



Medicines and Poisons Bill 2019

Report No. 32, 56th Parliament
State Development, Natural Resources and
Agricultural Industry Development Committee

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State Development, Natural Resources and Agricultural Industry Development Committee

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Abbreviations

AMA Queensland	Australian Medical Association Queensland
DAF	Department of Agriculture and Fisheries
department	Queensland Health/Department of Health
EPA	Extended Practice Authority
ISO	International Organization for Standardization
IT	Information Technology
LSA	<i>Legislative Standards Act 1992</i>
MIGA	Medical Insurance Group Australia
NDE	National Data Exchange
PSA	Pharmaceutical Society of Australia
QBCC	Queensland Building and Construction Commission
QNMU	Queensland Nurses and Midwives' Union
Queensland Health	Queensland Health/Department of Health
Schedule	Commonwealth Standard for the Uniform Scheduling of Medicines and Poisons
SMP	Substance Management Plan
SDRC	Southern Downs Regional Council

Chair's foreword

This report presents a summary of the State Development, Natural Resources and Agricultural Industry Development Committee's examination of the Medicines and Poisons Bill 2019.

The committee's task was to consider the policy to be achieved by the legislation and the application of fundamental legislative principles – that is, to consider whether the Bill has sufficient regard to the rights and liberties of individuals, and to the institution of Parliament.

The Bill establishes a new regulatory framework to modernise and streamline the regulation of medicines and poisons in Queensland. The key concept of the Bill is that any activity performed with a substance must be performed in an authorised way.

On behalf of the committee, I thank those individuals and organisations who made written submissions on the Bill and associated draft regulations and appeared before the committee. I also thank our Parliamentary Service staff and Queensland Health.

I also wish to thank all the members of the committee for their work on this inquiry.

I commend this report to the House.



Chris Whiting MP

Chair

Recommendations

- Recommendation 1** **2**
 The committee recommends the Medicines and Poisons Bill 2019 be passed.
- Recommendation 2** **10**
 The committee recommends that Queensland Health consult further with local governments to clarify the requirements to develop a substance management plan.
- Recommendation 3** **10**
 The committee recommends that in his second reading speech, the Minister for Health report on the development and roll out of Queensland Health’s comprehensive communications strategy, templates and sample substance management plans for different categories of entities, and its ongoing information campaign.
- Recommendation 4** **10**
 The committee recommends that, in his second reading speech, the Minister for Health outline how Queensland Health will ensure oversight and compliance of all made substance management plans.
- Recommendation 5** **11**
 The committee recommends that Queensland Health liaise with peak rural and agriculture industry bodies and regional local governments to run an extensive awareness campaign on the new regulatory approach to pest management and poisons.
- Recommendation 6** **12**
 The committee recommends that Queensland Health liaise with the rural sector, agriculture industry bodies and regional local governments to develop tailored guidance and education material on training and competency requirements to meet the new departmental standards on pest management and poisons.
- Recommendation 7** **12**
 The committee recommends that, in his second reading speech, the Minister for Health outline measures to ensure that the rural sector has sufficient time to comply with new departmental standards in regard to pest management and poison
- Recommendation 8** **17**
 The committee recommends the establishment of real-time prescription monitoring system across all Queensland’s hospitals should be a matter of priority, and the Minister for Health address this in his second reading speech.
- Recommendation 9** **17**
 The committee recommends that, in his second reading speech, the Minister for Health provide an update on cross-jurisdictional data sharing arrangements in relation to a national real-time monitoring prescription database.
- Recommendation 10** **22**
 The committee recommends that, in his second reading speech, the Minister for Health address the need for publication of S7 poisons held on private rural properties in the substance authority register.

1 Introduction

1.1 Role of the committee

The State Development, Natural Resources and Agricultural Industry Development Committee (committee) is a portfolio committee of the Legislative Assembly which commenced on 15 February 2018 under the *Parliament of Queensland Act 2001* and the Standing Rules and Orders of the Legislative Assembly.¹

The committee's areas of portfolio responsibility are:

- State Development, Manufacturing, Infrastructure and Planning
- Natural Resources, Mines and Energy, and
- Agricultural Industry Development and Fisheries.

Section 93(1) of the *Parliament of Queensland Act 2001* provides that a portfolio committee is responsible for examining each bill and item of subordinate legislation in its portfolio areas to consider:

- the policy to be given effect by the legislation
- the application of fundamental legislative principles, and
- for subordinate legislation – its lawfulness.

The Medicines and Poisons Bill 2019 (the Bill), the Draft Medicines and Poisons Regulation (Medicines) 2019 and the Draft Medicines and Poisons Regulation (Pest Management, Poisons and Other Regulated Substances) Regulation 2019 (draft regulations) were introduced into the Legislative Assembly on 14 May 2019. The Bill was referred to the committee on 16 May 2019. The committee was required to report to the Legislative Assembly by 11 July 2019.

1.2 Inquiry process

On 20 May 2019, the committee invited stakeholders and subscribers to make written submissions on the Bill. Twenty-five submissions were received and are listed in Appendix A.

The committee received a public briefing on the Bill from Queensland Health (department) on 27 May 2019. A list of officials is provided at Appendix B.

The committee received written advice from the department in response to matters raised in submissions and supplementary questions from the committee.

The committee held a public hearing on 20 June 2019. A list of witnesses is provided at Appendix C.

The submissions, correspondence from the department and transcripts of the briefing and hearing are available on the committee's webpage.

Submitters commented on the Bill and the draft regulations. Some submissions focussed only on the draft regulations.

While the draft regulations tabled with the Bill are integral to understanding the Medicines and Poisons Bill, the committee's task was to examine and report on the Bill.

Regulations will be made after the Bill is debated, potentially amended, and passed by the Parliament. The final form of the regulations will then be considered by a portfolio committee. It is possible the final regulations may vary from the draft regulations that were tabled to assist in understanding and implementing the intent of the Bill.

¹ *Parliament of Queensland Act 2001*, section 88 and Standing Order 194.

1.3 Government consultation on the Bill

The initial external stakeholder consultation on the new framework took place between 2014 and 2015. Stakeholders from a broad range of industries were consulted through discussion groups and information sessions about the proposed legislative approach.²

The explanatory notes state:

Between September and October 2018, the draft Bill and accompanying Regulations were released on the GetInvolved website for targeted stakeholder feedback, along with a detailed consultation paper and tailored fact sheets. The link to the GetInvolved website was provided to over 400 stakeholders, including relevant peak bodies. Several workshops were held for stakeholders and peak bodies. Stakeholders were invited to either submit their feedback online through the GetInvolved feedback form or via written submission.³

A total of 109 submissions were received in response to the targeted external consultation.⁴

The explanatory notes state that stakeholders were generally supportive of the new framework. In particular, support was expressed for the:

- Bill's intention to streamline and modernise the legislative framework⁵
- new real-time prescription monitoring system
- approved persons provisions
- approach to licences and general approvals.⁶

The QNMU stated:

The current Health (Drugs and Poisons) Regulation is dated, and greater alignment with national regulatory processes is timely. The QNMU believes that, properly considered, this legislation represents the opportunity for Queensland to implement exemplar legislation that can serve as a model for other jurisdictions.⁷

1.4 Should the Bill be passed?

Standing Order 132(1) requires the committee to determine whether or not to recommend that the Bill be passed.

After examination of the Bill, including consideration of the policy objectives to be implemented, stakeholders' views and information provided by the department, the committee recommends that the Bill be passed.

Recommendation 1

The committee recommends the Medicines and Poisons Bill 2019 be passed.

² Explanatory notes, pp 88–91.

³ Explanatory notes, p 89.

⁴ Explanatory notes, p 89.

⁵ For example, see submissions 5, 9, 13, 16, 19, 23.

⁶ Explanatory notes, p 89.

⁷ Mr Prentice, QNMU, Public hearing transcript, Brisbane, 20 June 2019, p 7.

2 Policy objectives of the Bill

2.1 Current regulation of drugs, poisons and fumigants

Medicines and poisons in Queensland are currently regulated by the *Health Act 1937*, Health (Drugs and Poisons) Regulation 1996 and the Health Regulation 1996.

The Health Act is one of the oldest Acts on the statute book, and the current framework is almost entirely contained in subordinate legislation or regulations.

The Health (Drugs and Poisons) Regulation 1996 regulates the possession, supply, administration and other activities related to the medicines and poisons in the Commonwealth *Standard for the Uniform Scheduling of Medicines and Poisons* (the Poisons Standard).

The Health Regulation 1996 provides controls for manufacturing, advertising and labelling substances, and also sets out requirements for dispensing substances at a pharmacy.

In addition, the *Pest Management Act 2001* and the Pest Management Regulation 2003 regulates access to, and the use of poisons, and provides for licensing and competency requirements for people who undertake pest management activities.⁸

2.2 Purpose of the Bill

The Bill will repeal and replace the current legislation with a new regulatory framework, which consists of the:

- Medicines and Poisons Bill 2019
- Therapeutic Goods Bill 2019
- Draft Medicines and Poisons (Medicines) Regulation
- Draft Medicines and Poisons (Pest Management, Poisons and Other Regulated Substances) Regulation
- Draft Therapeutic Goods Regulation.

The explanatory notes state that a new regulatory framework is needed to modernise and streamline the regulation of medicines and poisons, ensuring requirements are easier for industry and the community to understand and apply in practice. Additionally, it is stated that the new regulatory framework will be outcomes-focused and will enhance public safety.⁹

The primary objective of the Bill is to ensure that any activity performed with a substance must be performed in an authorised manner.¹⁰ Dr Young, the Chief Health Officer and Deputy Director-General, Queensland Health advised the committee:

The purposes of the new framework are: to ensure medicines and poisons are made, sold, used and disposed of in an appropriate, effective and safe way; to ensure health risks arising from the use of the substances are appropriately managed; and to ensure persons who are authorised to carry out activities using the substances have the necessary competencies to do so safely.¹¹

The Bill regulates all substances listed as medicines and poisons in the Commonwealth Standard for the Uniform Scheduling of Medicines and Poisons.¹² This standard classifies substances into ‘schedules’

⁸ Explanatory notes, p 1.

⁹ Explanatory notes, p 1.

¹⁰ Dr Young, Queensland Health, Public briefing transcript, Brisbane, 27 May 2019, p 2.

¹¹ Dr Young, Queensland Health, Public briefing transcript, Brisbane, 27 May 2019, pp 1-2.

¹² Poisons Standard June 2019, <https://www.tga.gov.au/publication/poisons-standard-susmp>.

from 'schedule 2' to 'schedule 10' based on risk and the level of regulatory control required. The Bill adopts the classification into schedules in accordance with the Commonwealth poisons standard, which promotes national consistency for stakeholders and industry.¹³

The Bill also regulates pesticides and fumigants registered or permitted for use by the Australian Pesticides and Veterinary Medicines Authority. Under the framework established by the Bill, an individual may undertake a regulated activity with a 'regulated substance' if they hold an authority under the Bill, such as a manufacturing licence, wholesale licence, retail licence, pest management licence, prescribing approval or a general approval. The Bill will authorise a regulation to prescribe classes of general approvals.¹⁴

Dr Young informed the committee that:

... the reach of this regulatory framework is significant. It impacts on manufacturers and wholesalers of regulated substances; licensed retailers of medicines and poisons; trained health professionals with authority to deal with medicines; pest management technicians and primary producers carrying out pest management activities; and landholders authorised to use regulated poisons. While the bill retains many features of the existing framework, the new framework has been modernised and streamlined. Many of the changes are to reduce regulatory costs or burdens and future-proof the legislation so it is more flexible and can better meet the needs of industry, while still appropriately managing public health and safety risks.¹⁵

The explanatory notes outline that the main purposes of the Bill will be achieved by:

- identifying particular activities and substances to be controlled
- authorising classes of persons to use these substances in controlled ways for particular purposes
- providing a scheme to authorise additional activities with the substances under approvals or licences
- requiring persons authorised to use the substances to have the necessary competencies and be accountable for their safe and effective use
- requiring that particular things be done to ensure that the safety, quality and appropriate use and disposal of the substances at all stages, from manufacture to supply to the consumer and final disposal as waste
- providing for compliance with this Act to be monitored and enforced.¹⁶

¹³ Dr Young, Queensland Health, Public briefing transcript, Brisbane, 27 May 2019, p 2.

¹⁴ Dr Young, Queensland Health, Public briefing transcript, Brisbane, 27 May 2019, p 2.

¹⁵ Dr Young, Queensland Health, Public briefing transcript, Brisbane, 27 May 2019, p 3.

¹⁶ Explanatory notes, p 94.

3 Matters raised during the inquiry

This section discusses issues raised during the committee's examination of the Bill.

The committee notes that a large number of the issues raised by stakeholders relate to the draft regulations and therefore are technically outside the committee's consideration of the Bill. However, given that these issues are significant to stakeholders and may have a bearing on the Bill, some of these matters were considered. The key issues raised during the inquiry were in relation to:

- administration of medicines by unregistered healthcare workers
- substance management plans
- departmental standards
- real-time prescription monitoring for particular medicines
- self-prescribing or self-administering high-risk medicines
- requirements for prescribing medicinal cannabis
- licensing and approvals for pest management activities and invasive animal control
- substance authority register
- matters contained in regulations.

3.1 Administration of medicines by unregistered healthcare workers

The Queensland Nurses and Midwives' Union (QNMU) raised concerns in relation to the competence of unregistered aged care workers to administer medicines to frail or cognitively impaired older Australians either through the draft Medicines and Poisons (Medicines) Regulation 2019 or by allowing aged care workers to be treated as carers under the agents and carers provision of the Bill.¹⁷

A significant concern of the QNMU is administration of medicines by unregistered healthcare workers in settings such as aged care and disability services. This is a disturbing trend in residential aged care in particular where the QNMU believes providers are taking advantage of the current ambiguity of the Health (Drugs and Poisons) Regulation to move medication administration away from nurses to unregistered healthcare workers who lack any knowledge of pharmacology and safe medication practice.¹⁸

QNMU argued that the aged care workforce, characterised by the loss of nurses from the sector, and the increase in unregistered care workers involved in medication practices, would result in increased risks in aged care. Mr Prentice from the QNMU informed the committee that:

The consequences of unregistered healthcare workers administering medication can be fatal. In fact, very recently we were made aware of the unexpected death of a woman in a Queensland residential facility shortly after being administered medication by an unregistered healthcare worker. Older Australians deserve the same standard of care, irrespective of where they receive that care. In relation to medication management, we would find it unacceptable for unregistered healthcare workers to administer medications in a hospital setting, so why do we think this is acceptable in the residential setting? The drugs are the same; therefore the risks are the same.¹⁹

¹⁷ Medicines and Poisons Bill 2019, cl 51.

¹⁸ Mr Prentice, QNMU, Public hearing transcript, Brisbane, 20 June 2019, p 7.

¹⁹ Mr Prentice, QNMU, Public hearing transcript, Brisbane, 20 June 2019, p 8.

