the maximum fees which HIS may impose in respect of Independent Medical Agencies (IMAs);
2. to raise the maximum fees which may be imposed by HIS on all regulated independent health care services in respect of:
 - applications for registration or cancellation of registration
 - annual continuation of any such registration,
 - applications for the variation or removal of a condition of registration.

The fee for issuing a new certificate of registration will remain at £100 and include IMAs.

IMAs are not currently included as a service in which HIS may impose fees in the existing fees regulations. The Healthcare Improvement Scotland (Fees) Regulations 2024, enable HIS to prescribe the maximum fees in relation to IMAs.

In prescribing the maximum fees, HIS will have regard to its reasonable expenses in being able to carry out its functions, as required under section 10Z5(3) of the 1978 Act. It is important for patient safety reasons that healthcare is adequately regulated.

EU Alignment Consideration

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

Consultation

HSCS/S6/24/16/3

To comply with the requirements of section 10Z5(1) of the 1978 Act, a public consultation took place from 16 October 2023 to 11 December 2023.

The consultation contained proposals to allow Healthcare Improvement Scotland (HIS) to increase the maximum fees they can charge independent healthcare providers. The current maximum fees HIS are permitted to charge are as follows:

Service	Application for Registration (£)	Annual Continuation (£)	Variation or Removal of Condition (£)	Cancellation of Registration (£)
Independent Hospital	5,000	250 per place*	100	100
Private Psychiatric Hospital	5,000	250 per place*	100	100
Independent Clinic	3,500	3,500	100	100
Independent Medical Agency	N/A	N/A	N/A	N/A

*per bed

Consideration was given to increasing the fees to the following:

Service	Application for Registration (£)	Annual Continuation (£)	Variation or Removal of Condition (£)	Cancellation of Registration (£)
Independent Hospital	10,000	500 per place*	1000	100
Private Psychiatric Hospital	10,000	500 per place*	1000	100
Independent Clinic	7,000	7,000	1000	100
Independent Medical Agency	7,000	7,000	1000	100

As a result of the consultation the following general themes emerged; the vast majority (83%) of respondents did not agree with the proposed maximum fees that HIS can charge and as a balance between not imposing an undue burden on business and prioritising adequate regulation, we are proceeding with the following reduced maximum fee cap:

Service	Application for Registration (£)	Annual Continuation (£)	Variation or Removal of Condition (£)	Cancellation of Registration (£)
Independent Hospital	7,500	500 per place*	1000	100

Private Psychiatric Hospital	7,500	500 per place*	1000	100
Independent Clinic	5,000	5,000	1000	100

Service	Application for Registration (£)	Annual Continuation (£)	Variation or Removal of Condition (£)	Cancellation of Registration (£)
Independent Medical Agency	5,000	5,000	1000	100

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, which includes responses from the Royal College of General Practitioners – Scotland, the Royal Pharmaceutical Society Scotland, and the Royal College of Surgeons of Edinburgh.

Impact Assessments

A Child Rights and Wellbeing, Equality, Fairer Duty Scotland, and Island Communities impact assessment have been completed on the SSI 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 a rise of business expenses.

Scottish Government
 Chief Operating Officer, NHS Scotland Directorate
 10 April 2024

Annexe D: Scottish Government Policy Note

THE PUBLIC SERVICES REFORM (SCOTLAND) ACT 2010 (COMMENCEMENT NO. 8) ORDER 2024

SSI 2024/131 (C. 11)

The above instrument was made in exercise of the powers conferred by Section 134(7) of the Public Services Reform (Scotland) Act 2010. The instrument is not subject to any procedure.

Summary Box

The purpose of the instrument is to commence HIS functions in the National Health Service (Scotland) Act 1978 in relation to “independent medical agencies” (IMAs).

Policy Objectives

The instrument will commence the provisions which permit HIS to regulate independent medical agencies, which will include wholly online healthcare services based in Scotland. The purpose is to increase public safety and avoid situations where wholly online providers are able to provide services to patients in Scotland without being regulated.

Online healthcare services do not currently fall within regulation by HIS. This is considered to pose a risk to public health and safety.

EU Alignment Consideration

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

Consultation

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 (76%) of respondents agree with the proposed regulation of IMAs, 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, which 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 on the draft SSI 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 expense for all IMAs.

Scottish Government
Chief Operating Officer, NHS Scotland Directorate
April 2024