APPLICATION OF BETTER REGULATION PRINCIPLES

Private Health Facilities Amendment (Reportable Incidents) Regulation 2021

Principle 1 - Need for government action
The *Private Health Facilities Amendment (Reportable Incidents) Regulation 2021* (**Amending Regulation**), has been prepared to operationalise amendments to the *Private Health Facilities Act 2007* (the Act) that Parliament passed in 2018 (**the 2018 amendments**).

The 2018 amendments to the Act are due to commence on 1 July 2021. Once commenced, these changes will amend the root cause analysis (**RCA**) provisions in the Act that apply to private health facilities. In particular, the 2018 amendments will:

- require a private health facility to conduct a preliminary risk assessment following a reportable incident,
- allow other types of prescribed reviews, other than an RCA, to be conducted following a reportable incident. These new types of reviews are collectively called a Serious Adverse Event Review; and
- enable the findings and recommendations of the final report to be separated.

Principle 2 - Objective of government action should be clear
The objective of the Amending Regulation is to make three key changes to operationalise the 2018 amendments. The three key amendments made by the Amending Regulation are to:

1. prescribe a Serious Adverse Event Review as a:
    - *NSW Health Concise Incident Analysis* (detailed and defined in the Ministry of Health's Incident Management Policy]
    - *NSW Health Comprehensive Incident Analysis* (detailed and defined in the Ministry of Health's Incident Management Policy)
    - *Systems Analysis of Clinical Incidents: The London Protocol*; published in August 2004 by the Imperial College London
2. set out when information from a preliminary risk assessment can be disclosed; and
3. facilitate notification and information exchange between public and private facilities to assist the other facility to undertake its reportable incident functions.

Principle 3 – The impact of government action should be properly understood by considering the costs and benefits of a range of options including non-regulatory options
There is no non-regulatory option to prescribe the types of review coming under the collective term Serious Adverse Event Review. The Amending Regulation will prescribe the types of review coming within the term Serious Adverse Event Review that are to be conducted following a reportable incident.

Principle 4 - Government action should be effective and proportional
The Amending Regulation is considered effective and proportional. The new types of review that are being prescribed for the purposes of the definition of Serious Adverse Event Review arise out of a detailed research process and thorough stakeholder consultation.

Principle 5 – Consultation with businesses and the community should inform regulatory development
The Clinical Excellence Commission engaged in a detailed research process and stakeholder consultation on the alternate types of Serious Adverse Event Review, prior to applying these types of reviews in public facilities in December 2020. The SAER types being prescribed in the Amending Regulation for private health facilities are consistent with what is

in place in the public system. The Ministry has engaged with private health facilities through development of the Amending Regulation, including via a roundtable in December 2020 and a written consultation process in March-April 2021.

Principle 6 - Simplification or reform of existing regulation
Once made, the Amending Regulation will be incorporated into the *Private Health Facilities Regulation 2017*.

Principle 7 - Periodic review of efficiency and effectiveness
The Amending Regulation will be subject to the normal five-yearly detailed staged review under the *Subordinate Legislation Act 1989*.