However, the QNMU supported the supervised role of the aged care workforce, noting that:

... the QNMU believes that unregistered healthcare workers have an essential role in aged care—for example, working under the delegation and supervision of registered nurses. Nursing professional standards identify that unregistered healthcare workers do have a place in assisting cognitively competent people to self-administer their medications.²⁰

In response to QNMU's concerns regarding the competence of unregistered aged care workers to administer scheduled medicines, the department noted that:

The approach taken in the Medicines and Poisons scheme reflects the evolving nature of medication management. Queensland Health data suggests that most, if not all aged care facilities use dose administration aids to assist with medication management and increase resident safety. A person's daily medication can be pre-packed into separate, sealed (tamper-proof) compartments for the times medication is due. The dose administration aid pack is usually prepared by a pharmacist and is labelled with the details of the resident. A photograph of the resident can be included to further ensure the right person is receiving their medication.²¹

Additionally, the department noted:

Queensland Health considers that adopting QNMU's suggested changes would prevent existing members of the aged care workforce from providing any form of medication administration in an aged care facility. This would impact on the aged care sector significantly and would conflict with previous consultation drafts distributed to stakeholders, including the aged care sector.²²

The QNMU also raised concerns in regard to clause 51 of the Bill. The explanatory notes state that:

Clause 51 (Agents and carers) provides that a person does not commit an offence against the Act if they supply a medicine by giving to it [sic] a patient, if the medicine has been lawfully supplied for the therapeutic treatment of the patient; for lawfully helping a patient, administer a medicine in accordance with the approved label of the medicine; or administer a medicine to an animal in accordance with the approved label of the medicine. This provision ensures that carers, for example, a child's parent, can administer a medicine without breaching an offence under the Act.²³

QNMU argued that:

... the original intent of section 51, when considering the examples in the section, was to distinguish agents and carers from the aged care workers in the previous draft of the regulation.²⁴

In contrast to QNMU, Anglicare Southern Queensland argued that given workforce shortages in the aged care sector, legislation should not limit the ability to adopt new models of care. Consequently, Anglicare Southern Queensland argued the need to ensure that aged care workers be covered in clause 51 exemptions and not prescribed under regulation.²⁵

In response to the QNMU's concerns regarding clause 51 of the Bill, the department stated:

A change to clause 51 of the Bill to only apply to unpaid carers, as suggested by the QNMU, would have broad and very serious implications beyond residential aged care facilities. It would prevent the administration of medication in other sectors, extending to people with disabilities,

²⁰ Mr Prentice, QNMU, Public hearing transcript, Brisbane, 20 June 2019, p 7.

²¹ Queensland Health, response to submissions, correspondence dated 12 June 2018, pp 2-3.

²² Queensland Health, response to submissions, correspondence dated 12 June 2018, p 2.

²³ Explanatory notes, p 81.

²⁴ QNMU submission 6, p 13.

²⁵ Anglicare Southern Queensland, submission 7, p 1.

*NDIS recipients, users of respite care, and the elderly who remain in their own home and receive aged care services at home through Commonwealth funding.*²⁶

Committee comment

The committee notes the multifariousness of the new regulatory framework and the comments made by Mr Prentice from the QNMU:

*I would also like to take the opportunity to thank Queensland Health and in particular the Office of the Chief Nursing and Midwifery Officer for their ongoing consultation and efforts to address the QNMU's concerns regarding this bill. We appreciate the opportunity to provide detailed feedback and look forward to ongoing collaboration to resolve these issues.*²⁷

The committee is satisfied that the department has, and will continue to, consult extensively.²⁸

3.2 Substance management plans

The Bill repeals prescriptive requirements contained in the Health (Drugs and Poisons) Regulation 1996 and introduces a new requirement for certain substance authority holders to develop a substance management plan (SMP).²⁹ The SMP is intended to assist substance authority holders to consider and manage known and foreseeable risks specific to regulated activities with regulated substances. The explanatory notes state:

*The requirement for a substance management plan supports a risk-management system for regulated substances that is dynamic and proportionate to the risk. The scheme will be outcomes-focused and set minimum risk management, accountability and governance criteria that must be met by certain entities in their dealings with regulated substances.*³⁰

The draft regulations require the following individuals or entities to have an SMP:

- holders of a manufacturing licence
- holders of a wholesaling licence
- holders of a prohibited substance general approval (if required as a condition of the approval)
- residential aged care facilities
- community pharmacies
- schools
- hospitals.³¹

The SMP must include measures for the:

- packaging, labelling, handling, storage, security, custody and transportation requirements of regulated substances
- competency, training and supervision requirements of staff
- maintenance and reconciliation processes for purchasing regulated substances and the disposal mechanisms of the substances.³²

²⁶ Queensland Health, response to submissions, correspondence dated 12 June 2018, pp 2-3.

²⁷ Mr Prentice, QNMU, Public hearing transcript, Brisbane, 20 June 2019, p 7.

²⁸ Explanatory notes, 91.

²⁹ Explanatory notes, p 10, clause 92.

³⁰ Explanatory notes, p 10.

³¹ Explanatory notes, p 10.

³² Explanatory notes, p 11.

The explanatory notes state that requirements for substance management plans will be outlined by regulation and included in the relevant departmental standard relating to SMPs.³³ Entities will have one year after the Bill commences to comply with the SMP requirements. Queensland Health proposes to roll out a comprehensive communications strategy during implementation, including templates and sample SMPs.³⁴

A number of submissions raised concerns in regard to SMPs and the associated draft regulations.³⁵

3.2.1 Management of poisons

Southern Downs Regional Council (SDRC) did not support the requirement for local governments to have an SMP as it was argued that pest management poisons are already regulated under the *Biosecurity Act 2014*. The requirement to hold an SMP could duplicate current regulatory requirements for local governments.³⁶ SDRC stated:

*Section 68 of the Bill states that a regulation may prescribe general approvals. It is therefore not apparent whether Councils will be required to prepare a substance management plan for the storage, provision, handling etc. of 1080 for invasive animal control. Council is of the view there is no benefit to SDRC in changing current arrangements in favour of a substance management plan approach. It would add to Council's administrative burden and risk exposure. Local government officers are currently authorised by the Department of Agriculture and Fisheries (DAF) under the Biosecurity Act 2014 and receive training by DAF in order to become authorised.*³⁷

In response, the department indicated that the requirement for local governments to have an SMP would be based on a number of factors:

*A substance management plan is a tool for local governments to demonstrate that they have appropriate governance and measures in place to protect public health from hazardous poisons used for invasive animal control. Based on the range of regulated activities, the size of the local government and governance arrangements, Queensland Health will consider whether the local government requires a substance management plan.*³⁸

3.2.2 Oversight and enforcement

The QNMU highlighted several concerns in regard to the use of SMPs as a core regulatory mechanism within the legislation.³⁹ The QNMU also expressed concern at the co-regulation nature of SMPs, specifically:

- the SMP document is not required to be lodged with any authorised external body
- there is no apparent oversight or quality control of the document
- there is no apparent enforcement mechanism or agency identified to audit facilities or ensure compliance, although there are penalties for non-compliance
- that it is necessary to ensure the department charged with this role is adequately staffed and resourced.⁴⁰

³³ Explanatory notes, p 11.

³⁴ Explanatory notes, p 11.

³⁵ See submissions 3, 6, 10, 16.

³⁶ Southern Downs Regional Council, submission 3, p 1.

³⁷ Southern Downs Regional Council, submission 3, p 1.

³⁸ Queensland Health, response to submissions, correspondence dated 12 June 2018, p 14.

³⁹ QNMU, submission 6.

⁴⁰ QNMU, submission 6.

Mr Prentice from the QNMU informed the committee:

... if we introduce a new mechanism within a regulatory framework, it has to be robust and of a reasonable standard. It does not really do very much good if it is only something that is consulted after, for example, some medication related incident. It does not seem to be a very proactive approach if it does not see the light of day. We think that for this to be adopted a much more proactive approach to the development and oversight of those documents would be appropriate and some kind of auditing mechanism would be warranted, as we do with all other kinds of plans like that, and the regulator having sufficient capacity in terms of resources to undertake that oversight role. I guess a bit of a concern is that, in other areas like financial services and, as you pointed out, aged care, what we have seen is oftentimes the regulators lack the capacity to regulate the patch over which their purview extends.⁴¹

The QNMU suggested that the department:

- *Provide an example or guidance on what constitutes a 'reasonable excuse' for noncompliance*
- *Identify the authorised external document for lodging the SMP*
- *Identify the authority that oversees quality control of SMPs*
- *Identify the enforcement mechanism and responsible agency for non-compliance*
- *SMPs should be piloted in a health service or facility prior to any state wide implementation under this legislation.⁴²*

The department responded to these concerns stating that:

The substance management plan is designed to be a co-regulatory tool that allows an entity to develop a plan that addresses the entity's unique risks around regulated dealings with regulated substances.

Under clause 93 of the Bill, a substance management plan will be required to address the matters prescribed by regulation and be written in a way that can be easily understood by staff. Under clause 109 of the draft Medicines Regulation, the matters to be addressed in a substance management plan will be set out in the Departmental Standard. In addition, Queensland Health will prepare template documents to assist entities to prepare their substance management plans.

Queensland Health will be responsible for oversight and enforcement of matters relating to substance management plans. Clauses 93 and 94 of the Bill contain offences for substance management plans to promote compliance and will be enforced by Queensland Health.⁴³

Dr Young added that many entities already have management plans in place as part of accreditation processes, such as hospital accreditation, Australian Council of Healthcare Standards or ISO accreditation:

... they are already part of accreditation processes and they would be expected to have them. In other cases we would monitor them when we are doing compliance assessments for other purposes, so we would ask to see them. Of course, if there were any complaints or any concerns we would ask to see them. Usually with these sorts of things we ask for a random sample so that we can keep a close eye on what is happening. We would not necessarily go and ask for every single plan to come to the department once a year or something like that. We would work

⁴¹ Mr Prentice, QNMU, Public hearing transcript, Brisbane, 20 June 2019, pp 9-10.

⁴² QNMU, submission 6, p 4.

⁴³ Queensland Health, response to submissions, correspondence dated 12 June 2018, p 14.

*through what is a reasonable amount to look at, to make sure that we are comfortable that industry overall has them in place.*⁴⁴

Committee comment

The health sector is the predominant stakeholder in the Bill and draft regulations, but the rural and agriculture sector will be impacted by this new regulatory framework, as well as local governments with a large agricultural constituency. The committee found that clarity should be provided to local governments regarding the impacts of an SMP.

Recommendation 2

The committee recommends that Queensland Health consult further with local governments to clarify the requirements to develop a substance management plan.

The committee found there to be uncertainty in the rural and agricultural sector around the requirement to develop SMPs. The committee acknowledges that:

*Queensland Health proposes to roll out a comprehensive communications strategy during implementation, including templates and sample substance management plans for different categories of entities, and ongoing information will be available to stakeholders. Stakeholders will also be advised that existing policies, procedures and accreditation documentation may form part, or all of their plan, thereby minimising any resource impacts.*⁴⁵

Recommendation 3

The committee recommends that in his second reading speech, the Minister for Health report on the development and roll out of Queensland Health's comprehensive communications strategy, templates and sample substance management plans for different categories of entities, and its ongoing information campaign.

The committee has heard concerns that the development of SMPs may become an administrative exercise and that the risk management measures set out in these documents may not be proactively followed without appropriate oversight and enforcement. The committee is seeking assurances in regard to Queensland Health's⁴⁶ ability to proactively maintain the necessary oversight and enforcement of substance management plans.⁴⁷

Recommendation 4

The committee recommends that, in his second reading speech, the Minister for Health outline how Queensland Health will ensure oversight and compliance of all made substance management plans.

3.3 Departmental standards

Clause 233 permits the chief executive to make a departmental standard about carrying out a regulated activity with a regulated substance and other matters relating to the purposes and administration of this Act.

Matters which may be dealt with under a departmental standard include, but are not limited to:

- procedures for carrying out regulated activities (for example, a standard stating how to prepare and lay baits for the control of wild dogs or a standard about prescribing or supplying monitored medicines)

⁴⁴ Dr Young, Queensland Health, Public hearing transcript, Brisbane, 20 June 2019, p 38.

⁴⁵ Explanatory notes, p 11.

⁴⁶ Mr Shepherd, QNMU, Public hearing transcript, Brisbane, 20 June 2019, p 10.

⁴⁷ Queensland Health, response to submissions, correspondence dated 12 June 2018, p 14.

- procedures for keeping, storing and managing regulated substances
- training and competency requirements for persons carrying out regulated activities with regulated substances
- procedures to ensure products containing regulated substances are safe and suitable for the intended use of the products
- requirements for tracing the movement of regulated substances from manufacture to final disposal, including requirements about documentation and electronic transactions.⁴⁸

Concerns were raised regarding the training and competency requirements to meet departmental standards and the impact this could have on land owners, land managers and rural businesses. In particular, concerns related to:

- the cost of training
- accessing training in rural and remote areas
- the high percentage of older individuals needing to meet competency training requirements
- the burden of additional paperwork
- the necessary levels of literacy and IT skills required to meet competency training requirements.⁴⁹

Ms Vitelli from AgForce highlighted the need for awareness campaigns and adequate time to allow individuals and industry in the rural sector to complete the necessary competency training:

Under the proposed regulations and standards, users will require those two levels of competency. Like everything, everyone is busy. Everyone needs to access the training. The registered training organisations—the ones that do good delivery—are out there, but they are going to be inundated... We need time because it is a new requirement. It is a bit like when they brought in the chainsaw licensing requirements... It took a long time for people to do that competency. Please give us time. There has to be awareness. A lot of rural people do not even know about the proposed changes.⁵⁰

Committee comment

The committee notes that Queensland Health have undertaken to conduct engagement and communication activities to assist with implementation prior to commencement of the new standard.⁵¹ The committee considers that it is important that the department conduct an extensive awareness campaign with the rural and agricultural sector and develop tailored guidance and education material on training and competency requirements to meet departmental standards for that sector.

Recommendation 5

The committee recommends that Queensland Health liaise with peak rural and agriculture industry bodies and regional local governments to run an extensive awareness campaign on the new regulatory approach to pest management and poisons.

⁴⁸ Explanatory notes, pp 164-165.

⁴⁹ Ms Vitelli, AgForce, Public hearing transcript, Brisbane, 20 June 2019.

⁵⁰ Ms Vitelli, AgForce, Public hearing transcript, Brisbane, 20 June 2019, p 30.

⁵¹ Queensland Health, response to supplementary questions on the Bill, correspondence dated 12 June 2018, p 5.

Recommendation 6

The committee recommends that Queensland Health liaise with the rural sector, agriculture industry bodies and regional local governments to develop tailored guidance and education material on training and competency requirements to meet the new departmental standards on pest management and poisons.

Given the additional challenges faced by some sections of the rural sector in undertaking training, there is a clear requirement to ensure that sufficient time is allowed to meet the training and competency requirements of the developed departmental standards in regard to pest management and poisons.

Recommendation 7

The committee recommends that, in his second reading speech, the Minister for Health outline measures to ensure that the rural sector has sufficient time to comply with new departmental standards in regard to pest management and poisons.

