# PATIENT SAFETY COMMISSIONER FOR SCOTLAND BILL

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# POLICY MEMORANDUM

## INTRODUCTION

1. As required under Rule 9.3.3 of the Parliament's Standing Orders, this Policy Memorandum is published to accompany the Patient Safety Commissioner for Scotland Bill introduced in the Scottish Parliament on 6 October 2022.

2. The following other accompanying documents are published separately:

- Explanatory Notes (SP Bill 19–EN);
- a Financial Memorandum (SP Bill 19–FM);
- a Delegated Powers Memorandum (SP Bill 19–DPM);
- statements on legislative competence made by the Presiding Officer and the Scottish Government (SP Bill 19–LC).

3. This Policy Memorandum has been prepared by the Scottish Government to set out the Government's policy behind the Bill. It does not form part of the Bill and has not been endorsed by the Parliament.

## POLICY OBJECTIVES OF THE BILL

4. The Independent Medicines and Medical Devices Safety Review ('the Cumberlege Review') was launched by the UK Government following a number of high profile instances where patients were not heeded when they expressed concerns about the safety of their medical treatment, suffering harm as a result. The review found that patients' concerns were often not given due weight by the healthcare system, and were not communicated enough between different parts of the patient safety landscape, resulting in a lack of trend-spotting.

5. The purpose of the Bill is to establish a new Parliamentary Commissioner, the Patient Safety Commissioner for Scotland, independent of the NHS and government, who will:

- promote and improve patient safety by amplifying the patient voice within the patient safety system;
- develop a system-wide view of the healthcare system in Scotland and use it to identify wider safety issues; and

- promote better coordination across the patient safety landscape in Scotland in responding to concerns about safety issues.

6. The Patient Safety Commissioner will work with health care providers and existing organisations which deal with patient feedback and complaints, advocating for patients to be listened to at the right level within the organisation and for communication with patients to be regular and clear. The Commissioner will involve the public in their work, which will require public promotion of their role and how to contact them, as well as ongoing consultation with patients, patient groups and the wider public.

7. The Commissioner's remit will cover all healthcare providers operating in Scotland, including NHS, NHS-contracted and independent healthcare providers. The Commissioner will work collaboratively with other organisations to improve patient safety, adding value to the patient safety system in Scotland rather than duplicating the work of existing organisations.

## BACKGROUND

8. In February 2018, in response to patient campaigns, the UK Secretary of State for Health and Social Care announced an independent review into how the healthcare system in England responds to reports about harmful side effects from the use of medicines and medical devices. This followed a number of instances in which patients raised concerns about the safety of medical interventions which were not heeded by healthcare professionals, resulting in harm.

9. For example, the use of transvaginal mesh to treat pelvic organ prolapse (a condition where organs in the pelvis shift out of position) and stress urinary incontinence was the subject of a lengthy patient-led campaign. This led to research demonstrating that poor outcomes and side effects affected hundreds of mesh patients. Another such case was the use of sodium valproate to treat epilepsy in women capable of childbearing. The drug was approved in 1972 although animal studies showed birth defects in foetuses carried by animals given it. This issue began to be identified in humans in the 1980s and guidance was updated in 1990 and again in the early 2000s. A patients' group began litigation against the manufacturer in 2003. In 2018 the NHS instituted a policy of only prescribing sodium valproate to women capable of childbearing if they were also prescribed highly effective contraception. These cases damaged trust in the healthcare system.

10. The Independent Medicines and Medical Devices Safety Review, led by Baroness Cumberlege, examined how the healthcare system in England responds to reports received from patients of adverse outcomes and side effects caused by medicines and medical devices.

