



An Roinn Sláinte  
Department of Health

# Patient Safety Bill 2019

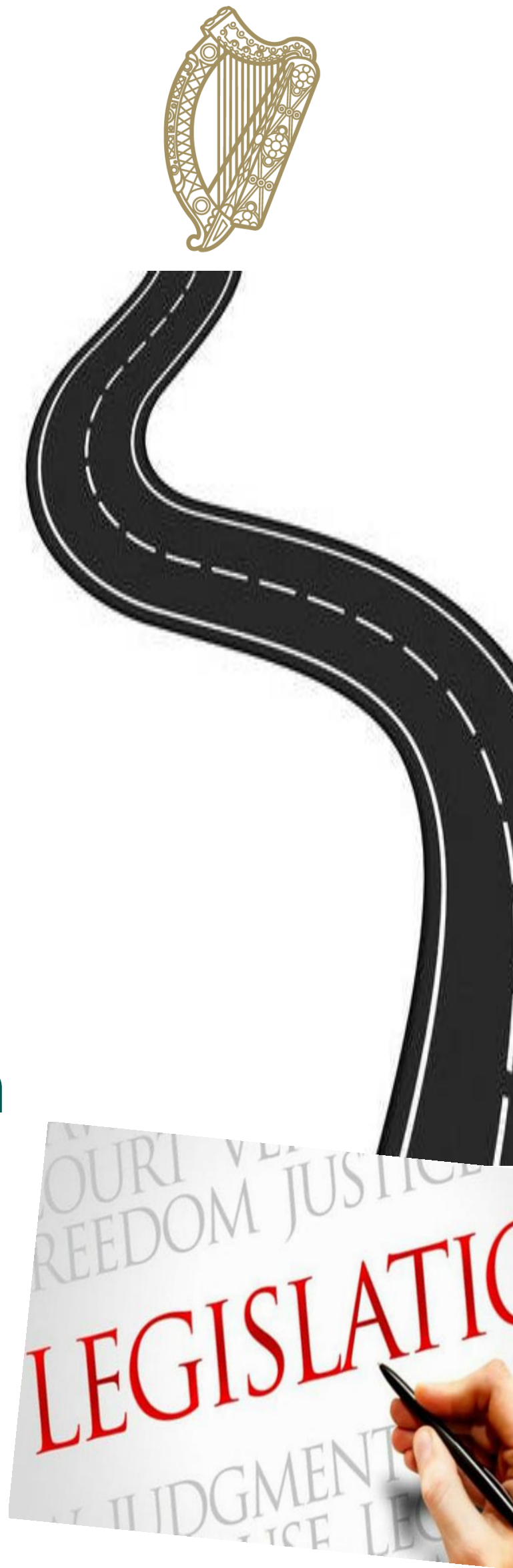
*and related amendments*

## National Patient Safety Office

12<sup>th</sup> May 2021

# Background to Patient Safety Bill

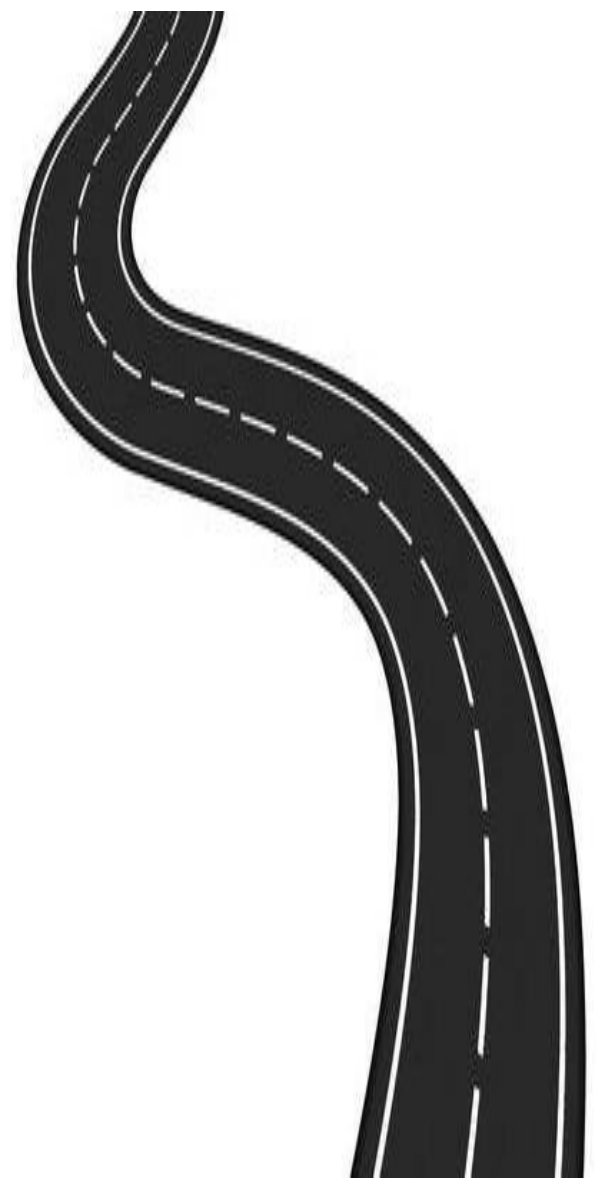
- This Bill forms part of a broader programme of legislative and policy initiatives, including the Civil Liability (Amendment) Act 2017, that seek to embed a culture of open disclosure across the Irish Health Sector.
- The legislation was informed by the Report of the Commission on Patient Safety and Quality Assurance (Madden 2008).
- Draft Heads for voluntary open disclosure and clinical audit were provided for in the General Scheme of the Health Information and Patient Safety Bill (HIPS) November 2015. It was subsequently decided by Government that the provisions for open disclosure should be separated from HIPS and included in the Civil Liability (Amendment ) Act 2017.