3.4 Real-time prescription monitoring

The Medicines and Poisons Bill provides a head of power for the establishment of a real-time prescription monitoring scheme to essentially align with other jurisdictions and to meet Queensland's obligations under the national agreement to manage the use of dependence-forming medicines.⁵² The scheme will include all S8 medicines and some high-risk S4 medicines, such as Valium, Codeine and Stilnox.⁵³

The Bill requires that before prescribing or supplying a monitored medicine, prescribers will be required to check the monitored medicines database to establish if the person has previously been prescribed or supplied a monitored medicine.⁵⁴ Dr Young outlined the need for a real-time prescription monitoring system to manage the use of dependence-forming medicines:

Misuse of pharmaceutical opioids is an increasing concern for our community. Unlike illicit opioid drugs, access to pharmaceutical opioids is enabled by the writing of a prescription. In Australia, there is considerable evidence of the widespread misuse of prescription opioids. Levels of prescription opioid overdose, including accidental overdose, are at record levels in Australia and internationally.

In Queensland we are seeing an increase in cases of prescription opioid related overdoses and deaths, an increase in people on treatment programs, increased referrals to alcohol and drug treatment services, and more evidence of these drugs entering into illicit markets.⁵⁵

Dr Kidd, Chair of the Australian Medical Association (AMA) Queensland Council of General Practice told the committee that 'every day four Australians die from overdose and the majority of those are from prescription medicines, particularly opioids and benzodiazepines'.⁵⁶

The existing prescription monitoring system in Queensland requires pharmacies to report the dispensing of S8 medicines to Queensland Health every seven days. Given the time taken to manually

⁵² The April 2018 Council of Australian Governments (COAG), Health Council meeting, agreed to support the implementation of a national real-time prescription medicines reporting solution; Explanatory notes, p 7.

⁵³ Dr Young, Queensland Health, Public briefing transcript, Brisbane, 27 May 2019, p 4

⁵⁴ Explanatory notes, pp 7-8.

⁵⁵ Dr Young, Queensland Health, Public briefing transcript, Brisbane, 27 May 2019, p 4.

⁵⁶ Dr Kidd, AMA Queensland Council of General Practice, Public hearing transcript, Brisbane, 20 June 2019, p 2.

record and compile the information by Queensland Health, the information is generally up to 14 days out of date.⁵⁷ Doctor Young noted:

*During that 14-day period there is the opportunity for individual patients to seek large amounts of different drugs from different doctors who would not know that they have already sought the medications from somewhere else. If they go to different pharmacies, pharmacies would not know that the person has already obtained various scripts. We have unfortunately had a number of deaths that have gone to the coroner and we have seen exactly that happen.*⁵⁸

Dr Kidd, provided a recent example of 'doctor shopping' to the committee:

A lady presented fairly late on a Friday afternoon, which is kind of a red-flag time, with a letter that looked to me to be a forgery from Victoria. She was seeking some opioids and benzodiazepines. She had conditions that were on the letter that would be appropriate for that sort of medication but the letter ... had a number of things that were inconsistent.

*I checked with Queensland's medicines regulatory unit, or DDU as it used to be known. They had no record of her as she had just recently arrived in the state. She had very cleverly changed her date of birth, which made her invisible to the system. I had such a strong suspicion that I called the Victorian equivalent organisation, and because of the change of the date of birth initially they did not have a record either. I was still very suspicious so I tried to call the doctor and the doctor was not available. Then I got onto someone else in Victoria and started to put together that, in fact, she was a doctor shopper. By the time I had done all of this and informed the medicines regulatory unit in Queensland, I had lost an hour and a half. If I had real-time prescription monitoring it would have taken 30 seconds.*⁵⁹

While real-time prescription monitoring was supported by stakeholders,⁶⁰ some stakeholders highlighted potential issues with the roll-out of the system.⁶¹

3.4.1 Clinical workflow of prescribers and pharmacists

Concerns were raised regarding the possible impacts on the clinical workflow of prescribers and pharmacists. The AMA Queensland highlighted the need to ensure that the proposed system integrates with current IT systems used by doctors and pharmacists:

*... if we have technological systems that seamlessly integrate with the software of the doctors and the pharmacists then this will become a workable system. If it is a system that involves doctors and pharmacists having to go out of their own software and do some sort of double log-in process at some other website every single time they need to check a new patient, it is going to add significantly to the workload and expense and is going to greatly reduce the efficiency of primary care and delivering the excellent services that we provide to date.*⁶²

Similarly, Dr Willett, Chair, Royal Australian College of General Practitioners Queensland argued:

... it is necessary that the real-time prescription monitoring system becomes implemented into the software prescribing systems. We would not like to see it become compulsory until at least 95 per cent of medical software is compliant with the system. That is purely from a usability point

⁵⁷ Explanatory notes, p 7.

⁵⁸ Dr Young, Queensland Health, Public briefing transcript, Brisbane, 27 May 2019, p 6.

⁵⁹ Dr Kidd, AMA Queensland Council of General Practice, Public hearing transcript, Brisbane, 20 June 2019, p 3.

⁶⁰ See submissions 8, 9, 16, 18 and 19.

⁶¹ See submissions 8, 9, 16, and 18.

⁶² Dr Kidd, AMA Queensland Council of General Practice, Public hearing transcript, Brisbane, 20 June 2019, p 3.

*of view. Any other web based system will require such security that it would be unwieldy and too difficult to use during a consultation unless it is built into the software that we are using.*⁶³

Dr Ifediora from the Royal Australian College of General Practitioners Queensland told the committee:

*What this system does is compel doctors to look. What we are asking for ... is to make it appear similar so that we do not have to be burdened with having to check this thing. It will come up automatically on the screen because it is built into the system.*⁶⁴

The department acknowledged the high demands on the time of prescribers and pharmacists during their clinical interactions with patients and confirmed that:

*Work will be undertaken to identify ways of minimising impact on workflow, including integration with existing practice and pharmacy software and access via mobile app.*⁶⁵

Dr Kidd proposed that software developers could be incentivised to produce a product that would work with current general practice IT systems:

*A recent example of that is My Health Record. That is an Australian government development and now all of the software providers, including a lot of the hospital software computer providers—and, for that matter, the software that goes into pharmacies, which is a different group again—talk with My Health Record in a fairly seamless way. It would be the same kind of process as the one we used to get My Health Record working seamlessly. We should be able to get this system working seamlessly, but it would probably take some incentivising.*⁶⁶

3.4.2 Education and training

The importance of providing comprehensive education and training on the use of the database and additional or associated responsibilities was also raised during the inquiry.⁶⁷

The department stated that education will be delivered before the commencement of the relevant provision, to ensure practitioners are upskilled and supported in the use of the system and their legislative obligations prior to the system becoming mandatory.⁶⁸ The department confirmed that it is currently developing a comprehensive education and communication strategy to ensure:

- *all stakeholders will be well-informed about the database and how to use it; and*
- *users of the database will have access to sufficient educational opportunities and resources to enable them to efficiently navigate the database, understand the information being displayed and work within the new medicines and poisons regulatory framework with confidence.*

Education and training will cover a wide range of topics and be delivered multi-modally (for example including online and face-to-face delivery), covering issues such as:

- *clinicians' obligations under the new legislation;*
- *how to safely prescribe and dispense monitored medicines;*

⁶³ Dr Willett, Royal Australian College of General Practitioners Queensland, Public hearing transcript, Brisbane, 20 June 2019, p 12.

⁶⁴ Dr Ifediora, Royal Australian College of General Practitioners Queensland, Public hearing transcript, Brisbane, 20 June 2019, p 14.

⁶⁵ Queensland Health, response to submissions, correspondence dated 12 June 2018, p 11.

⁶⁶ Dr Kidd, AMA Queensland Council of General Practice, Public hearing transcript, Brisbane, 20 June 2019, p 6.

⁶⁷ See submissions 8, 9, 16, and 18.

⁶⁸ Queensland Health, response to submissions, correspondence dated 12 June 2018, p 9.

- *management of difficult situations and drug-seeking patients.*

*Online resources will be developed and made available for health practitioners to access. Further consideration will be given to how to facilitate easy access to training materials so that it is available when and where most relevant.*⁶⁹

3.4.3 Cross-jurisdictional data sharing

A significant concern in regard to the establishment and operation of the real-time monitoring prescription database was that of cross-jurisdictional information sharing.

The explanatory notes state that the Queensland database will leverage off the national solution being developed by the Commonwealth, the National Data Exchange (NDE). The NDE will capture the prescription dispensing event data from all states and territories. Under this arrangement, Queensland will have access to its own data and the data of other States only upon agreement with the respective jurisdiction.⁷⁰ Dr Young clarified:

*Each state is rolling out their own version, but the Commonwealth is setting up a process that all scripts throughout the country come into one place and then each database accesses that, but they can only access their state's scripts.*⁷¹

The committee was informed of the difficulties in regard to cross-jurisdictional information sharing:

*At this point in time, it has been slowly rolled out in a couple of states. There is a concern at the moment, given our close border with New South Wales. New South Wales at this time have not publicly announced whether or not they are going with real-time reporting. We will need to work closely with them on what happens going forward as to whether we can see scripts of people who reside particularly in northern New South Wales if they come across the border, because there is a lot of movement of people on the Gold Coast. There is some work there that we are doing but we are working quite closely at the national level. We expect that our real-time monitoring system will be in place towards the end of 2020.*⁷²

Dr Kidd highlighted that currently the hard borders in terms of data sharing is problematic but Queensland's substances steering committee is currently examining this issue.

*I know that on the Gold Coast it is a real problem with people who jump back and forth across the border. At the moment the systems do not speak to each other. A doctor who is concerned would have to phone New South Wales as well as Queensland and try to put a picture together. The other thing that the AMA federally is really wanting is a nationally integrated system so that we can see what this person is doing across different states.*⁷³

3.4.4 Hospital issued prescriptions

The committee heard evidence about the necessity for prescriptions generated outside of primary care to be captured in the proposed real-time prescription monitoring system. This requirement was felt to be critical as emergency departments and hospitals are increasingly prescribing monitored substances. Dr Kidd informed the committee:

... we feel it is very important that the real-time prescription monitoring and the framework of prescribing monitored substances around that applies to all prescriptions that are going into the community... While many prescriptions are generated in primary care, I would suggest possibly

⁶⁹ Queensland Health, response to submissions, correspondence dated 12 June 2018, p 10.

⁷⁰ Explanatory notes, p 8.

⁷¹ Dr Young, Queensland Health, Public briefing transcript, Brisbane, 27 May 2019, p 11.

⁷² Dr Young, Queensland Health, Public briefing transcript, Brisbane, 27 May 2019, p 8.

⁷³ Dr Kidd, AMA Queensland Council of General Practice, Public hearing transcript, Brisbane, 20 June 2019, p 3.

*a majority of monitored substances are initiated outside of primary care—either in an emergency department or as part of a discharge—so it is important that those prescriptions are monitored and subject to the framework as well.*⁷⁴

Additionally, Dr Kidd noted:

*A few years ago there was a coroners [sic] case of a nurse from Toowoomba who ended up seeing, I think, about 50 different prescribers. Most of those were in emergency departments. We have to remember that we are not just talking about GPs; we are also talking especially about emergency departments.*⁷⁵

Dr Young confirmed that while more hospitals are actually prescribing monitored substances under the PBS the inclusion of hospital generated prescriptions would not be captured in the first tranche of the system roll-out but would be included as more hospitals move to electronic medical records.

Similarly, more of our hospitals are moving onto electronic medical records, with electronic systems in place for prescribing medications in the wards and for inpatients. Again the plan is for that to be included.

*This will not all happen at once. Initially we will be rolling it out for GPs and specialists in their rooms, so that will be the first focus but, yes, there is every intent for this to roll out on all occasions.*⁷⁶

The committee sought clarification as to why real-time monitoring of monitored substances would be established at the GP level and then rolled out to the hospital system, given the government's jurisdiction. Dr Young told the committee:

*What we need is the scripts, and that is in place at the Commonwealth level and that is what has been done around the country... Most people get their primary health care in the community, and that is where the focus for this is. We know that there is a role in what hospitals prescribe and that can transition when people go back into the community. That is why we want to engage, but it is a different process and it is different IT systems. In actual fact, it is about getting it right in the community before we add in the hospital data.*⁷⁷

Dr Young highlighted that emergency hospital care and primary care are different clinical situations as the role of an emergency department is to: 'fix up that one problem that is in front of them at that point in time. It is not to look at the ongoing care, so they would refer that person back to their GP...They are two totally different settings'.⁷⁸

Committee comment

The committee considers that given that emergency departments and hospitals are increasingly prescribing monitored substances, it is critical that this information be captured in the proposed real-time prescription monitoring system. The committee appreciates the wide range of barriers in implementing this system and notes that the department has undertaken to capture this information after the real-time prescription monitoring scheme is established in the community. However, the inclusion of monitored substances prescriptions initiated in an emergency department or hospital in the real-time prescription monitoring system should be a matter of priority.

⁷⁴ Dr Willett, Royal Australian College of General Practitioners Queensland, Public hearing transcript, Brisbane, 20 June 2019, p 12.

⁷⁵ Dr Kidd, AMA Queensland Council of General Practice, Public hearing transcript, Brisbane, 20 June 2019, p 4.

⁷⁶ Dr Young, Queensland Health, Public hearing transcript, Brisbane, 20 June 2019, p 40.

⁷⁷ Dr Young, Queensland Health, Public hearing transcript, Brisbane, 20 June 2019, p 43.

⁷⁸ Dr Young, Queensland Health, Public hearing transcript, Brisbane, 20 June 2019, p 43.

Recommendation 8

The committee recommends the establishment of real-time prescription monitoring system across all Queensland's hospitals should be a matter of priority, and the Minister for Health address this in his second reading speech.

The committee recommends the creation of rigorous and appropriate cross-jurisdictional data sharing arrangements in relation to a national real-time monitoring prescription database, especially at the New South Wales-Queensland boarder, be prioritised.

Recommendation 9

The committee recommends that, in his second reading speech, the Minister for Health provide an update on cross-jurisdictional data sharing arrangements in relation to a national real-time monitoring prescription database.

3.5 High-risk medicines

The Bill provides that it is an offence to self-prescribe or self-administer high-risk medicines without a reasonable excuse. This offence carries a maximum penalty of 100 penalty units.⁷⁹

The Medical Insurance Group Australia (MIGA) raised concerns in regard to clause 40 and recommended the removal of the offence in favour of education and counselling and, where necessary, referral to the Medical Board of Australia as the regulator.⁸⁰ Mr Bowen from MIGA outlined:

On the issue of self-prescribing and health issues, we agree that self-prescription by doctors of high-risk medications is problematic, potentially risky to them and the community, and may indicate an impairment issue. The Medical Board has well-developed paths for dealing with impairment and doctors' health issues, reinforcing in our mind the need for referral of these matters to the board rather than seeking a financial penalty through a court process.⁸¹

The committee sought clarity on how medical practitioners who are found to have self-prescribed schedule 8 prescriptions are currently managed. Mr Bowen stated:

If that occurs, it would normally be handled by the Medical Board through its health program, or health pathway as it is called. Where it is an issue of being able to remediate and stop that occurring, they would involve other independent health professionals to work with that doctor—perhaps impose some conditions that they consult a GP or other specialist regularly—to avoid that issue arising again. We think that is a good path and a good approach.⁸²

Mr Bowen also noted that there is a range of criminal provisions around how things are prescribed and supplied.⁸³

The department argued that the offence in clause 40 of the Bill was 'considered reasonable and proportionate, as self-prescribing or self-administering high-risk medicines carries a risk of harm for the practitioner and the practitioner's patients'.⁸⁴ Further the department advised:

An offence for self-administration already exists under section 123 of the Health (Drugs and Poisons) Regulation 1996, with a maximum penalty of 80 penalty units. The extension of the offence to self-prescribing makes it very clear that practitioners must only access high-risk medicines through an authorised person who can prescribe. The increase in the maximum

⁷⁹ Explanatory notes, p 62, cl 40.