11. In her report, published in July 2020, Baroness Cumberlege noted that patients' concerns were often considered anecdotal and not given due weight. She also observed that trends or repeated reports were not brought together as there is limited communication of safety reports between parts of the patient safety landscape. The report made a number of recommendations, including:

> *'Recommendation 2: The appointment of a Patient Safety Commissioner who 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.'*

12. Although the review focused on England, it also took evidence from Scottish residents and its findings were recognised by healthcare practitioners to apply to all four UK nations. Consequently, the Scottish Government committed to implement its recommendations insofar as they fell into devolved competence.

13. The UK Government has already implemented Baroness Cumberlege's recommendation, using the Medicines and Medical Devices Act to create the office of Commissioner for Patient Safety (for England).

**Current legislation and landscape regarding patient safety and complaints**

*The Scottish Patient Safety Programme*

14. The Scottish Patient Safety Programme (SPSP) was launched in January 2008 and is designed to improve the safety of healthcare. It is co-ordinated nationally by Healthcare Improvement Scotland, who support implementation within NHS Boards through local teams within hospitals, GP practices, mental health inpatient units and community pharmacies. The SPSP includes safety improvement programmes for Acute Adult Care, Maternity and Children, Medicines, Mental Health and Primary Care. Whilst each work-stream focuses on a different part of the healthcare system, improvement areas such as leadership, communication, safety culture and safer use of medicines are key elements of every work-stream.

*Incident Reporting*

15. The NHS Incident Reporting and Investigation Centre (IRIC) is a specialist safety and risk management unit with responsibility for medical devices. IRIC operates a national adverse incident reporting system and a safety alert system. Central to IRIC's functions is its network of liaison contacts known as Incidents and alerts Safety Officers (ISOs). The network covers Scotland's local authorities and health boards and it also has formal links with England's Medical Device Safety Officer (MDSO) network.

*Healthcare Improvement Scotland*

16. Healthcare Improvement Scotland (HIS) has produced a national framework to support healthcare providers effectively manage adverse events. The scope includes all events that could have contributed to, or did result in, harm to people or groups of people. This includes harm to patients and service users, as well as harm to staff. Duty of candour (see paragraph 22) will apply to specific events or incidents that have resulted in death or harm. HIS also manages an Adverse Events Network comprising representatives of all NHS Boards, which allows members to share experiences and develop best practice.

17. HIS carries out regular safe delivery of care acute hospital inspections within NHS settings through observation of care and virtual discussion with teams. Inspections are

unannounced and focus on infection prevention and control; the care of patients; staffing within clinical areas; and the systems and processes that NHS boards have in place to mitigate risks in relation to the delivery of safe care. HIS inspects against the Health and Social Care Standards (2017), Healthcare Associated Infection (HAI) Standards (2015), the HIS Quality of Care Framework (2018), and any other standards that become relevant during the course of the inspection. HIS will identify areas where NHS Boards are required to take action to meet national standards. Findings are published under HIS's Quality of Care Framework domains and quality indicators.

18. HIS also regulates and inspects independent hospitals, voluntary hospices, private psychiatric hospitals and independent clinics in Scotland. This work is informed by the Scottish Government's Health and Social Care Standards and HIS's own Quality Assurance System Quality Framework.

*Professional regulation*

19. Professional regulatory bodies such as the General Medical and Dental Councils can carry out performance or fitness to practice investigations into the behaviour or performance of individual health professionals where a complaint is deemed sufficiently serious. Where there are concerns these bodies will work with the individual's employer, for example the health board or independent healthcare provider. They also tend to have regular engagement with stakeholders, including patients.