# Background ctd.



- The Civil Liability( Amendment ) Act 2017, Part 4 of which provides for voluntary open disclosure, passed all stages in the Dáil and Seanad on 15<sup>th</sup> November 2017 and was signed into law by the President on 22<sup>nd</sup> November 2017
- The Act was formally commenced by the Minister on 22<sup>nd</sup> September 2018 with the accompanying Civil Liability (Amendment) Act 2017 (Prescribed Statements) regulations 2018 Regulations signed on 23<sup>rd</sup> September 2018 .
- It should be noted that during Report Stage of the Dáil on 6<sup>th</sup> Nov 2017, the Minister committed to progress legislation regarding mandatory open disclosure for a defined set or list of serious events.





## **Amendment to align the open disclosure procedural requirements set out in the Civil Liability (Amendment) Act 2017 with the provisions of this Bill**



- Schedule 2 of the Bill contains a number of amendments to Part 4 of the Civil Liability (Amendment) Act 2017 which established the original scheme for open disclosure.
- These amendments ensure that only one prescribed form is now necessary to complete when making an open disclosure.

# The Patient Safety (Notifiable Patient Safety Incidents) Bill 2019



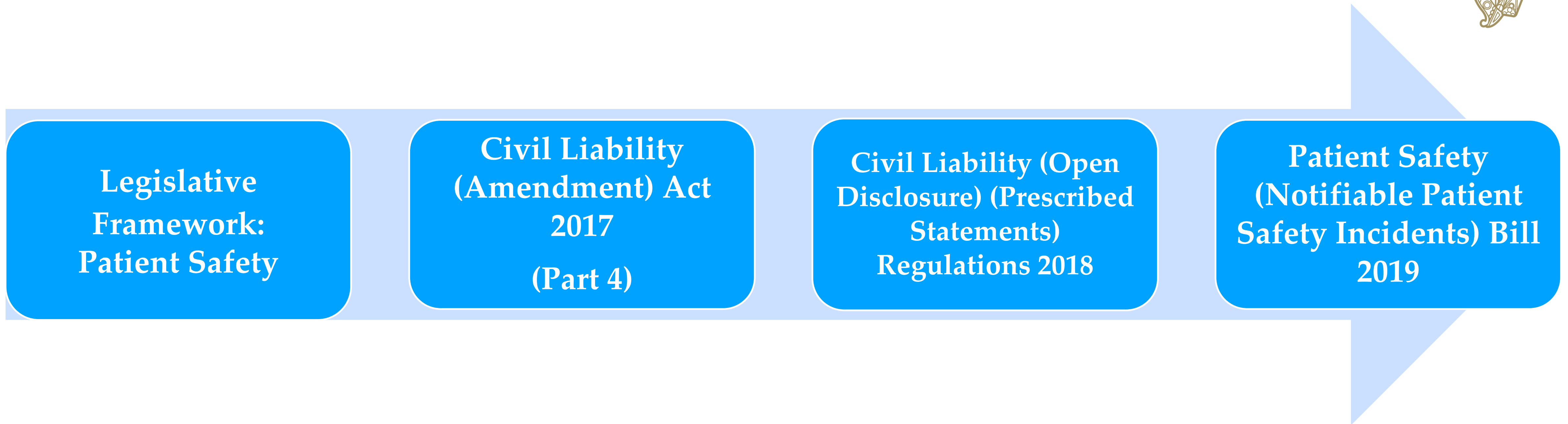
- The Bill introduces a new requirement for mandatory open disclosure of specific patient safety incidents, (referred to as notifiable patient safety incidents). This mandatory open disclosure and external notification of notifiable incidents will equally apply to the public and private health services.
- The Bill includes a schedule containing a list of very serious, primarily death related incidents, that will be subject to mandatory open disclosure and notification, e.g. wrong site surgery, patient death associated with a medication error.
- The Bill also provides the Minister for Health with the power to make regulations setting out additional incidents that will be subject to mandatory notification. Ensures provision for very serious incidents captured in primary legislation while the regulatory power reserved to the Minister provides scope to respond to changes in practice and advances in medical understanding.