⁸⁰ Medical Insurance Group Australia (MIGA), submission 18.

⁸¹ Mr Bowen, MIGA, Public hearing transcript, Brisbane, 20 June 2019, p 23.

⁸² Mr Bowen, MIGA, Public hearing transcript, Brisbane, 20 June 2019, p 24.

⁸³ Mr Bowen, MIGA, Public hearing transcript, Brisbane, 20 June 2019, p 24.

⁸⁴ Queensland Health, response to submissions, correspondence dated 12 June 2018, p 7.

penalty to 100 penalty units is considered appropriate given the risk associated with the offence.⁸⁵

Dr Young informed the committee:

A key purpose of the new legislative framework is to protect public health and safety. To ensure the legislation is robust in achieving this, it is necessary to include the option for penalties to promote compliance and enable effective enforcement.

Queensland Health will take a risk based approach to enforcement that uses the least punitive method first. Education assistance for people to voluntarily comply with the legislation will always be the starting point. If this is not effective, Queensland Health may issue a compliance notice. If noncompliance continues, the chief executive may need to escalate the matter and take administrative action such as cancelling the person's substance authority. Prosecution of offences would only be considered as a last resort where compliance is not being achieved and there is a continuing risk to the public.⁸⁶

Committee comment

The committee notes that the inappropriate supply of a schedule 8 drug to a member of the community is a criminal offence⁸⁷ and that the regulatory approach to this practice must be consistent across all members of the society. The committee notes a number of professions in which practitioners are not permitted self-approval or provision of a product:

A bank manager cannot write out a loan for himself for a very good reason. He or she knows the processes and by virtue of the fact that you know the processes, you know how to work around the processes and it also exposes the individual and the entity they are working for to risk.⁸⁸

The committee supports the MIGA call to move the profession away from self-prescription but does not support an approach for the Medical Board, as the professional regulator, to manage the self-prescription of schedule 8 drugs by medical practitioners as the principal approach. The committee supports the penalties proposed in the regulatory framework.

3.6 Medicinal cannabis

The Bill will streamline the regulatory framework for prescribing medicinal cannabis in Queensland by enabling non-specialist medical practitioners to prescribe medicinal cannabis without the need for approval from Queensland Health. The explanatory notes state that this will eliminate duplication of the Commonwealth approval process and remove the potential for Queensland Health and the Therapeutic Goods Administration to reach different conclusions about applications for access to eligible patients.⁸⁹

Dr Young highlighted the benefits that these reforms would have for the prescription and use of medicinal cannabis:

This is now going to enable medicinal cannabis to be treated as any other therapeutic agent... It will make it, I believe, easier for prescribers because they do not need to know a different system; they just then use this system.⁹⁰

⁸⁵ Queensland Health, response to submissions, correspondence dated 12 June 2018, p 7.

⁸⁶ Dr Young, Queensland Health, Public hearing transcript, Brisbane, 20 June 2019, p 38.

⁸⁷ Mr Batt MP, Member for Bundaberg, Public hearing transcript, Brisbane, 20 June 2019, p 24.

⁸⁸ Mr Mickelberg MP, Member for Buderim, Public hearing transcript, Brisbane, 20 June 2019, p 25.

⁸⁹ Explanatory notes, p 7; Dr Young, Queensland Health, Public briefing transcript, Brisbane, 27 May 2019, p 4.

⁹⁰ Dr Young, Queensland Health, Public briefing transcript, Brisbane, 27 May 2019, p 9.

A number of submitters noted their support for the ‘reduction of the regulatory burden associated with the prescribing of medicinal cannabis in Queensland, allowing it to be regulated and treated in the same manner as other Schedule 4 or Schedule 8 medicines’.⁹¹

AMA Queensland supported the revised regulatory framework which enables non-specialist medical practitioners to prescribe medicinal cannabis in Queensland without the need for approval from Queensland Health on the following bases:

- *That the practitioner takes into consideration the patient’s medical history, ensuring there will be no interactions with current medications taken by the patient, considering the current evidence demonstrating the conditions in which medical cannabis may have a therapeutic benefit, and is involved in the ongoing monitoring of use and the effect of medicinal cannabis for the condition for which it was prescribed.*
- *That doctors undertake the available training in prescribing medicinal cannabis before providing this service to their patients.*⁹²

In response, the department noted that a ‘range of guidance materials have been produced by the Commonwealth in collaboration with State/Territory health departments supporting clinical practice’ and that professional bodies also play a role in professional development opportunities for their members in regard to prescribing medicinal cannabis.⁹³

3.7 Licensing and approvals for pest management activities and invasive animal control

All states and territories have legislation requiring the licensing of pest management technicians and the activities they can undertake. Similarly, control of wild dogs and other invasive pests using high-risk poisons, such as strychnine and fluoro acetic acid, are regulated using similar mechanisms as proposed under the Bill.⁹⁴ The explanatory notes state that:

*Based on evidence of harm to public health, the Medicines and Poisons framework applies to pest management businesses undertaking pest management activities in primary production. This will ensure safety of primary produce.*⁹⁵

However, Mr Sayer, the Technical and Training Manager of Garrards Pty Ltd, argued:

*There is concern about the incorporation of the Pest Management Act into the Medicines and Poisons Bill. There are always unintended consequences when something like a use is put into something that is really for manufacture and distribution. We are the only use industry, I believe, in the bill.*⁹⁶

Additionally, it was noted that historically medicines and poisons were regulated separately in Queensland and that this model was used in a number of other states:

Licensing started in Queensland for pest managers in 1976. It was included in the Act then, and fumigation was earlier than that. In 1996 the Health (Drugs and Poisons) Regulation came out, and after that it was decided to split because the Health Act at that time included manufacturers, wholesalers and sellers. We did not fit then and I would argue that we do not fit now.

The Pest Management Act was created to demonstrate and recognise the status and significance of the pest management industry. Its purpose was to regulate the industry, and it is no different

⁹¹ Pharmaceutical Society of Australia, submission 16, p 7.

⁹² AMA Queensland, submission 9, p 2.

⁹³ Queensland Health, response to submissions, correspondence dated 12 June 2018, p 14.

⁹⁴ Explanatory notes, pp 92-93.

⁹⁵ Explanatory notes, p 9.

⁹⁶ Mr Sayer, Garrards, Public hearing transcript, Brisbane 20 June 2019, p 33.

*from plumbing and drainage and so on. Not all of our activities involve the use of chemicals. We do a lot of inspections in premises and so on and provide advice to clients, and it is not something that the Health Act of the past and the Medicines and Poisons Bill will appear to solve.*⁹⁷

In response to these issues, Queensland Health advised:

*... The inclusion of pest management regulation in the Bill reflects the fact that pest management technicians currently have obligations under the Health (Drugs and Poisons) Regulation 1996, for example, for the manufacture, sale or supply of pesticides. Queensland Health is aware that some licensed technicians do not know about these requirements and unknowingly contravene requirements for the sale and supply of pesticides and fumigants. The inclusion of all pest management requirements in one scheme is intended to simplify and consolidate regulatory requirements under a single framework.*⁹⁸

Chapter 3, Part 2, Division 1 provides that the chief executive may grant a range of licences and approvals under the Act, known as substance authorities. Substance authorities include manufacturing licences, wholesale licences, retail licences, pest management licences, prescribing approvals and general approvals.⁹⁹

The Australian Environmental Pest Managers Association and Garrards submitted that Queensland is the only state that requires two licences for certain pest management activities. Mr Graham informed the committee:

*Traditionally, we have had occupational licences for the actual users, our pest control technicians. There is no company licence required under the Health Act. Going back nearly 10-plus years ago, QBCC [Queensland Building and Construction Commission] cast a net and threw it out and we got tangled up in it, so anybody conducting termite related activities has to be licensed by the QBCC as well.*¹⁰⁰

The submissions argued for:

- consideration of a single licence or administration by a single department, rather than being split between the Queensland Building and Construction Commission (QBCC) and Queensland Health
- for improved mutual recognition of interstate licences for pest management
- abolition of individual pest control licences and licencing of businesses to ensure they only employ accredited technicians
- introduction of business registration to improve recordkeeping, contact points and ensure effective service to consumers.¹⁰¹

In response to concerns regarding licence requirements, the department argued:

The purpose and scope of the two licences are different and there are no current plans to combine them into a single licence. A QBCC licence has considerations that include business related requirements, such as financial management, appropriate insurance for consumer protection against defective building work and can be granted to an individual or an entity. The technical

⁹⁷ Mr Sayer, Garrards, Public hearing transcript, Brisbane, 20 June 2019, p 35.

⁹⁸ Queensland Health, response to submissions, correspondence dated 12 June 2018, p 6.

⁹⁹ Explanatory notes, p 24.

¹⁰⁰ Mr Graham, Queensland Representative, Australian Environmental Pest Managers Association, Public hearing transcript, Brisbane 20 June 2019, p 33.

¹⁰¹ Submissions 1 and 12.

competency requirements require that the business supervisor is a licensed pest management technician.

Pest management licences administered by Queensland Health are issued to individuals and are based on competency and skills to safely and effectively apply poisons for pest management in commercial and domestic premises and the need to protect public health from the use of pesticides and fumigants. It is considered appropriate for these licences to be regulated by separate departments.¹⁰²

The department noted that currently no States or Territories have automatic recognition of interstate licences and that mutual recognition of interstate licences would require agreement between all States and Territories through the Council of Australian Governments, which is beyond the scope of the Bill.¹⁰³

The committee sought clarity on the impact of the Bill on primary producers and the use of poisons such as Roundup, Paraquat and 1080 baits. The explanatory notes state that ‘primary producers will continue to be able to use pesticides or fumigants in compliance with label instructions approved by the Australian Pesticides and Veterinary Medicines Authority’.¹⁰⁴ Dr Young confirmed:

The bill also provides that a primary producer, or an agent of a primary producer, can carry out a pest control activity or fumigation activity on land owned or occupied by the primary producer without requiring a licence, for example, when the primary producer sprays fruit using a pesticide to protect the fruit from insects.¹⁰⁵

Additionally:

Primary producers undertaking pest management activities on their own properties will not require a pest management licence... That also applies to their agents or employees... Neighbours providing in-kind services in relation to pesticides used on a primary producer’s property are considered an agent of the property owner and, therefore, also do not require a pest management licence.¹⁰⁶

3.8 Substance authority register

Clauses 228 to 231 set out the requirements for the chief executive to keep, and if required, publish a substance authority register. The explanatory notes state:

Clause 230 provides that the substance authority register for substance authorities must contain the following information about each substance authority:

- *the identification number allocated to the authority;*
- *the name of the holder or, if the holder trades as a business, the entity’s business or trading name and the name of the person responsible for overseeing or supervising the regulated activity authorised under the authority;*
- *the type of the authority or regulated activity authorised under the authority;*
- *the term of the authority and the day the authority ends;*
- *the postcode of the place where the regulated activity under the authority will be carried out.*

The purpose of clause 230 is to allow information that would otherwise be confidential information to be provided regarding whether a person has a substance authority. For example,

¹⁰² Queensland Health, response to submissions, correspondence dated 12 June 2018, p 4.

¹⁰³ Queensland Health, response to submissions, correspondence dated 12 June 2018, p 5.

¹⁰⁴ Explanatory notes, p 9.

¹⁰⁵ Dr Young, Queensland Health, Public briefing transcript, Brisbane, 27 May 2019, p 2.

¹⁰⁶ Dr Young, Queensland Health, Public briefing transcript, Brisbane, 27 May 2019, p 5.

*if a member of the public wanted to verify that a pest management technician was licensed, it would not be possible to otherwise provide this information.*¹⁰⁷

Ms Vitelli from AgForce highlighted concerns in regard to publishing the personal details of primary producers who have S7 poisons on a public register.

*There is a risk that a public register could be misconstrued and used against producers, especially when we see the increased level of activists invading farms and sometimes when pet owners are quick to blame someone for the death of their pet dog if they suspect toxicity. A public register of producers with some of those restricted schedule 7 substances, such as 1080, PAPP and strychnine, could be misconstrued and that puts people at risk.*¹⁰⁸

*... We do not want that information to be made public. It is a bit like knowing what you might have in your medicine cabinet at home with some of the high-level schedule 7 substances. Would you like that to be on a public register so anyone can know what is in your home?... I am not saying that you should not have it on the register; just do not put it out on a public website.*¹⁰⁹

Ms Dwyer from the department informed the committee:

*We keep a register and we are obliged to keep a register. That is part of the administration of the Act as you would expect. With regard to the publishing of them, the chief executive 'may' publish rather than 'will' publish. I think that explanation of the risks of publishing certain information would have to be taken into account and can be taken into account in a decision as to whether or not you publish.*¹¹⁰

Committee comment

The committee notes that the authority of the chief executive to publish a register is discretionary and will be based upon a number of public interest factors. However, given the potential sensitivity of information regarding the ownership and location of S7 poisons on rural properties, the committee considers that, in his second reading speech, the Minister for Health should address the need to make this information publicly available.

Recommendation 10

The committee recommends that, in his second reading speech, the Minister for Health address the need for publication of S7 poisons held on private rural properties in the substance authority register.

3.9 Regulations

The committee notes that most submissions made comment on the draft Medicines and Poisons (Medicines) Regulation 2019 and Medicines and Poisons (Pest Management, Poisons and Other Regulated Substances) Regulation 2019.¹¹¹ As Ms Vitelli from AgForce highlighted '... like a lot of legislation, it is the regulation that has the detail and you need to be aware of the impact of that'.¹¹²

As noted earlier in this report, regulations will be made after the Bill is debated, potentially amended, and passed by the Parliament. The final form of the regulations will then be considered by the relevant portfolio committee. It is possible the final regulations may vary from the draft regulations that were tabled to assist in understanding the Bill.

¹⁰⁷ Explanatory notes, p 163.

¹⁰⁸ Ms Vitelli, AgForce, Public hearing transcript, Brisbane, 20 June 2019, p 28.

¹⁰⁹ Ms Vitelli, AgForce, Public hearing transcript, Brisbane, 20 June 2019, p 30.

¹¹⁰ Ms Dwyer, Queensland Health, Public hearing transcript, Brisbane, 20 June 2019, p 42.

¹¹¹ See submissions 6, 8, 10, 11, 13, 14, 18, 19, 20, 21, 22.