*Raising concerns and complaints*

20. There are a number of avenues through which concerns and complaints about patient safety can be raised in Scotland:

- The Patient Rights (Scotland) Act 2011 (PRSA) provides a specific right for people to make complaints, raise concerns, make comments and give feedback on health care. The PRSA also places a duty on NHS Boards to thoroughly investigate and respond to any concerns raised, to take improvement actions where appropriate and to share learning from the views they receive. When a person has concerns about their treatment or care, this should be addressed at a local level through the NHS body which provided their treatment. Where the complainant is not happy with the outcome of this process they may refer their complaint to the Scottish Public Services Ombudsman.
- The PRSA also provides for the establishment of a Patient Advice and Support Service (PASS), to provide independent support and advice to patients and members of the public in relation to health services, including with regard to raising concerns and complaints. Currently the PASS is provided by Citizens Advice Scotland.
- The Scottish Public Services Ombudsman (SPSO) is the final stage for complaints about public services in Scotland, including those relating to the NHS. Where SPSO decides to take on a case it will publish its findings in order to share learning, and can alert the NHS or government to potential safety issues.
- Care Opinion is a not-for-profit social enterprise that provides an online feedback service that enables people in Scotland to give real-time feedback and engage in constructive dialogue with healthcare service providers about the services they, their

families, or the people they care for, have received. Care Opinion is a valuable source of information about what really matters to people about health and care services across Scotland, what they think works well and what could be better. By listening to the stories, staff at all levels can take action to provide the care and support people want. The Scottish Government has supported the roll out of Care Opinion across Scotland since 2013. The current four-year Care Opinion contract began in April 2022. It provides for every territorial health board in Scotland, and relevant special health boards, to be fully registered with the service.

21. The NHS Model Complaints Handling Procedure (MCHP), developed in partnership between SPSO, the Scottish Health Council (SHC) and other NHS bodies, was introduced across Scotland in April 2017, following a recommendation made in SHC's 'Listening and Learning' report. The MCHP brings a much sharper focus to the early local resolution of complaints, wherever that is appropriate, and it is intended to support a more consistently person-centred approach to complaints handling.

22. The organisational duty of candour provisions of the Health (Tobacco, Nicotine etc. & Care)(Scotland) Act 2016 and The Duty of Candour (Scotland) Regulations 2018 came into force on 1 April 2018. This places a legal requirement on all care providers, including NHS, NHS-contracted and independent service providers, to review certain types of adverse events, meet personally with those affected, offer an apology and consider how the learning can be applied. The purpose of the duty of candour provisions is to support the implementation of consistent responses across health and social care providers when there has been an unexpected event or incident that has resulted in death or harm, that is not related to the course of the condition for which the person is receiving care.

23. In 2011 the Scottish Government introduced a model whistleblowing policy for use by the NHS in Scotland, with the aim of encouraging employees to be open and to guarantee that their concerns would be considered.

## KEY PROVISIONS OF THE BILL

### Establishment, governance and accountability

24. The Cumberlege Review considered that "[patient] experience must no longer be considered anecdotal and weighted least in the hierarchy of evidence-based medicine" and that "we … need a new voice, with statutory powers, to talk and act from the perspective of the patient, to encourage the system to do what needs to be done and hold it to account". The Scottish Government's engagement with patients and the wider public (see paragraphs 49-52) showed clear support for an independent commissioner with statutory powers to fulfil the recommendation in the Cumberlege Review.

25. The Bill therefore provides that the Patient Safety Commissioner will be a parliamentary commissioner, to be appointed by His Majesty the King on the nomination of the Parliament and accountable to the Parliament. A parliamentary appointment is also consistent with arrangements for other independent scrutiny bodies. While other models were considered, these were discounted for the reasons set out at paragraphs 47 to 48 below.

26. The Scottish Parliamentary Corporate Body (the SPCB) will take forward the appointment process for the Commissioner. The Commissioner will serve a single term of a maximum of eight years' duration, which is in line with the terms and conditions of other parliamentary commissioners. This flexible approach allows the SPCB to determine at the time of appointment how long the term will last. For example, a relatively long period of appointment may be appropriate for the first Commissioner to allow sufficient time to establish the office and embed its practices. Eight years is a sufficiently long maximum period to give the SPCB the flexibility to ensure that an appointment does not come to an end at a time that the Parliament is in recess or dissolved.