# PSB ctd



- The Bill provides for notification of incidents to HIQA, the Chief Inspector of Social Services, the Mental Health Commission and the State Claims Agency.
- The Bill also provides for the extension of HIQA's remit to the private hospital sector.
- The Bill contains provisions supporting the conduct of clinical audit in the health service.
- The Bill provides for offences for failure to comply with the requirements of this legislation: However, these apply to the **health services provider and not individual practitioners.**

# Legislative process to date - Patient Safety (Notifiable Patient Safety Incidents) Bill 2019



- General Scheme of the Bill was approved by Government 5 July 2018 and the Oireachtas Committee on Health pre-legislative scrutiny - 26 September 2018.

# Legislative process to date - Patient Safety (Notifiable Patient Safety Incidents) Bill 2019



- Government Decision 3 December 2019 approved text and authorised the Minister to introduce to Dáil Éireann
- Progressed through first and second stage on 12 December, 2019
- Restored to the Dáil Order paper on 28 July 2020.
- Due to progress to Committee Stage shortly.





## Houses of the Oireachtas Website

- Progress of the Bill can be followed on the Oireachtas website at any point in time:

<https://www.oireachtas.ie/en/bills/bill/2019/100/>

- 11 stages to progress:
  - 5 stages Dáil Éireann
  - 5 stages Seanad Éireann
  - President signs into law
- Commencement timelines for the Bill to be considered

## Amendments arising from first & second stage:



- Amendment connected with Section 9 of the Health Act 2007 (Investigations by HIQA)
- Amendment to expand the provisions of the Bill regarding “openness and transparency”
- Amendment to align the open disclosure procedural requirements set out in the Civil Liability (Amendment) Act 2017 with the provisions of this Bill

# Amendment of Section 9 of the Health Act 2007(Investigations by HIQA)



- Section 9 of the 2007 Act provides the Minister(s) and HIQA with the power to instigate an investigation into a health or social service if they believe on reasonable grounds there is a serious risk to patient safety of users of that service.
- In September 2018 a decision by the Minister for Health to instigate a Section 9 investigation was struck down by the High Court. The Judgement in this case highlighted the need for further clarity on the criteria and grounds upon which such an investigation can be commenced.
- The proposed amendment will provide clarity, giving the Minister and HIQA appropriate powers to address patient safety concerns in Ireland's Health and Social Services.

## Amendment to expand the provisions of the Bill regarding “openness and transparency”



- The Bill provides for a clear obligation on health practitioners to bring the occurrence of a notifiable incident to the attention of the health services provider, making a health services provider aware that a notifiable patient safety incident has occurred.
- The Bill also contains an openness and transparency section which places a duty on health service providers and health practitioners to provide all relevant information in relation to a notifiable patient safety incident to the patient.
- Further amendment is being made to ensure this obligation is reflected in the relevant policies and codes of conduct that operate across Ireland’s Health and Social Services.





- The 3<sup>rd</sup> Amendment aligns the open disclosure procedural requirements set out in the Civil Liability (Amendment) Act 2017 with the provisions of this Bill.
- These draft amendments are currently with the Office of Parliamentary Counsel.



Resource Pack – DoH website - <https://www.gov.ie/en/publication/9e2562-patient-safety-bill/>