¹¹² Ms Vitelli, AgForce, Public hearing transcript, Brisbane, 20 June 2019, p 28.

Given the concerns raised on matters included in the draft regulations, there is a requirement for the department to genuinely engage with stakeholders in the finalisation of regulations. The committee notes Dr Young's undertaking that:

Many of the submissions noted the technical nature of the bill and the need for consultation to finalise the regulations and develop departmental standards and extended practice authorities. Queensland Health is committed to consulting with all relevant stakeholders and professional bodies during this process.¹¹³

Committee comment

The committee acknowledges Queensland Health's undertaking to consult with stakeholders in finalising the regulations. Parliament will scrutinise the Medicines and Poisons (Medicines) Regulation and Medicines and Poisons (Pest Management, Poisons and Other Regulated Substances) Regulation when made and tabled in Parliament. The committee notes that this will provide an opportunity to review issues raised in this inquiry.

¹¹³ Dr Young, Queensland Health, Public hearing transcript, Brisbane, 20 June 2019, p 38.

4 Compliance with the *Legislative Standards Act 1992*

4.1 Fundamental legislative principles

Section 4 of the *Legislative Standards Act 1992* (LSA) states that ‘fundamental legislative principles’ are the ‘principles relating to legislation that underlie a parliamentary democracy based on the rule of law’. The principles include that legislation has sufficient regard to:

- the rights and liberties of individuals, and
- the institution of Parliament.

Numerous clauses of the Bill raise potentially significant issues of fundamental legislative principle.

The Bill also includes a number of provisions which introduce new offences and penalties or effect increases to existing penalties. These provisions are set out at Table 1 at the end of this chapter. These clauses are considered in more detail below under the consideration of proportionality.

The committee notes that a number of potential issues of fundamental legislative principle identified and considered briefly in the explanatory notes are not considered to raise significant issues of fundamental legislative principle.

Moreover, in some cases, the content of the explanatory notes serves to demonstrate, and appears aimed at demonstrating, *consistency* with fundamental legislative principles, rather than addressing and offering justification or reasons for instances of *inconsistency*.¹¹⁴

On this basis, these matters were not considered in this report.

The following table provides a summary of the potential breaches of fundamental legislative principle in the Bill, which are then discussed in detail.

SUMMARY TABLE OF ISSUES OF FUNDAMENTAL LEGISLATIVE PRINCIPLE

CLAUSES	ISSUES OF FUNDAMENTAL LEGISLATIVE PRINCIPLE
<p>Clause 216 allows the minister to ask the police commissioner for a report about the criminal history of a person.</p> <p>Clause 217 applies if the chief executive has obtained a criminal report about a person. If the person is later convicted of an indictable offence, the person must, within 14 days of conviction, give notice of the conviction to the chief executive.</p>	<p>Rights and liberties of individuals – legislation should have regard to an individual’s right to privacy of their personal information.</p> <p>A person has a right to privacy, particularly in relation to their personal information. The personal information of a person is requested and used by government agencies.</p>
<p>Clauses 221 to 231 relate to disclosure to entities performing relevant functions and to health professionals.</p>	<p>Rights and liberties of individuals – legislation should have regard to an individual’s right to privacy of their personal information – information sharing and disclosure.</p> <p>The personal information of an individual is disclosed to other government agencies.</p>

¹¹⁴ Section 23(1)(f) of the *Legislative Standards Act 1992* requires explanatory notes to include *a brief assessment of the consistency of the Bill with fundamental legislative principles and, if it is inconsistent with fundamental legislative principles, the reasons for the inconsistency*.

CLAUSES	ISSUES OF FUNDAMENTAL LEGISLATIVE PRINCIPLE
<p>Various offence and penalty provisions.</p> <p>The offence framework has the following features:</p> <ul style="list-style-type: none"> • the concept of ‘the authorised way’ (clauses 30 and 31) • various key offences (clauses 32 to 35) • medicines offences (clauses 36 to 420) • poisons and pest management offences (clauses 43 to 47) • various miscellaneous offences 	<p>Rights and liberties of individuals – penalties should be reasonable and proportionate.</p> <p>The explanatory notes contain various justifications for the imposition and amount of these penalties.</p>
<p>The Bill introduces a number of provisions, relating to the use of an administrative power, including:</p> <ul style="list-style-type: none"> • the use of state intervention powers on public interest grounds, which are final and conclusive (clause 118) • recall orders which may require a person to recall a product from manufacture and supply (clause 119) • power to make an emergency order (clause 58) 	<p>Rights and liberties of individuals – legislation should have sufficient regard to the rights and liberties of individuals.</p> <p>Administrative power – rights, obligations and liberties of individuals should be dependent on administrative power only if the power is sufficiently defined and subject to appropriate review.</p> <p>The use of these powers may affect an individual’s ordinary activities in conducting a business and impose additional obligations on them.</p>
<p>Various clauses relate to power to:</p> <ul style="list-style-type: none"> • take administrative action (clause 102) • issue compliance notices (clause 108) • issue public warnings (clause 127) 	<p>Natural justice – legislation should be consistent with the principles of natural justice.</p> <p>With the use of these powers, consideration must be given to whether sufficient notice has been given and the individual has been given sufficient opportunity to respond and present their case.</p> <p>With relation to administrative action, the committee might be satisfied that any breach of fundamental legislative principle has been sufficiently justified.</p>
<p>Clause 208 provides that a certificate purporting to be signed by the chief executive stating a range of matters is evidence of the matter.</p> <p>Clause 209 provides that a particular substances is a regulated substance of the</p>	<p>Reversal of onus of proof – the onus of proof should only be reversed with adequate justification.</p> <p>The Bill introduces evidentiary presumptions which effectively reverse the onus of proof by placing the onus on a defendant to rebut the presumption established.</p>

CLAUSES	ISSUES OF FUNDAMENTAL LEGISLATIVE PRINCIPLE
<p>same type as a regulated substance commonly supplied under the same name.</p> <p>Clause 214 provides that if a corporation commits a serious offence, each executive officer is taken to have also committed the offence, if certain conditions are met.</p>	
<p>Various provisions where it is an offence for a person to do certain acts unless the person 'has a reasonable excuse'.</p>	<p>Reversal of onus of proof – the onus of proof should only be reversed with adequate justification.</p> <p>Clauses that contain 'reasonable excuse' provisions may be seen to reverse the onus of proof.</p>
<p>Various provisions – 140, 154, 158, 159, 161, 162, 175, 177, 180</p> <p>The Bill provides for powers of entry and wide range of consequential powers, including powers of search and seizure and potential forfeiture of property, which are not subject to consent or warrant.</p> <p>The inspector may also stop or move vehicles.</p> <p>Certain provisions relating to seizure of property require a threshold of a 'reasonable suspicion' on the part of the inspector.</p>	<p>Power to enter premises – the power to enter premises and search for or seize documents, should only be pursuant to a warrant.</p> <p>These powers affect the rights and liberties of an individual who is the subject of the inspector's attention.</p>
<p>Clauses 178 and 179 provide that it is not a reasonable excuse for a person to fail to comply with a document production or certification requirement if doing so might incriminate the person or expose them to a penalty.</p>	<p>Protection against self-incrimination – a person should not be obliged to incriminate themselves.</p>
<p>Various clauses include references to a range of external documents such as codes, guidelines, protocols or standards.</p>	<p>Scrutiny by the Legislative Assembly – the exercise of the proposed legislative power should be subject to the scrutiny of the Legislative Assembly.</p> <p>The use of external documents that are not reproduced in full in subordinate legislation, may not come to the attention of the House.</p>
<p>Clause 282 contains a transitional regulation-making power which allows a transitional regulation to make provision of a saving or transitional nature about any matters to achieve the transition</p>	<p>Delegation of legislative power – a Bill should allow the delegation of legislative power only in appropriate cases and to appropriate persons.</p>

CLAUSES	ISSUES OF FUNDAMENTAL LEGISLATIVE PRINCIPLE
from the Health Act or Pest Management Act to the new Act.	<p>Retrospectivity – a Bill should not adversely affect rights and liberties, or impose obligations, retrospectively.</p> <p>The clause contains a sunset period of 2 years after the clause commences and the power to make a transitional regulation also expires at that time.</p>
The Bill contains many provisions for matters to be prescribed by regulation.	<p>Amendment of an Act by another Act – a Bill should allow or authorise the amendment of an Act only by another Act.</p> <p>Appropriate delegation of legislative power – a Bill should sufficiently subject the exercise of a delegated legislative power to the scrutiny of the Legislative Assembly.</p> <p>Matters to be set out in regulation should appropriately belong in regulation rather than in the Act.</p>

4.2 Right to privacy regarding personal information – disclosure of criminal history

Summary of provisions - criminal history

Clause 216 allows the chief executive to ask the police commissioner for a written report (including a brief description of the circumstances of any conviction *or allegation*), about the criminal history of a person, when considering if the person is a fit and proper person in relation to a substance authority, or whether to take administrative action in relation to the person.

By virtue of clause 215 a criminal history here includes spent convictions.¹¹⁵

The person must have given their prior written consent before the chief executive can seek a report.

Any report must be destroyed as soon as practicable after it is no longer needed for the purpose for which it was given (clause 218). There is no sanction in the Bill for a failure to comply.

Clause 217 applies if the chief executive has obtained a criminal history report about a person, the person is later convicted of an indictable offence, and at the time of the conviction the person is an approved person or a relevant person for a substance authority. The clause requires such a person to, within 14 days after the conviction, give notice of the conviction to the chief executive, unless the person has a reasonable excuse.

The notice must include information about when the offence was committed, details adequate to identify the offence, and the sentence imposed. A failure to so notify attracts a maximum penalty of 100 penalty units.

Issue of fundamental legislative principle

Clauses 216 and 217 raise an issue of fundamental legislative principle relating to the rights and liberties of individuals, particularly regarding an individual's right to privacy with respect to their personal information.¹¹⁶

¹¹⁵ Clause 215 provides that the *Criminal Law (Rehabilitation of Offenders) Act 1986* does not apply to a request, disclosure or notification made in relation to an individual's criminal history.

¹¹⁶ See *Legislative Standards Act 1992*, section 4(2)(a).

The right to privacy, and the disclosure of private or confidential information are relevant to a consideration of whether legislation has sufficient regard to the rights and liberties of the individual.

Comment

The breach of fundamental legislative principle is heightened here, given that spent convictions are required to be disclosed. (The *Criminal Law (Rehabilitation of Offenders) Act 1986* provides that an individual does not have to disclose a conviction for which the rehabilitation period has expired and not revived, except in limited circumstances.)

The explanatory notes offer this justification:

The scope of the criminal history provisions is considered justified due to the need to ensure that appropriate people are granted and hold a substance authority, noting the seriousness of harm that can be caused by the substances involved and the need to protect the safety of the public. The effective mitigation of public health and safety risks relies on authorised persons performing regulated activities in the way specified in the Bill and regulations. A person's criminal history is relevant to determining whether the person is a fit and proper person. By ensuring only appropriate people are authorised to deal with certain substances, the risk of diversion and/or inappropriate use of substances can be mitigated. Additionally, for pest management licensing, where technicians may have unsupervised access to domestic residences and other sensitive locations, relevant criminal history may be considered to protect the health and safety of the public. The provisions will enable the chief executive to have a more complete picture of the criminal history of an applicant, including information about convictions which may indicate a pattern of behaviour that may compromise the ability of a person to hold a substance authority and deal with regulated substances appropriately. Provisions of this nature are not uncommon in occupational regulation legislation where for public health and safety reasons, the integrity of applicants must be rigorously assessed.¹¹⁷

In considering similar provisions in Bills, committees have considered whether adequate safeguards are included in the Bill, such as whether:

- The criminal history can only be obtained with consent.
- There are strict limits on further disclosure of that information.
- The criminal history information must be destroyed when it is no longer required for the purpose for which it was obtained.¹¹⁸

Consideration has also been given in the past to the extent of information covered by the term 'criminal history', including for example, whether the term extends to charges that do not result in convictions, and to 'spent' convictions, and convictions that are quashed or set aside, and convictions which are 'not recorded'.

Here, the following can be noted:

- A person's criminal history can only be obtained with their consent.
- There are limits on disclosure, and an offence for unauthorised disclosure.
- There is a requirement for destruction of the information as soon as practicable after the information is no longer needed.
- The convictions included in a criminal history *do* extend to spent convictions.

¹¹⁷ Explanatory notes, p 66.

¹¹⁸ See for example, Transportation and Utilities Committee, report No. 13, 55th Parliament, *Plumbing and Drainage and Other Legislation Amendment Bill 2015*, March 2016, p 24.

Clause 220 of the Bill goes some way to addressing confidentiality issues regarding criminal history information by making it an offence for an administrator to directly or indirectly disclose confidential information or criminal history information to another person, unless the disclosure is:

- permitted under the Act or otherwise required or permitted by law
- made with consent of the person to whom the information relates, or
- is in a form that does not identify the person to whom the information relates.

Clause 220 sets the maximum penalty for an unauthorised disclosure at 50 penalty units. Many recent similar provisions, aimed at safeguarding personal criminal history information, provide for a maximum penalty of 100 penalty units.

The maximum penalty in the Ministerial and Other Office Holder Staff and Other Legislation Amendment Bill 2018 is 100 penalty units, and that amount is consistent with like provisions in some other legislation, including section 172 of the *Public Service Act 2008*. The maximum penalty in some other recent Bills (including the Hospitals Foundation Bill 2018, the Personalised Transport Ombudsman Bill 2019, and the Plumbing and Drainage Bill 2018) is also 100 penalty units. On the other hand, a maximum of 50 penalty units was prescribed in the Tow Truck and Other Legislation Amendment Bill 2018.

Committee comment

The committee is satisfied that there are sufficient protections for the privacy of the individual (including an adequate level of penalty) and there is sufficient justification for the breach of the individual's right to privacy.

4.3 Right to privacy regarding personal information – information sharing and disclosure

The Bill makes provision for a number of schemes regarding the keeping and disclosure of information. These raise issues regarding the confidentiality of private information.

Summary of provisions

4.3.1 Disclosure to entities performing relevant functions, and to health professionals, information sharing

Clause 221 allows an 'administrator' (defined in clause 219 as including the chief executive or a person involved in administering the Act, such as a health service employee or public service employee) to disclose confidential information to:

- a health ombudsman official
- a coroner investigating the death of a person
- the chief executive of the department in which the *Food Act 2006* or the *Food Production (Safety) Act 2000* is administered
- a law enforcement agency for the purposes of detecting, investigating, preventing or prosecuting an offence in relation to a regulated substance
- the Australian Health Practitioner Regulation Agency, or a National Health Practitioner Board, established under the Health Practitioner Regulation National Law
- the Australian Pesticides and Veterinary Medicines Authority for performing its functions under the *Agricultural and Veterinary Chemicals Act 1994* (Cwlth) or the *Agricultural and Veterinary Chemicals Code Act 1994* (Cwlth)
- the Secretary under the *Therapeutic Goods Act 1989* (Cwlth) for performing the Secretary's functions under that Act or the *Therapeutic Goods Act 2019*
- a corresponding law entity

- another entity of the Commonwealth or another State for performing its functions relating to a practitioner law (the Health Practitioner Regulation National Law or the *Veterinary Surgeons Act 1936* or its interstate equivalents); to the management of health and safety risks in public places and workplaces; or to the importation or exportation of goods or substances into or from Australia, or
- a foreign regulatory authority for performing its functions relating to the importation or exportation of regulated substances into or from Australia.