27. It is expected that the SPCB will commence the recruitment process for the Commissioner once the Bill has received Royal Assent. The Commissioner would then appoint their own staff on terms and conditions which will need to be approved by the SPCB.

28. The first Commissioner will produce a set of principles governing their ways of working. The Commissioner can review and revise these principles at any time as the need arises, and must make the latest version of the statement publicly available. It is important to the effectiveness of the role that the Commissioner works co-operatively with other organisations such as health boards, independent providers and inspection and regulatory bodies so that information is shared and improvements can be made across the system, and the principles should reflect this.

29. The Commissioner will need input from specialists. Responses to the public consultation suggested the Commissioner could require support from experts including lawyers, clinicians, analysts, academics, and experts on ethics and equalities. While it will be for the Commissioner to determine the in-house staff they require, they should also be supported by an advisory group, to be established by the first appointed Commissioner. As well as patient representation, the advisory group will allow the Commissioner to obtain specialist and professional guidance that is not able to be provided by their core staff. The membership of the advisory group should consist of 50% patients and representatives of patients. While the advisory group will give the Commissioner advice on matters relating to their work, for example from a clinical, legal, ethical and patient point of view, the Commissioner should also engage with stakeholders, patients and members of the public in other ways, such as through stakeholder workshops and public consultation exercises.

30. The Commissioner will prepare a strategic plan, to be reviewed at least every four years, setting out their objectives and priorities for that period along with the associated estimated costs.

31. The Commissioner will also prepare and publish an annual report on their activities, which will include a summary of their activity in the year the report covers, any issues identified, any investigations carried out and recommendations made. The annual report will be laid before the Parliament. This reporting is in addition to the reports that the Commissioner must prepare and publish following any formal investigations they carry out throughout the year.

32. The Scottish Ministers will pay for the set-up costs and the first year's operating costs incurred by the office of Patient Safety Commissioner for Scotland. Thereafter, the

Commissioner's budget will be provided by Parliament. The ongoing running costs of the Commissioner to the Parliament will be considered as part of the annual Scottish Government budget process. The Commissioner will report on their spend each year within its annual accounts which will be audited by the Auditor General for Scotland.

33. The Scottish Ministers estimate that the Commissioner's post will be full-time and that the staffing complement will be four full-time equivalents. This is based on an analysis of the staffing complements of other parliamentary commissioners and the main duties the Patient Safety Commissioner's office will be expected to perform to carry out their role effectively. However, the staffing complement will be a decision for the Commissioner. The Commissioner's terms and conditions will be determined by the SPCB.

**General purposes**

34. The Patient Safety Commissioner will:

a) advocate for systemic improvements in the safety of health care in Scotland, and
b) promote the importance of the views of patients and other members of the public in relation to the safety of health care.

35. While it will be for the Commissioner to determine how they accomplish their overall purpose, they will play a key role in promoting better co-ordination among different healthcare providers in dealing with safety issues. The Commissioner will engage with healthcare professionals and organisations to amplify the weight given to patient feedback and the experience of patients in considering safety matters. They will promote awareness of existing safety processes and guidelines, both amongst the healthcare professions and with the public. They will bring together information and patient feedback in order to undertake fact finding and horizon scanning to identify wider safety issues, and they will carry out investigations into patient safety concerns.

36. The Commissioner will be able to consider safety issues relating to any healthcare provided in Scotland. This includes NHS, NHS-contracted healthcare delivered by providers like NHS general practitioners and NHS dentists, and wholly independent or private healthcare providers. The Commissioner will also be able to consider safety issues relating to forensic medical services delivered by NHS Health Boards under the Forensic Medical Services (Victims of Sexual Offences) (Scotland) Act 2021.

