Impact Analysis Statement

Summary IAS

Details

Lead department	Queensland Health
Name of the proposal	*Health Legislation Amendment Regulation (No. 2) 2025*
Submission type	Summary IAS
Title of related legislative or regulatory instrument	*Public Health Regulation 2018* *Hospital and Health Boards Regulation 2023* *Medicines and Poisons (Medicines) Regulation 2021* *Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021* *Medicines and Poisons (Pest Management Activities) Regulation 2021.*
Date of issue	November 2025

Proposal type	Details
Minor and machinery in nature	The *Health Legislation Amendment Regulation (No. 2) 2025* (Amendment Regulation) amends the following: • *Public Health Regulation 2018*; • *Hospital and Health Boards Regulation 2023;* • *Medicines and Poisons (Medicines) Regulation 2021* (Medicines Regulation); • *Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021* (Poisons Regulation); and • *Medicines and Poisons (Pest Management Activities) Regulation 2021* (Pest Management Regulation). The amendments enable access to important data that will improve public health outcomes and ensure that Queensland legislation aligns with other States and Territories, removing unnecessary administrative burden for both public and private pathology providers. The amendments also ensure that initial applicants are not required to pay a processing fee for general approvals and prescribing approvals, nor a fee for replacing lost, stolen or damaged hard copy documents evidencing a general approval. The amendments are minor and machinery in nature and are likely to result in no or negligible costs on business or the community. No further regulatory impact analysis is required under the *Queensland Government Better Regulation Policy*. Further detail about the amendments is provided below.

	Public Health Regulation 2018 The Amendment Regulation amends the Public Health Regulation to remove Japanese encephalitis (JE) and Murray Valley encephalitis (MVE) as pathology request notifiable conditions. Under schedule 1 of the Public Health Regulation, JE and MVE are prescribed as both pathology request notifiable conditions and pathological diagnosis notifiable conditions. This means laboratories are required to notify Queensland Health when they receive a request to test for JE and MVE, and on diagnosis. JE and MVE are nationally notifiable diseases under the National Notifiable Diseases List.[1] Only confirmed and probable JE and MVE cases are required to be notified for national reporting purposes. Queensland is the only jurisdiction that prescribes JE and MVE as pathology request notifiable conditions, going beyond the national minimum reporting requirements set by the Communicable Diseases Network Australia and the notification requirements in all other Australian jurisdictions. To reflect contemporary public health practice and align Queensland with national requirements, the Amendment Regulation will amend schedule 1 of the Public Health Regulation to remove JE and MVE as pathology request notifiable conditions. This will reduce administrative burden for both public and private laboratories. The proposal will have no or negligible costs on the community as JE and MVE will remain as pathological diagnosis notifiable conditions that are immediately notifiable on pathological diagnosis, ensuring Queensland Health continues to receive timely and essential data to monitor and understand the disease epidemiology and respond effectively to diagnosed cases and potential outbreaks. ***Hospital and Health Boards Regulation 2023*** The Amendment Regulation amends the Hospital and Health Boards Regulation to update the references to the information sharing agreement between Queensland Health and Services Australia to allow for the identification of women eligible for BreastScreen Queensland's free breast screening service. In 2019, Queensland Health entered into an agreement with the Commonwealth Department of Human Services, now known as Services Australia (2019 Agreement). The 2019 Agreement allows Queensland Health to access Services Australia's Medicare enrolment information for the purposes of identifying women in the target age group and inviting them to participate in the BSQ program. A new agreement has been entered into between Queensland Health and Services Australia (2025 Agreement). The 2025 Agreement must be provided for in the Hospital and Health Boards Regulation to give it effect. The 2025 Agreement will allow for the sharing of additional contact information for eligible women, such as telephone numbers and email addresses. The additional information will enable Queensland Health to contact eligible women via SMS, telephone and email. Recent trials have demonstrated this to be a more effective means of communication for increasing participation in the BSQ program. While the amendment allows for the disclosure of patient information, any privacy concerns are outweighed by the benefits to public health and mitigated by the information only being shared in accordance with legal requirements, including compliance with the *Privacy Act 1988*

	(Cth), *Information Privacy Act 2009* and Information Privacy Principles. ***Medicines and Poisons scheme*** The Amendment Regulation amends the: • Medicines Regulation to clarify that the processing fee for an initial application for a substance authority[2] applies only to licences and has not applied to general and prescribing approvals since the commencement of the regulation on 27 September 2021; • Poisons Regulation to clarify that the processing fee for an initial application for a substance authority and the fee for replacing a lost, stolen, or damaged hard copy document applies only to licences. These fees have not applied to general approvals since the commencement of the regulation on 27 September 2021; and • Pest Management Regulation to make a minor and consequential amendment to ensure consistency in the language used across the medicines and poisons scheme. The Amendment Regulation clarifies that processing fees are only payable for specific initial applications, that is: • a manufacturing licence or wholesale licence for an S2, S3, S4 or S8 medicine; • an S2 retail licence; • a manufacturing licence or wholesale licence for a hazardous poison; and • an S7 retail licence. Additionally, the Amendment Regulation clarifies holders of general approvals are not required to pay a fee for replacement hard copy documents evidencing their approvals. The amendments apply retrospectively to confirm that this interpretation has always been in effect since the commencement of the medicines and poisons regulatory scheme on 27 September 2021. No fees have ever been sought or paid for these types of approvals. The amendment to the Pest Management Regulation is minor and consequential and intended to maintain consistency in language across the regulations. It does not substantively alter the effect of the provision.

Signed

Dr David Rosengren
Director-General, Queensland Health
Date: 11 November 2025

Tim Nicholls MP
Minister for Health and Ambulance Services
Date: 23 NOV 2025

[1] List of nationally notifiable diseases. Accessed here: www.health.gov.au/topics/communicable-diseases/nationally-notifiable-diseases/list.

[2] A substance authority is a manufacturing licence; wholesale licence; retail licence; pest management licence; prescribing approval; or a general approval.