An administrator may disclose confidential information to an entity under clause 221 only if satisfied:

- the disclosure is reasonably necessary for the entity to exercise its functions, and
- the confidential information will be collected, stored and used by the entity in a way that protects the privacy of the persons to whom the information relates from unjustified intrusion.

Clause 222 provides that an administrator may disclose confidential information to a health practitioner if the health practitioner is providing therapeutic treatment to the person to whom the information relates, and the disclosure is reasonably necessary for such treatment.

4.3.2 Information requests

Clause 223 authorises the chief executive to direct the head of a public sector unit to give information to the chief executive within a stated reasonable time, if the chief executive considers that public sector unit has information, including confidential information that is reasonably necessary to:

- carry out the chief executive's functions under the Act, and
- urgently prevent a health risk in relation to a substance.

The unit head must comply with the direction, unless they reasonably consider the disclosure of the information:

- would prejudice the investigation of a contravention, or possible contravention, of a law
- would prejudice the effectiveness of a lawful method or procedure for preventing, detecting, investigating or otherwise dealing with a contravention or possible contravention of a law, or
- would endanger a person's life or physical safety.

In complying with a direction, a unit head must ensure, as much as possible, that the privacy of any person to whom the information relates is 'protected from unjustified intrusion'.

4.3.3 Databases and registers

Clause 224 (and following) provide for the establishment of the monitored medicines database. Under **clause 225**, this will include the recording of information to be prescribed by regulation, which may include personal information. Under **clause 227**, the chief executive can grant access to such information only for a purpose 'prescribed by regulation' to a 'user', being an entity 'prescribed by regulation'.

Clauses 229 and 230 provide for the content of the administrative action register and the substance authority register (both to be maintained by the chief executive under clause 228). This content can include personal information. **Clause 231** allows for the publication of the content of the registers, which is to exclude confidential information unless the chief executive is satisfied the inclusion of the confidential information:

- is reasonably necessary to avoid a health risk, and
- will not place a person at risk of harm.

Issue of fundamental legislative principle

These provisions raise the same issue of fundamental legislative principle relating to the rights and liberties of individuals as discussed above regarding criminal history requests, regarding an individual's right to privacy with respect to their personal information.

The right to privacy, and the disclosure of private or confidential information are relevant to a consideration of whether legislation has sufficient regard to the rights and liberties of the individual.

Comment

The explanatory notes offer the following justifications for these provisions:

- **Clause 221**

*Clause 221 is justified to enable information-sharing between appropriate entities for the purpose of administering the scheme. The provision may also be used to support the operation of the monitored medicines database and corresponding databases in other jurisdictions, as it will allow Queensland Health to disclose information through the National Data Exchange, which will underpin the monitored medicines database. The information in the database will be used to promote safe practices for supplying, prescribing and dispensing regulated substances.*¹¹⁹

- **Clause 222**

*This provision is justified as it balances the individual's right to privacy with the need to ensure appropriate information-sharing to enable the therapeutic treatment of a person. For example, Queensland Health may need to disclose confidential information to a pharmacist who is authorised to dispense a regulated substance and needs to clarify or confirm that the prescriber is authorised to prescribe that substance. This would also be applicable in situations where a doctor may contact Queensland Health in relation to a patient's methadone treatment to prevent instances of doctor shopping.*¹²⁰

- **Clause 223**

*This provision is justified as the public sector unit may have been notified of an incident that has associated public health impacts. For example, the Department of Environment and Science may be investigating an environmental chemical spill and be unable to issue a public warning due to the status of their investigation. The chief executive could request details of the spill so that a timely health warning can be issued.*¹²¹

- **Clauses 224 to 227**

Granting users access to and use of the database is justified to support the operation of the scheme and to implement the Health Ombudsman's recommendation in the 2016 Investigation report, Undoing the knots constraining medicine regulation in Queensland, to introduce a real-time prescription monitoring system. ... Granting users access to the database is also strongly advocated for by peak medical, pharmacy and consumer bodies, including the Australian Medical Association, the Pharmaceutical Society of Australia, the Pharmacy Guild of Australia, the Royal Australian College of General Practitioners, Consumers Health Forum of Australia and others. Appropriate safeguards have been included in the Bill, with prescribers and dispensers bound by their professional obligations in relation to confidentiality of patient information. Apart from the automated 'upload' of dispensing data by dispensers, the monitored medicines

¹¹⁹ Explanatory notes, p 53.

¹²⁰ Explanatory notes, p 53.

¹²¹ Explanatory notes, p 54.

*database will be read-only for prescribers and dispensers. It is intended they will be unable to record information in the database.*¹²²

- **Clauses 229 to 231**

*These provisions may be seen to breach individuals' right to privacy by providing for the recording and publishing of information relating to substance authorities and administrative action. These concerns have been balanced against the need to protect and promote the health of the public and are considered justified. If Queensland Health has issued an authority to undertake a regulated activity, consumers and members of the public would have an expectation of regulatory oversight. The registers enable the public to verify that authority holders are authorised to undertake the activity, and whether any administrative action has been taken in relation to the authority holder. The purpose of the registers is to provide transparency and public assurance.*¹²³

Collectively, the explanatory notes give this general justification regarding these clauses:

*These provisions are considered to be justified as adequate safeguards are in place and the provisions enable the operation of the Act and protect the health and safety of the public. In addition, information that is shared may also assist relevant compliance entities to undertake well-informed and comprehensive investigations into activities that may endanger the health and safety of the public. The inability of Queensland Health to provide this information may cause a public health risk if not addressed appropriately through compliance orders or prosecution.*¹²⁴

Committee comment

The committee is satisfied that there are sufficient protections for the privacy of the individual and that the provisions for disclosure of information have sufficient regard to the rights and liberties of individuals.

4.4 Penalty provisions

Summary of provisions

Various clauses establish new offences and penalties. [These provisions are set out at Table 1.] The offence framework established by the Bill can be seen as having these features:

- the concept of 'the authorised way' (clauses 30 and 31)
- various key offences (clauses 32 to 35)
- medicines offences (clauses 36 to 42)
- poisons and pest management offences (clauses 43 to 47)
- various miscellaneous offences.

The committee sets out a summary of some of these offence provisions, together with some comment.

4.4.1 Proportion and relevance

The creation of new offences and penalties affects the rights and liberties of individuals.

Whether legislation has sufficient regard to rights and liberties of individuals depends on whether, for example, penalties and other consequences imposed by legislation are proportionate and relevant to the actions to which the consequences relate. A penalty should be proportionate to the offence:

¹²² Explanatory notes, pp 56.

¹²³ Explanatory notes, p 57.

¹²⁴ Explanatory notes, p 51.

In the context of supporting fundamental legislative principles, the desirable attitude should be to maximise the reasonableness, appropriateness and proportionality of the legislative provisions devised to give effect to policy.

*... Legislation should provide a higher penalty for an offence of greater seriousness than for a lesser offence. Penalties within legislation should be consistent with each other.*¹²⁵

4.4.2 The provisions

4.4.2.1 The authorised way

Fundamental to the regulatory offence framework created by the Bill is the concept of the authorised way. Persons must deal with regulated substances in the authorised way.

Clause 31 provides that a person carries out a regulated activity with a regulated substance in the authorised way if the person:

- is authorised (under clause 54(4), 57 or 62) to carry out the regulated activity with the regulated substance
- complies with any requirement prescribed for carrying out the regulated activity with the regulated substance, and
- complies with any substance management plan that applies to the person.

Clause 30 provides that a person is authorised to carry out a regulated activity with a regulated substance if they are an approved person, a person acting under an emergency order, the holder of a substance authority, or another person acting under a substance authority.

Key offences

- **Clause 32** makes it an offence for a person to deal with prohibited substances unless the person deals with the substance in the authorised way or has a reasonable excuse. There is a maximum penalty of 750 penalty units. (This is a little over \$100,000.)¹²⁶
- **Clause 33** makes it an offence for a person to manufacture a medicine or hazardous poison unless the person manufactures the medicine or poison in the authorised way or has a reasonable excuse. There is a maximum penalty of 750 penalty units.
- **Clause 34** makes it an offence to buy or possess an S4 or S8 medicine or hazardous poison unless done in the authorised way or the person has a reasonable excuse. There is a maximum penalty of 200 penalty units.
- **Clause 35** makes it an offence for a person to supply a medicine or hazardous poison to someone else unless the supplier lawfully possesses the medicine or poisons and supplies it in the authorised way or has a reasonable excuse. There is a maximum penalty of 500 penalty units.

(This offence would apply to a person supplying substances to another person in an unlawful way, such as a pharmacist selling large quantities of pseudoephedrine tablets to a person where such a drug may be used to make methamphetamine (also known as 'ice') or selling a medicine to a person who did not know how to use it safely because, for example, no instructions for use were provided.)

¹²⁵ Office of the Queensland Parliamentary Counsel, *Fundamental Legislative Principles: The OQPC Notebook*, p 120.

¹²⁶ Based on the increased penalty unit value of 133.45 as from 1 July 2019.

Comment – key offences

The explanatory notes give these justifications for these offences and the various penalties:

- *Clause 32 (Offence to deal with prohibited substances)*

This offence is considered appropriate and reasonable because prohibited substances, which include substances such as heroin and cocaine, are highly subject to abuse and misuse and pose a significant risk to public health, given that if misused, they are known to cause serious illness and death in humans. There are legitimate uses for these substances, such as in medical research and for calibrating machinery used by pathology laboratories for drug testing. However, the substances have a high value on the illicit drug market. The penalties for not complying with, for example, the storage and record-keeping requirements for these substances, should be high to act as a deterrent to aberrant behaviour. The sale, supply or use of other substances is prohibited because of their known dangerous properties such as being carcinogenic or toxic to tissues, skin or eyes.

Although the maximum penalty of 750 penalty units is high, it is considered proportionate to the offence noting the seriousness of the offence and the potential harm. The significant penalty is considered necessary to ensure a person takes responsibility for preventing and minimising the risks associated with their activities and the adverse effects their activities may cause. It reflects the principle that those who are responsible for posing a risk should manage the risk. A penalty of 750 penalty units is included in section 24 of the Biosecurity Act, section 32 of the Explosives Act 1999 and section 31 of the Mining and Quarrying Safety and Health Act 1999.¹²⁷

- *Clause 33 (Offence to manufacture medicines or hazardous poisons)*

This offence is considered appropriate and reasonable in light of the potential for widespread public harm if manufactured products do not meet appropriate safety and quality requirements. Manufacturers who do not comply with relevant manufacturing principles, or who do not have adequate facilities for the steps that they perform in manufacturing, place consumers of their products at significant risk of harm if the products they make are not fit for use ... Similarly, product labelling is an important step in the manufacturing process where errors, such as labelling one product as another or omitting safety warnings, have led to significant harms to individuals and to the general public. Furthermore, inappropriate or unsafe manufacturing processes present a significant risk to public health and safety if they contribute to antimicrobial resistance or otherwise cause environmental contamination.

Although the maximum penalty of 750 penalty units is high, it is considered proportionate noting the seriousness of the offence. Similar offences, also carrying a penalty of 750 penalty units, are included in, for example section 104C of the Fire and Emergency Services Act 1990, section 34 of the Coal Mining Safety and Health Act and section 168B of the Liquor Act 1992. As manufacturing for medicines and poisons is the first step in the supply chain, any error or contamination has the potential for harm for many end users. As such, the penalty is considered commensurate with the public health and safety risks of unauthorised or improper manufacturing of medicines or hazardous poisons.¹²⁸

- *Clause 34 (Offence to buy or possess S4 or S8 medicines or hazardous poisons)*

This offence would capture possession of substances without authority, that may have a range of public health implications. For example, the misuse of S4 and S8 medicines, some of which can be subject to abuse and physical or psychological dependence, can cause harm to

¹²⁷ Explanatory notes, p 59.

¹²⁸ Explanatory notes, p 60.

individuals. It would present significant risks to public health and safety and undermine the integrity of the health system if it were possible to possess these medicines without appropriate authorisation. In addition, the scheme imposes storage and record-keeping requirements for substances, for example, mandating the use of child-proof packaging and storage out of public access. This offence covers non-compliance with these important safety requirements. The offence also covers possession of hazardous poisons without authority. For example, it would apply to a person in possession of an S7 hazardous poison without authority who intends to dispose of it in a public water source. This offence allows for a proactive approach to protecting public health, as the person may be charged with possession prior to negatively impacting public health. It is also intended to cover situations where a home owner purchases schedule 7 poisons on the internet to avoid supply restrictions in Australia.

The [maximum penalty of 200 penalty units] is considered proportionate to the offence noting the seriousness of the conduct it applies to. Similar offences, also carrying a penalty of 200 penalty units, are included in, for example section 733 of the Petroleum and Gas (Production and Safety) Act 2004.¹²⁹

- *Clause 35 (offence to supply medicines or hazardous poisons)*

Although the maximum penalty of 500 penalty units is high, it is considered proportionate to the offence noting the seriousness of the conduct it applies to. Similar offences, also carrying a penalty of 500 penalty units, are included in, for example the Public Health Act.¹³⁰

- *Collectively:*

Key offences ... have a high maximum penalty to reflect the seriousness of the conduct to which it applies, the significant consequences for public health and safety of breaches, and the fact it is designed to cover a number of different scenarios.¹³¹

... the penalties for these offences are considered justified and proportionate noting the seriousness of the offences... A high maximum penalty allows a court to determine the appropriate penalty applying to the most serious cases, while allowing discretion to apply a lower penalty for offences involving less serious breaches.¹³²

Medicines offences

- **Clause 36** (Offence to administer medicines) makes it an offence for a person to administer a medicine to another person or to an animal unless the person undertakes the action in the authorised way or has a reasonable excuse. There is a maximum penalty of 200 penalty units.
- **Clause 37** (Offence to supply or administer animal medicines to humans) makes it an offence to supply or administer animal medicines to humans unless the person has a reasonable excuse (which is stated to include where no other medicine is available to treat a human ailment or injury). There is a maximum penalty of 100 penalty units.
- **Clause 38** (Offence to prescribe or make standing orders) provides it is an offence to prescribe or make a standing order for a medicine unless the person does it in the authorised way or has a reasonable excuse. This offence carries a maximum penalty of 200 penalty units.
- **Clause 39** (Unlawfully buying diversion-risk medicines) provides it is an offence to use a document the person has unlawfully prepared, or knows has been unlawfully prepared, to buy a diversion-risk medicine. This offence carries a maximum penalty of 100 penalty units. It is

¹²⁹ Explanatory notes, p 61.

¹³⁰ Explanatory notes, p 61.

¹³¹ Explanatory notes, p 59.