37. Patients and the general public will be able to raise concerns and relate their experiences directly to the Commissioner. However the Commissioner will not undertake complaints casework or advocacy on behalf of individual patients, their families or carers. Statutory mechanisms are already in place for patients to raise questions, give feedback and make complaints, in particular the NHS Model Complaints Procedure. There are also well-established responsibilities for other bodies to investigate issues relevant to individual complaints and patient safety. The Scottish Public Services Ombudsman (SPSO) can investigate individual complaints and may appoint independent professional advisors to provide specialist advice. There is also an established role for HIS in undertaking inspections of healthcare settings to ensure that they are meeting the required standards of care, that good practice is identified and areas for improvement are addressed. The Scottish Ministers can also instruct HIS to launch thematic investigations into patient safety issues. The Commissioner

will not duplicate any of this work. Instead, the Commissioner will take a macro view of patient safety in Scotland and seek to improve overall safety rather than address individual cases.

38. The Commissioner will be expected to work with other organisations in the healthcare sector, as well as the SPSO, to gather information to support the fact-finding and horizon-scanning activity. It is anticipated that most of this activity will happen on a voluntary basis, but the Commissioner will also have a power to require any healthcare provider in Scotland, whether an NHS body, an NHS-contracted provider or an independent/private provider, to provide the Commissioner with such information through a written request.

39. The Commissioner will be able to carry out their own formal investigations into patient safety-related concerns where they decide there is a need for such an investigation. To support their investigations, they will have additional statutory powers to require information from any organisation (and from individual members of staff depending on the circumstances of the investigation) which the Commissioner deems relevant by use of a written request.

40. In order for the Commissioner's investigatory function to be meaningful, it is important that they have access to the information they require in a full and timely manner. Therefore organisations and staff will be legally required to provide the requested information within a stated period of time. Organisations or staff members who fail to comply with written requests for information described in paragraphs 38 and 39 above can be publicly named or referred by the Commissioner to the Court of Session for consideration as a potential contempt of court.

41. The Commissioner will be required to make reports on the findings of their formal investigations to the Scottish Parliament and will make recommendations to which the organisations concerned are legally required to respond within a set period of time. A response of some form will be required but the content of the response is not restricted in any way. An organisation would not be bound to accept the recommendation or implement it: for example it would be open to an organisation to submit a response disagreeing with the recommendation entirely or setting out the approach they will take towards implementing it as far as they are able. Where an organisation fails to give any response at all, the Commissioner will be able to publicise that failure as they see fit.

42. When carrying out a formal investigation the Commissioner will have the power to require that organisations and persons provide the Commissioner with confidential information which may include identifiable or anonymised patient information. The Commissioner will be required to produce terms of reference for each investigation that justify their decision to require this patient information. The Commissioner's office will be required to handle this information in a way that is compliant with data protection legislation. It will not always be necessary for the Commissioner to have access to patient information to complete their work. Where patient information is required, it may be sufficient for the Commissioner's work for anonymised information to be used.

43. In order to further protect patient identifiable information the Bill will create a new criminal offence of breach of confidentiality of information which is shared with the Commissioner. The offence will apply to the Commissioner, their staff (including agency, contracted staff and staff working for another organisation in a shared office space) and members of their advisory group. It will cover any instance in which someone intentionally,

carelessly or negligently shares confidential information obtained for the purposes of exercising the Commissioner's functions outside the Commissioner's office, with the exception of certain circumstances (where the subject of the information has given their consent, where disclosure is necessary for court proceedings or the investigation of crime, or where it is required to carry out the Commissioner's functions). Anyone found guilty will be subject to a fine not exceeding the statutory maximum of £10,000 when tried by a sheriff or an unlimited fine when tried by a jury.

Forensic Medical Services

44. The Forensic Medical Services (Victims of Sexual Offences) (Scotland) Act 2021 requires all Health Boards to provide "forensic medical services", that is examinations to persons who present to the Health Board after an incident which may constitute a sexual offence. The purpose of this examination is to collect physical evidence which may later be used in a criminal investigation or prosecution. This examination in itself is not "healthcare" because it is not concerned with the prevention, diagnosis or treatment of any medical condition, but the person who undergoes an examination may in the same visit receive healthcare to address any injuries. Forensic medical services are therefore included within the scope of the Commissioner's patient safety responsibilities.

