



Dear Colleague

## PATIENT SAFETY COMMISSIONER FOR SCOTLAND ACT 2023

### Summary

1. This Director's Letter advises Chief Executives that the [Patient Safety Commissioner for Scotland Act 2023](#) ("the 2023 Act"), which received Royal Assent in November 2023 and establishes the new office of Patient Safety Commissioner for Scotland, comes into force on 1 May 2024. Recruitment to the post is being taken forward by the Scottish Parliament.

### Background

2. The [report](#) of the Independent Medicines and Medical Devices Safety Review', led by Baroness Cumberlege, was published in July 2020.

3. The Review followed a number of high profile instances in which patients raised concerns about the safety of medical interventions, and these concerns were not heeded by healthcare professionals, resulting in harm. It examined how the healthcare system in England responds to reports about harmful side effects from medicines and medical devices, and made recommendations on how to respond to concerns more quickly and effectively in the future.

4. Although the report focused on England, the issues it discussed applied to all four nations of the UK, and evidence was taken from some Scottish patients. Therefore, the Scottish Government accepted all of the recommendations in the report and agreed to implement them where this was within devolved competence. This included Recommendation 2:

The appointment of a Patient Safety Commissioner who

**DL (2024) 10**

30 April 2024

---

### Addresses

For action  
Chief Executives

For information  
Chairs of Boards

### Enquiries to:

E-mail: [psc@gov.scot](mailto:psc@gov.scot)

---

would be an independent public leader with a statutory responsibility. The Commissioner would champion the value of listening to patients and promoting users' perspectives in seeking improvements to patient safety around the use of medicines and medical devices.

5. A [Patient Safety Commissioner for England](#) was established by the Medicines and Medical Devices Act 2021. Dr Henrietta Hughes has been in post since September 2022.

### **Powers of the Patient Safety Commissioner for Scotland**

6. The Patient Safety Commissioner will promote the importance of the views of patients and other members of the public in relation to the safety of health care, and to advocate for systemic improvement in the safety of health care. For the purposes of this legislation 'health care' means services provided for or in connection with the prevention, diagnosis or treatment of illness, and includes forensic medical examinations.

7. The Commissioner will be able to hear stories from patients and the public that will inform their work in identifying patterns and trends in systemic patient safety issues..

8. The Commissioner will have powers to require information from all NHS bodies in Scotland, and other health care providers, which is relevant to the Commissioner's work, within a specified timescale ([section 12](#) of the 2023 Act). This may be one-off requests or there may information the Commissioner requests on a regular basis, such as certain types of reports. The Commissioner cannot request information about an individual staff member or patient using this power.

9. The Commissioner will be able to initiate formal investigations into health care safety issues ([section 8](#)). As part of a formal investigation the Commissioner will have powers to require relevant information from any person or organisation, which may include any NHS body or other health care provider in Scotland, within a specified timescale ([section 13](#)). During the course of a formal investigation, the Commissioner can request information about individual staff members and patients where it is relevant.

---

10. Failure or refusal to supply the required information in either case may result in the Commissioner publicising the details of the failure or refusal or reporting the matter to the Court of Session. The Court of Session may make an order for enforcement or treat the matter as contempt of Court, with associated penalties ([section 14](#)).

11. On conclusion of a formal investigation the Commissioner must prepare a report, to include their findings and recommendations. ([section 10](#)). Recommendations may be addressed to specific organisations. Those organisations must respond within a given timeframe, setting out what they have done or propose to do to give effect to the recommendation or, where they do not intend to do anything, their reasons for that. The Commissioner may publish all or part of an organisation's response. Failure to respond to a recommendation can be publicised by the Commissioner ([section 11](#)).

12. The Commissioner will be required to produce and publish a Patient Safety Charter, setting out what the Commissioner expects of health care providers in terms of standards and good practice in relation to patient safety. The Charter may also make provision in relation to the way that health care providers engage with patients and their families. The Commissioner will be obliged to take the expectations set out in the charter into account when considering a health care provider's handling of an incident ([section 6](#)).

13. The Commissioner will be independent of government and the NHS, and will be accountable to the Scottish Parliament.

### **Amendment of the Health and Care (Staffing) (Scotland) Act 2019**

14. The 2023 Act requires that certain information on staffing is copied to the Commissioner. [Section 2\(3\)](#) of the Health and Care (Staffing) (Scotland) Act 2019 ("the 2019 Act") places a duty on every Health Board and NHS National Services Scotland to provide the following information to Scottish Ministers as soon as reasonably practicable at the end of each financial year. The information is:

- (a) the steps they have taken to comply with the requirement to have regard to the guiding principles when they are carrying out the duty to
-

- ensure appropriate staffing; and
- (b) the steps they have taken when planning and securing health care services from third parties to have regard to the guiding principles for health and care staffing and the need for that third party to have appropriate staffing arrangements in place

The 2023 Act requires that this information is also copied to the Commissioner. Contact details for the Commissioner will be provided in due course.

15. Note that this amendment **only** applies to the information reporting duties in section 2(3) of the 2019 Act. However Boards are welcome to send their full report to the Commissioner if this is easier.

**Action**

16. I would be grateful if you could cascade this information as appropriate within your organisation.

Yours sincerely

A handwritten signature in black ink that reads "John Burns". The signature is written in a cursive style with a large, sweeping underline.

JOHN BURNS  
Chief Operating Officer, NHS Scotland

Scottish Government Directorate for the Chief Operating  
Officer, NHS Scotland