¹³² Explanatory notes, p 61.

also an offence for a person to give a statement to someone who is authorised to prescribe or supply a diversion-risk medicine that the person knows is false or misleading, or omits anything without which the statement is false or misleading. This offence carries a maximum penalty of 100 penalty units.

- **Clause 40** (Offences for self-prescribing or self-administering high-risk medicines) provides it is an offence to self-prescribe or self-administer high-risk medicines, without a reasonable excuse. This offence carries a maximum penalty of 100 penalty units.
- **Clause 41** (Restrictions for monitored medicines) requires prescribers and dispensers to check the database before prescribing, supplying, dispensing or giving a treatment dose of a monitored medicine to a person. A maximum penalty of 20 penalty units applies for noncompliance with these requirements.
- **Clause 42** (Offence to dispose of waste from S8 medicine) makes it an offence to dispose of waste from an S8 medicine unless the person disposes of the waste by giving it to an appropriate person, disposes of the waste in the authorised way or has a reasonable excuse. This offence carries a maximum penalty of 200 penalty units.

Comment – medicines offences

The explanatory notes do not make any comment on these offences other than the following, regarding clause 42:

The unsafe disposal of waste from regulated substances may pose a risk to public health and safety if, for example, the waste contaminates the environment or, in the case of substances that have a high value on the illicit drug market, the waste comes into the possession of an unauthorised person. Improper disposal may allow a person to collect residual amounts of hazardous poisons from used containers and use it for unauthorised dealings. This offence carries a maximum penalty of 200 penalty units. The maximum penalty of 200 penalty units is considered proportionate to the offence noting the seriousness of the conduct it applies to. Similar offences, also carrying a penalty of 200 penalty unit, are included in, for example section 296 and 297 of the Waste Reduction and Recycling Act 2011.¹³³

Poisons and pest management offences

There is a maximum penalty of 200 penalty units for all of the following offences.

- **Clause 43** (Offence to apply poisons) makes it an offence to apply a poison unless the person does it in the authorised way, applies the poison in accordance with the approved label, or has a reasonable excuse.
- **Clause 44** (Offence to carry out pest management activities) makes it an offence to carry out pest management activities unless the activity is carried out in the authorised way or there is a reasonable excuse.
- **Clause 45** (Offence to offer to carry out pest management activities if unauthorised) makes it an offence for a person to offer to carry out a pest management activity for a pest management business unless the person has a pest management licence, or the person employs someone else with a pest management licence to carry out the pest management activity.
- **Clause 46** (Offence to require or permit unauthorised persons to carry out pest management activities) makes it an offence for a manager to permit or require another person who they know is not authorised to carry out a pest management activity to do so unless the manager has a reasonable excuse.

¹³³ Explanatory notes, p 63.

- **Clause 47** (Offence to dispose of waste from hazardous poison, pesticide or fumigant) makes it an offence to dispose of waste from a hazardous poison, pesticide or fumigant unless the person disposes of the waste in the authorised way or has a reasonable excuse.

Comment – poisons and pest management offences

The explanatory notes justify these offences:

*Poisons, pesticides and fumigants pose a risk to human health if not used appropriately. The inclusion of offences relating to poisons and pest management is necessary to ensure that substances are used safely and effectively and do not cause harm. As with the general offences, these offences include safeguards of carrying out the activity in the authorised way. A number of the clauses also include a reasonable excuse defence.*¹³⁴

In relation to clause 47, the explanatory notes, after noting that *the unsafe disposal of waste from regulated substances may pose a risk to public health and safety*, address the penalty level in similar terms as for clause 42 (see above):

*The maximum penalty of 200 penalty units is considered proportionate to the offence noting the seriousness of the conduct it applies to... similar offences, also carrying a penalty of 200 penalty units, are included in, for example section 296 and 297 of the Waste Reduction and Recycling Act.*¹³⁵

4.5 Miscellaneous offences

There are a range of other offences in the Bill, with a maximum penalty generally of no more than 200 penalty units. (These are not further considered in this brief, but further details can be provided if required. As noted earlier, all offences are set out in the table at the end of this chapter.) Offences in this category with a higher maximum penalty include:

- **Clause 93(1)** makes it an offence for a responsible person to fail to make a substance management plan for a regulated place before any dealings happens at the place. There is a maximum penalty of 250 penalty units.
- **Clause 93(2)** provides makes it an offence not to include certain prescribed matters in a substance management plan for a regulated place (for example, the day the plan starts, the location of the place, the dealings and regulated substances to which it applies, the persons at the place whom it applies, and matters prescribed by regulation). There is a maximum penalty of 250 penalty units.
- **Clause 116** makes it an offence to fail to comply with an emerging risk declaration, unless the person has a reasonable excuse. There is a maximum penalty of 500 penalty units.
- **Clause 125** provides it is an offence to fail to comply with a recall order, unless the person has a reasonable excuse. There is a maximum penalty of 500 penalty units.

Comment – miscellaneous offences

The explanatory notes contain no specific comment on these offences and associated penalties.

General comment

Addressing the offences and penalties generally, the explanatory notes state:

The ... Bill establishes several key offences to replace more than 50 separate offences in the existing legislation relating to the manufacture, supply, possession and use of medicines and poisons.

¹³⁴ Explanatory notes, p 63.

¹³⁵ Explanatory notes, p 64.

Given the age of the existing legislation, the maximum penalties have been reviewed to better align with penalties under the Commonwealth Therapeutic Goods Act and Agricultural and Veterinary Chemicals Code Act, and other comparable legislation in Queensland and interstate.

Where an offence aligns directly to the Health (Drugs and Poisons) Regulation, the penalties remain the same under the Medicines and Poisons framework. However, due to the restructuring of the scheme, where a series of specific offences are covered by a single new offence, it was necessary for penalties to be consistent with key legislation in Queensland and other jurisdictions.¹³⁶

Some of the offences and penalty levels have been criticised in the submission from MIGA.¹³⁷

In many instances, the other Queensland offence provisions referred to in the explanatory notes as similar offences are not really useful as comparative offences, though the maximum penalty might often be the same. Some of those offences are summarised here:

- Section 24 of the *Biosecurity Act 2014* provides a penalty of 750 penalty units or 6 months imprisonment for a failure to discharge a general biosecurity obligation in relation to restricted matter. (A breach in relation to prohibited matter attracts a penalty of 1,000 penalty units or 1 year's imprisonment.)
- Section 104C of the *Fire and Emergency Services Act 1990* imposes a range of penalties on an occupier of a building who fails to maintain at all times free from obstruction adequate means of escape in the event of fire threatening any part of the building. Maximum penalties are:
 - (a) if the contravention causes multiple deaths - 2,000 penalty units or 3 years imprisonment
 - (b) if the contravention causes death or grievous bodily harm - 1,000 penalty units or 2 years imprisonment
 - (c) if the contravention causes bodily harm - 750 penalty units or 1 year's imprisonment
 - (d) otherwise - 100 penalty units.
- Section 34 of the *Coal Mining Safety and Health Act 1999* and section 31 of the *Mining and Quarrying Safety and Health Act 1999* each impose a similar range of penalties for failure to discharge a safety and health obligation, from 500 penalty units or 6 months imprisonment, through to 750 penalty units or 1 year's imprisonment if bodily harm results, to 3000 penalty units and 3 years imprisonment for multiple deaths.
- Section 168B of the *Liquor Act 1992* imposes penalties for a breach of the prohibition on possession of liquor in restricted areas: 375 penalty units for a first offence; 525 penalty units or 6 months imprisonment for a second offence; 750 penalty units or 18 months imprisonment for a third or later offence.

Committee comment

Given that the primary objective of the Bill is to ensure that any activity performed with a substance must be performed in an authorised manner,¹³⁸ the committee considers that the various offences and associated penalties are reasonable and proportionate and relevant to the conduct being proscribed.

¹³⁶ Explanatory notes, p 58.

¹³⁷ Submission 18, p 2.

¹³⁸ Dr Young, Queensland Health, Public briefing transcript, Brisbane 27 May 2019, p 2.

4.6 Administrative power

Summary of provisions

The Bill contains a number of provisions which allow for an exercise of administrative power. The committee notes that the rights, obligations and liberties of individuals dependent on administrative power only if the power is sufficiently defined and subject to appropriate review. The exercise of administrative power are noted below.

Clause 58 – power to make an emergency order

The chief executive may make an emergency order authorising a person to carry out a regulated activity with a regulated substance in relation to a biosecurity event under the *Biosecurity Act 2014*, a disaster situation under the *Disaster Management Act 2003*, a declared public health emergency under the *Public Health Act 2005*, an emergency under the *Public Safety Preservation Act 1986* or another event at a State or local level that poses a health risk, including an event that has the potential to cause human disease through exposure to infection.

Clause 69 – duration of an authority

The chief executive may decide the term of an authority.

Clause 74 – finalising a substance authority

If a person stops being the holder of a substance authority, the chief executive may give the person a notice authorising the person to carry out a stated regulated activity with the regulated substance in a stated way for a stated period.

Clause 87 – further information request

The chief executive may give an applicant for a substance authority a notice stating further information the chief executive reasonably considers is required from the applicant to decide the application.

Clause 89 – period for deciding application

The chief executive must decide an application for a substance authority on or before the final consideration day or by an agreed date decided under clause 88.

Clause 95 – definitions for part

Administrative action in relation to a substance authority means changing a condition of an authority, or suspending an authority for a stated period or indefinitely, or cancelling a substance authority.

Clause 111 – what is an emerging risk declaration

An emerging risk declaration can be made by the chief executive declaring that a substance that is not a regulated substance must not be made, sold or used in the State, the substance may only be used with a particular device or in a particular way, a particular device must not be used with the substance, or the substance must be disposed of in a particular way.

Clause 119 – chief executive may make recall order

The chief executive may make a written recall order that is directed to a responsible person who the chief executive believes is responsible for controlling the manufacture, possession or supply of the product.

Clause 121 – chief executive may make urgent recall order

The chief executive may make an urgent written recall order.

Clause 54 - authorisation of prescribed classes of persons

A regulation may prescribe a class of persons to carry out a regulated activity with a regulated substance.

Clause 232 - making extended practice authorities

The chief executive may make a document, known as an extended practice authority (EPA), stating the places or circumstances in which an approved person may deal with a regulated substance; or requiring an approved person to hold particular qualifications or training to deal with a regulated substance.

Clause 58 – chief executive may make emergency order

An emergency order may include conditions applying to the regulated activity, including the circumstances in which a person may carry out the activity.

Clause 76 – deciding initial application

The chief executive must decide whether or not to grant an initial application for a substance authority.

Clause 113 – matters to be included in emerging risk declaration

This clause sets out the matters that must be included in an emerging risk declaration, including any conditions that apply to carrying out an activity with substance.

Clause 96 – grounds for taking action

If the chief executive believes a relevant person is not a fit and proper person, this is grounds for the chief executive to take administrative action in relation to an authority.

Clause 90 – health assessment for pest management licences

The chief executive may ask an applicant for a pest management licence to undergo an assessment of their physical and mental health by a medical practitioner.

Issue of fundamental legislative principle

The reasonableness and fairness of treatment of individuals is relevant in deciding whether legislation has sufficient regard to the rights and liberties of individuals.

Legislative Standards Act 1992, section 4(2)(a) – Sufficient regard to rights and liberties of individuals - ordinary activities should not be unduly restricted.

The concept of liberty requires that an activity (including a business activity) should be lawful unless there is a sufficient reason to declare it unlawful by an appropriate authority.

Whether legislation has sufficient regard to rights and liberties of individuals depends on whether, for example, the legislation makes rights and liberties, or obligations, dependent on administrative power only if the power is sufficiently defined and subject to appropriate review:

*Depending on the seriousness of a decision and its consequences, it is generally inappropriate to provide for administrative decision-making in legislation without providing for a review process. If individual rights and liberties are in jeopardy, a merits-based review is the most appropriate type of review.*¹³⁹

Comment

The explanatory notes provide a general statement of justification for the powers listed above:

*Given the size and complexity of the scheme, the Bill contains administrative powers for the chief executive to support the operation and administration of the scheme. These powers are considered to be sufficiently defined and subject to appropriate review...*¹⁴⁰

¹³⁹ Office of the Queensland Parliamentary Counsel, *Fundamental Legislative Principles: The OQPC Notebook*, p 18.

¹⁴⁰ Explanatory notes, p 16.

Committee comment

From a general perspective, the committee is satisfied with the use of power and that the effects on an individual's rights and liberties are justified.

However some of these provisions contain more significant powers. These are now explored individually.

4.7 Recall orders

By **clause 119**, the chief executive may make a written recall order that is directed to a 'responsible person' – a stated person who the chief executive believes is responsible for controlling the manufacture, possession or supply of the product. The recall order may require the responsible person to recall the product from manufacture, possession or supply.

Failure to comply with a recall order without a reasonable excuse carries a maximum penalty of 500 penalty units (clause 125).

This is a significant power. It would affect the rights and liberties of an individual who is a responsible person by requiring them to take certain actions under the recall order, including:

- stopping the manufacture of the product
- take reasonable steps to recover the product from another person
- isolate or dispose of the product
- repackage or relabel the product, or
- publish warnings about the product.

The explanatory notes set out a number of safeguards, including:

- Before the chief executive makes a recall order, the chief executive must give the responsible person a notice, setting out the terms of the proposed order, the reasons for it, and that the person may provide written submissions within seven days (clause 120).
- After considering written submissions, the chief executive must decide whether to make the order (clause 122).

Clause 124 sets out the contents of a recall order

Clause 121 allows for the making of an urgent recall order, which can be made without first providing the responsible person with a notice under clause 120.

Committee comment

The committee considers given wider situations of public health and safety sufficient justification has been provided for the use of power and the effect on an individual's rights and liberties.

4.8 Health assessment for pest management licences

Clause 90 provides that the chief executive may ask an applicant for a pest management licence to undergo an assessment of their physical and mental health by a medical practitioner.

Requiring a person who applies for a pest management licence to undergo a health assessment of physical and mental health, could be seen as affecting a person's rights and liberties.

The explanatory notes provide the reasoning:

This [a health assessment] may be appropriate if, for example, a person applying for a pest management licence will be required to work in enclosed spaces, as a person with a permanent back injury may not be physically able to access a ceiling space to effectively undertake pest control activities... The provision is also necessary as technicians may have unsupervised access

*to domestic residences and other sensitive locations, and it is important to ensure that appropriate people are granted a licence to protect the health and safety of the public.*¹⁴¹

4.9 Emergency order

Clause 58 gives the chief executive the power to make an emergency order authorising a person to carry out a regulated activity with a regulated substance in relation to certain any of these specified events, including:

- a biosecurity event for which a biosecurity emergency order applies
- a disaster situation under the *Disaster Management Act 2003*
- a declared public health emergency under the *Public Health Act 2005*
- an emergency under the *Public Safety Preservation Act 1986*
- another event, at a State or local level, that poses a health risk, including an event that has the potential to cause human disease through exposure to infection.