Cosmetic procedures

45. Healthcare is defined in the Bill as "services provided for or in connection with the prevention, diagnosis or treatment of illness", and so while cosmetic procedures which form part of healthcare are included within the Commissioner's remit, purely cosmetic procedures which do not form part of healthcare are not.

46. The SG consulted on the further regulation of non-surgical cosmetic procedures that pierce or penetrate the skin in 2020, and published its response in July 2022. This is a complex area and will require further consideration.

## ALTERNATIVE APPROACHES

47. The policy of the Scottish Ministers is that the number of new public bodies should be kept to a minimum. The Scottish Government considered whether it would be possible to implement Baroness Cumberlege's recommendation without creating a new standalone Commissioner, such as by strengthening existing functions and processes within Healthcare Improvement Scotland and the Scottish Public Services Ombudsman, or by creating a new post within the Scottish Government or the NHS with specific responsibility for monitoring and reviewing patient safety. The main potential advantage of each of these alternatives would be that they would not require primary legislation so they could be accomplished sooner than the creation of a standalone Commissioner, allowing potential improvements to be made sooner. Arguably, these options would also pose less risk of unnecessarily duplicating existing functions and processes than creating a standalone Commissioner.

48. However, after careful consideration, the Scottish Government determined that these options would not fulfil the recommendation for an independent advocate for patients as put forward in the Cumberlege report. A new non-statutory post in government or the NHS would have limited power to enforce change and, importantly, would be unlikely to be perceived by

patients and the public as independent. The public consultation the Scottish Government ran on the role of the Commissioner strongly indicated that the independence of the new office was important to patients and the public. Given that patient trust in the healthcare system was damaged by the high profile patient safety issues examined in the Cumberlege report, patients affected by these issues may also be less likely to engage with a safety body that is part of the NHS or a Scottish Government department. The consultation responses also made it clear that patients and the public want a role that is backed by statutory powers to hold the healthcare system to account and achieve real change. Legislating to create an independent Patient Safety Commissioner with powers established in law emerged as the best option for achieving these things.

## PUBLIC CONSULTATION AND STAKEHOLDER ENGAGEMENT

49. The public consultation on the role of the Patient Safety Commissioner ran from 5 March to 28 May 2021. It received 96 responses: 46 from organisations and 50 from individuals.

50. The Scottish Government published an analysis of the responses, along with all responses that we had permission to publish, on 2 December 2021. 52% of responses came from individuals and 48% from organisations including NHS Boards, health and social care partnerships, professional and professional regulatory bodies and patient representative groups. The key findings from the report were:

- There was strong support for the Patient Safety Commissioner being independent of government and the NHS, slightly more so from organisations than individual respondents;
- There was strong support for the Commissioner being established in legislation, equally from individuals and organisations;
- Around two thirds of individuals and half of those organisations who responded supported the proposition that the Commissioner should initially focus on medicines and medical devices, although there was also broad support for the scope subsequently expanding. A sizeable minority (29%) supported an expanded scope from the start;
- When asked to comment on existing patient safety processes and policies, responses across the board highlighted:
    - there is a lack of awareness of options for feeding back or complaining about the safety of care;
    - many processes for raising concerns and complaints are time-consuming and complex to engage with;
    - processes are not joined up, so patients have to make complaints multiple times to different organisations;
    - patients are dismissed or not believed, and feel that processes for raising complaints and concerns are tokenistic; and
    - patients are not given feedback on actions that are taken in response to complaints.

- When asked about the functions, skills and support a Patient Safety Commissioner should have, responses highlighted:
    - **Functions:** Respondents mentioned the Commissioner should provide a clear route for patients to express concerns and should listen to and act upon the patients' voice as well as ensuring learning and change happens as an outcome of patients raising concerns. Investigating or intervening in the care and treatment of patients (including holding organisations to account, scrutiny, reporting and monitoring) was also seen as important. There was also an emphasis on the Commissioner acting quickly as some of the existing processes are seen as taking a long time; and
    - **Support:** Respondents mentioned the need for an office system to support the role as well as different kinds of expertise, including analytical, communications, IT, professional, clinical, legal, safety, ethics, equalities and human rights experts.

51. The broad status of the role (an office with statutory powers that is independent of government and the NHS, supported by a support structure) received strong support in the consultation. Only one policy aspect that received minority support in the consultation is included in this Bill: a majority (56%) of respondents supported the idea that the Patient Safety Commissioner would focus first on the safety of medicines and medical devices, with the scope of the role expanding subsequently, whereas the current proposal is that the role will immediately be able to consider the safety of all aspects of healthcare. Although the option chosen only received minority support, this was still substantial (29% of responses) and on balance, the Scottish Government has assessed that this is most consistent with creating a Commissioner who can take a truly system-wide view of patient safety issues in Scotland. It will be for the Commissioner themselves to set their initial goals. It is reasonable to anticipate that they will choose particular areas to focus on at different times. The most practical mechanism in legislation to achieve a gradual roll out of the Commissioner's role would be to grant the Scottish Ministers a delegated power to change the Commissioner's role by later regulations. However, given the Commissioner is intended to be independent of government, the Scottish Government assesses that this would be best achieved by allowing the Commissioner to determine the priorities for the role and how it should work, rather than restricting this initially and granting the Scottish Ministers a delegated power to change it at a later date.

52. Further stakeholder engagement has helped to refine proposals:

- In March 2021 the Scottish Government held two stakeholder workshops which were predominantly attended by members of the patient and specialist representative groups that had helped to put together the public consultation paper. The workshops identified some issues around the effectiveness of existing patient safety policies and concerns about the Commissioner's power to make real change;
- In May 2021 People First, the Health and Social Care Alliance and PAMIS (Promoting A More Inclusive Society) ran consultation events on the Scottish Government's behalf to engage with those with lived experience who are considered harder to reach. The outputs from these events largely mirrored those from the Scottish Government's previous engagement with patients and specialists and were fed back into the consultation; and

- In August 2021 the Scottish Government submitted a question to HIS's Citizens Panel on whether the scope of the PSC should be limited to safety in relation to medicines and medical devices only. The outcome re-affirmed feedback from the consultation, with a majority of respondents indicating a preference for an initial focus on medicines and medical devices, but with a substantial minority (47%) of respondents saying the focus should include other aspects of patient safety from the outset.

## EFFECTS ON EQUAL OPPORTUNITIES, HUMAN RIGHTS, ISLAND COMMUNITIES, LOCAL GOVERNMENT, SUSTAINABLE DEVELOPMENT ETC.

### Equal opportunities

53. The policy relates to an area – health – where there are known inequalities associated with a range of factors including socio-economic deprivation, poor health literacy, disability and poor health outcomes that disproportionately affect ethnic minority groups.

54. A combined Equality, Fairer Scotland and Health Inequalities Impact Assessment has been carried out in respect of the proposals contained in the Bill and has been published separately. It found that in general the proposals would have a positive impact on all of the groups covered by these categorisations; certainly there should be no negative impacts as long as the Patient Safety Commissioner takes time to understand the health inequalities experienced by different groups in Scotland, engages proactively with representatives of these groups and makes every effort to be visible and available to members of these groups.

### Human Rights

55. The Bill's provisions are compatible with rights under the European Convention on Human Rights (the Convention) and act to promote certain rights most specifically:

a) article 2 – the right to life, which requires that states have in place adequate regulation and controls to promote high standards in healthcare. The Commissioner will not act to regulate anyone, but will contribute to this right by working to make improvements to patient safety and thereby reducing the risk of patient harm.

b) article 10 – freedom of expression, by providing an independent mechanism for patients, their families and carers to speak candidly about the healthcare experiences. This provides an additional forum not previously available for holding public services to account.

56. The Scottish Government acknowledges that information gathering conducted by the Commissioner will often concern private information and may concern very sensitive personal health information. The privacy of such information is an important element of the article 8 right to private and family life. It is for this reason that the Scottish Government has proposed that the Commissioner should only access health information relating to individuals in the context of formal investigations. The Commissioner will therefore have to satisfy themselves that the seriousness of the issue in question justifies accessing such sensitive information. The Scottish Government anticipates that patients may choose to volunteer health information in their contact with the Commissioner, such that even outwith investigations the Commissioner will have access to a degree of sensitive health information which must be kept confidential. It

is for this reason that the Scottish Government has proposed that it should be a criminal offence for persons working within the office of the Commissioner to share information received by the Commissioner without a lawful reason.

57. Article 12 of the International Covenant on Economic, Social and Cultural Rights provides that all persons have a right to enjoy the highest attainable standard of physical and mental health. The quality of healthcare available is a key element of fulfilling this right (paragraph 12 of General Comment No. 14 of the UN Committee on Economic, Social and Cultural Rights (2000)). The Scottish Government anticipates that, in amplifying the views of patients, the Patient Safety Commissioner will help the healthcare system in Scotland make positive changes in response to patient concerns about safety, thereby improving the overall quality of healthcare available in Scotland.

58. Article 24 of the United Nations Convention on the Rights of the Child and Article 25 of the Convention on the Rights of Persons with Disabilities also recognise this right and commit State Parties to take account of the different health needs of children and persons with disabilities as distinct from the general population. The Scottish Government anticipates that the Patient Safety Commissioner will act as an independent and approachable public advocate for patients to whom children (and their parents) and people with disabilities will be able to bring concerns about patient safety. In amplifying these concerns, the Commissioner will help to make the healthcare system in Scotland more responsive to the different health needs of children and people with disabilities.

**Island communities**

59. The Bill's provisions will apply equally to all parts of Scotland. The Patient Safety Commissioner will have to take account of the healthcare and communication needs of people living in remote, rural and island communities, be visible to them and amplify the voices of patients in those communities as much as those in more populous mainland areas.

**Local authorities**

60. The Bill has no implications for local authorities as they do not provide healthcare services.

**Sustainable development**

61. The potential environmental impact of the Bill has been considered. A pre-screening report confirmed that the Bill has minimal or no impact on the environment and consequently that a full Strategic Environmental Assessment does not need to be undertaken. It is therefore exempt for the purposes of section 7 of the Environmental Assessment (Scotland) Act 2005.

62. The Bill supports the United Nations Sustainable Development Goal 3 (ensure healthy lives and promote wellbeing for all at all ages), and in particular target 3.8 (achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all), by establishing an independent office that will work towards promoting and making improvements in patient safety for all population groups across Scotland.

**CROWN CONSENT**

63. Paragraph 7 of Schedule 3 to the Scotland Act 1998 requires that Crown consent be signified to the Parliament if the same Bill would need such consent were it passed by the UK Parliament. Crown consent is therefore required where a Scottish Bill impacts the Royal prerogative, the hereditary revenues of the Crown or the personal property or interests of the Sovereign. As the Bill is drafted on introduction, it is the Scottish Government's view that it does not require Crown consent.

*This document relates to the Patient Safety Commissioner for Scotland Bill (SP Bill 19) as introduced in the Scottish Parliament on 6 October 2022*

# PATIENT SAFETY COMMISSIONER FOR SCOTLAND BILL

## POLICY MEMORANDUM



Produced and published in Scotland by the Scottish Parliamentary Corporate Body.

All documents are available on the Scottish Parliament website at: www.scottish.parliament.scot/documents