The explanatory notes give various examples of when an emergency order may be required. These include:

- During an outbreak of an infectious disease, an order would provide the ability for a vaccine or medicine to be easily and quickly distributed to treat the infection and help prevent further spread of the disease.
- When there is a natural disaster and health or storage facilities are under threat of flooding, fire or other damage, an order may allow for variations to the authorised way of dealing with substances, such as different storage conditions, or creation of a temporary facility where health professionals may provide necessary care to the public.
- Following a flood event, the chief executive could authorise qualified persons who do not have a current management licence to spray mosquitoes, due to the scale of the required spraying activity and the public health risk.
- In support of a biosecurity emergency order made due to the presence of Asian honey bees (declared prohibited matter under the *Biosecurity Act 2014*), an order could allow suitable Department of Agriculture and Fisheries employees, without a pest management licence, to use specified pesticides to respond to the biosecurity event in a timely manner.¹⁴²

An emergency order could affect an individual's rights and liberties.

The explanatory notes state that the power is justified:

*... as the Bill places appropriate limits on when the order applies and under what circumstances, including that the order cannot be in place for more than three months. Subsection (2) sets out matters that must be included in the emergency order, including the event the order applies to; a description of the area the order relates to; the day the order starts and ends; the regulated activity with the regulated substance that may be carried out; the class of persons who may carry out the regulated activity; and any conditions applying to the regulated activity, including, for example, the circumstances in which a person may carry out the activity.*¹⁴³

Committee comment

The committee is satisfied that any breach of fundamental legislative principle is sufficiently justified.

¹⁴¹ Explanatory notes, p 27.

¹⁴² Explanatory notes, p 17.

¹⁴³ Explanatory notes, p 17.

4.10 Natural justice

The committee considered whether the Bill was consistent with the principles of natural justice.

Summary of provisions

A number of provisions raise issues of natural justice.

Administrative action regarding an authority

Chapter 4, part 3, of the Bill provides for the process of administrative action under the regulatory framework. Administrative action in relation to a substance authority or an approved person's authorisation means:

- changes to conditions of an authority
- suspension of an authority for a stated period or indefinitely, or
- cancellation (for a substance authority).

Clause 102 allows the chief executive to take immediate administrative action based on grounds set out in clause 96, without first giving the authority holder a show cause notice, if the chief executive considers it reasonably necessary to take the action immediately because there is an urgent need to prevent a serious health risk to any person.

Compliance notices

Under **clause 108**, the chief executive or an inspector may give a person a compliance notice requiring a person to rectify a matter. Clause 109 sets out the matters to be included in a compliance notice, including how the chief executive believes there has been a contravention of the Act.

Procedural fairness – public warnings

Clause 127 provides that the minister, chief executive or chief health officer (each is a senior administrator) may make a public statement identifying, and giving warnings or information about certain matters. This statement may identify particular contraventions, practices, offences and persons.

A senior administrator must be satisfied:

- it is in the public interest to make the statement, and
- a public statement or warning has not been made, and is not about to be made under another Act or process that is more appropriate in the circumstances

It is in the public interest if the senior administrator is satisfied the statement is reasonably necessary to prevent or minimise a health risk in relation to a regulated substance.

Issue of fundamental legislative principle

Whether legislation has sufficient regard to rights and liberties of individuals depends on whether, for example, the legislation is consistent with principles of natural justice.¹⁴⁴

These principles have been developed by the common law and include the following:

- nothing should be done to a person that will deprive them of a right, interest, or legitimate expectation of a benefit without the person being given an adequate opportunity to present their case to the decision-maker
- the decision-maker must be unbiased

¹⁴⁴ *Legislative Standards Act 1992*, section 4(3)(b).

- procedural fairness should be afforded to the person, including fair procedures that are appropriate and adapted to the circumstances of the particular case.¹⁴⁵

4.10.1 Administrative action

Under these provisions, the chief executive may take administrative action to suspend the authority indefinitely or change the conditions of the authority. By way of background, clause 96 sets out the criteria for the process of administrative action. The chief executive action may take administrative action if the chief executive has a reasonable belief of certain matters:

- a relevant person for an authority has contravened a requirement under this Act or a corresponding law
- the administrative action is reasonably necessary to prevent or minimise a health risk
- a relevant person for the authority is not a fit and proper person, or
- a relevant person for the authority has made a materially false or misleading representation to obtain the authority.

Clause 100 provides that the chief executive can take administrative action, once a show cause period has ended and after consideration of any written response made, if the chief executive believes there is a ground to do so. (Clause 97 requires the chief executive to give an authority holder a show cause notice if they are proposing to take administrative action. The notice must give the authority holder the opportunity to give a written response. Clause 98 requires the chief executive to consider the written response.)

By contrast, clause 102 allows the chief executive to take *immediate* administrative action based on the criteria in clause 96, without first giving a show cause notice.

The explanatory notes provide the following justification in relation to immediate action under clause 102:

*The power is justified noting the high bar for immediate administrative action – the chief executive is required to consider immediate administrative action is reasonably necessary because there is an urgent need to prevent a serious health risk to any person.*¹⁴⁶

In relation to administrative action under clause 100 or 102, the explanatory notes provide:

*If the chief executive decides to take administrative action under clause 100 or 102, they must give the authority holder an information notice. This means that the chief executive's decisions under these clauses are subject to internal review. An affected person may apply to QCAT for external review if a decision on an application for internal review of the decision has been made.*¹⁴⁷

Clause 102 provides an authority holder with notice of action to be taken, an opportunity for the authority holder to respond, a notice setting out the decision, and an opportunity to review the decision.

Committee comment

The committee is satisfied that any breach of fundamental legislative principle has been sufficiently justified.

¹⁴⁵ Office of the Queensland Parliamentary Counsel, *Fundamental Legislative Principles: The OQPC Notebook*, p 25.

¹⁴⁶ Explanatory notes, p 30.

¹⁴⁷ Explanatory notes, p 31.

4.10.2 Compliance notices

Compliance notices may be issued to a person where the chief executive or an inspector reasonably believes:

- the person has contravened a provision of the Act in circumstances that make it likely the contravention will continue to be repeated
- a matter relating to the contravention is reasonably capable of being rectified, and
- it is appropriate to give the person an opportunity to rectify the matter.

The explanatory notes state:

*The compliance provisions are considered to be consistent with the principles of natural justice as they provide clear criteria for when the chief executive or an inspector may give a compliance notice and provide the person with an opportunity to rectify the matter.*¹⁴⁸

The provisions provide a person with a compliance notice that contains the reasons the chief executive or officer believes there has been a contravention. It also provides the person with an opportunity to rectify the matter.

4.10.3 Public warning statements

A public statement of warning may identify particular individuals in relation to contraventions of the Act, unlawful practices and offences committed against a relevant law. Clause 127 provides that no liability is incurred by the State for the making of the statement in good faith.

An individual that is named is not given the opportunity to provide contrary reasons for their behaviours. This could be seen to be a denial of a person's right to procedural fairness.

The explanatory notes state that any potential breach of fundamental legislative principle is considered justified on the basis that:

*... publication is restricted to matters that are in the public interest which may include, but are not limited to, preventing or minimising a health risk. As the senior administrator is required to be satisfied that publication is in the public interest, the circumstances covered by this clause are inherently serious and with potentially serious public health consequences.*¹⁴⁹

The explanatory notes set out a further safeguard:

*Given the significance of this power to make a public statement and to address related FLP issues, this power is not able to be delegated by the chief executive (see clause 238 (Delegation by chief executive)). This means the power is only able to be exercised by the Minister, chief executive or chief health officer.*¹⁵⁰

Committee comment

This is a significant power, only able to be used by a senior administrator and in relation to serious matters.

The committee acknowledges that a public statement of warning which may identify particular individuals is a significant power but is sufficiently justified by the reasons for this power.

¹⁴⁸ Explanatory notes, p 32.

¹⁴⁹ Explanatory notes, p 33.

¹⁵⁰ Explanatory notes, p 33.

4.11 Onus of proof

The committee considered whether the Bill reverses the onus of proof in criminal proceedings without adequate justification.

Summary of provisions

Executive officer may be taken to have committed an offence

Clause 214 provides that if a corporation commits an offence against a serious offence provision, each executive officer of the corporation is taken to have also committed the offence if:

- a) they authorised or permitted the corporation's conduct constituting the offence, or
- b) they were knowingly concerned, either directly or indirectly, in the corporation's conduct.

Proceedings may be taken against an executive officer, and they may be convicted of the offence, whether or not the corporation has been proceeded against or convicted of the offence.

Evidentiary provisions

Clause 208 provides that a certificate purporting to be signed by the chief executive stating a range of matters is evidence of the matter, for example, that a stated document is a departmental standard.

Clause 209 provides that a particular substance is a regulated substance of the same type as a regulated substance commonly supplied under the same name, description or labelling as the particular substance.

These clauses set out evidentiary presumptions that will be applicable to legal proceedings under the Act.

Such evidentiary aids clauses involve a reversal of the onus of proof.

Issue of fundamental legislative principle

Whether legislation has sufficient regard to rights and liberties of individuals depends on whether, for example, the legislation does not reverse the onus of proof in criminal proceedings without adequate justification.¹⁵¹

Legislation should not reverse the onus of proof in criminal matters, and it should not provide that it is the responsibility of an alleged offender in court proceedings to prove innocence:

*For a reversal to be justified, the relevant fact must be something inherently impractical to test by alternative evidential means and the defendant would be particularly well positioned to disprove guilt.*¹⁵²

4.11.1 Executive officer offences

The explanatory notes state that clause 214 is justified, and moreover, does not involve a reversal of the onus:

This provision is considered justified as the executive officer is taken to have committed the offence only where they authorised or permitted the corporation's conduct or were, directly or indirectly, knowingly concerned in the conduct. This is not considered to be a reverse onus of proof, as the State would have the burden of proving that the officer authorised or permitted the conduct, or was knowingly concerned in it ... This type of provision requires the prosecution to

¹⁵¹ *Legislative Standards Act 1992*, section 4(3)(d).

¹⁵² Office of the Queensland Parliamentary Counsel, *Fundamental Legislative Principles: The OQPC Notebook*, p 36.

*prove that the individual knew the essential facts that constitute the corporate offence, and through their own act or omission, was a participant in that offence.*¹⁵³

The *Personal Liability for Corporate Fault - Guidelines for applying the COAG Principles* explain the effect on the onus of proof of provisions such as clause 214:

A variety of statutory provisions exist that provide for a director or other officer to be liable if they were personally and directly complicit as an accessory in the corporation's offence.

There are numerous variations in the drafting of these provisions, depending upon the particular words used. For example, some provisions require proof that the director "aided, abetted, counselled or procured" the corporation's offence; others that the director "knowingly authorised or permitted" or was "knowingly involved" or "knowingly concerned" in the offence.

What is common to all of these provisions is that, for the director to be held liable, the prosecution must prove that the individual personally participated in the corporate contravention as an accessory. This requires proof, beyond reasonable doubt, that the individual knew the essential facts that constitute the corporate offence and, through his or her own act or omission, was a participant in that offence.

*Normal accessorial liability provisions of this type are not objectionable in principle...*¹⁵⁴

A somewhat similar provision is discussed in the OQPC guide on onus of proof. Clause 164 of the Economic Development Bill 2012 provided that, if a corporation committed an offence, an executive officer of the corporation would also commit an offence unless he or she took all reasonable steps to ensure the corporation did not engage in the offending conduct.

The guide quotes from the consideration of clause 164 in the relevant portfolio committee's report on that Bill:

*... this provision does not directly reverse the onus of proof (i.e. it is not expressly couched as putting the onus on the accused officer to prove they took reasonable steps, as occurs in some pieces of legislation) and it appears to still be for the prosecution to establish to the criminal standard of proof (beyond reasonable doubt) that reasonable steps were not taken by the officer.*¹⁵⁵

It can also be noted that clause 214 essentially replicates the current section 153ZN of the Health Act. (The only difference of substance is that the Health Act provision applies to any offence committed by a corporation under that Act, whereas the scope of clause 214 is narrower, applying only to specified serious offences.)

Committee comment

Given the explanation the committee is satisfied with this provision, in the context of fundamental legislative principles.

4.11.2 Evidentiary provisions

As noted, clauses 208 and 209 are evidentiary presumptions which effectively reverse the onus of proof by placing the onus on a defendant to rebut the presumption established.

¹⁵³ Explanatory notes, p 36.

¹⁵⁴ *Personal Liability for Corporate Fault - Guidelines for applying the COAG Principles*, p 2. Accessed at arp.nsw.gov.au/sites/default/files/Personal_Liability_for_Corporate_Fault_-_Guidelines_for_Applying_the_COAG_Principles.pdf

¹⁵⁵ Office of the Queensland Parliamentary Counsel, *Principles of good legislation: OQPC guide to FLPs - Reversal of onus of proof*, legislation.qld.gov.au/file/Leg_Info_publications_FLP_Reversal_of_Onus1.pdf at p 20, referring to the State Development, Infrastructure and Industry Committee, *Economic Development Bill 2012*, report no 15, November 2012, at p 39.

The explanatory notes state that these clauses:

*... are considered appropriate to remove an unnecessary administrative burden for the prosecution to prove administrative, technical and scientific matters that are unlikely to be in dispute in proceedings. This makes efficient use of a court's time and streamlines proceedings.*¹⁵⁶

Further, the explanatory notes state clause 209:

*... is considered justified as the Poisons Standard and assessments undertaken by the Australian Pesticides and Veterinary Medicines Authority (APVMA) contain very specific labelling requirements for regulated substances to manage public health risk associated with their use. There is therefore an expectation that businesses will be truthful in the labelling of their products to avoid public health risk or misleading users regarding the efficacy of their product. The evidence provision allows the identity of the substance to be inferred without needing to analyse every container of the substance subject to the legal proceedings.*¹⁵⁷

Committee comment

Provisions that provide for the use of evidentiary certificates clauses are relatively common and can enhance administrative and court efficiency. The use of evidentiary aids enables an administering authority to put evidence before courts about a range of non-contentious matters without the need to call witnesses. An individual can still submit material to rebut the evidence if desired.

The committee is satisfied that any reversal of the onus of proof in these provisions is sufficiently justified.

4.11.3 Reasonable excuse provisions

Summary of provisions

As mentioned, the Bill creates many offences. A large number of these make it an offence for a person to do certain acts unless the person 'has a reasonable excuse'.

Some examples include clauses 33 to 38, 40 to 44, 46 and 47. In some cases the clause gives an example of what would, or would not, constitute a reasonable excuse.

Comment

Generally, in criminal proceedings:

- the legal onus of proof lies with the prosecution to prove the elements of the relevant offence beyond reasonable doubt, and
- the accused person must satisfy the evidential onus of proof for any defence or excuse he or she raises and, if the accused person does satisfy the evidential onus, the prosecution then bears the onus of negating the excuse or defence beyond reasonable doubt.¹⁵⁸

Such 'reasonable excuse' provisions are discussed in some detail in the Office of the Queensland Parliamentary Counsel, *Principles of good legislation: Reversal of onus of proof*. That discussion starts with the following:

If legislation prohibits a person from doing something 'without reasonable excuse' it would seem in many cases appropriate for the accused person to provide the necessary evidence of the reasonable excuse. While there is no Queensland case law directly on point, the Northern Territory Supreme Court has held that the onus of proving the existence of a reasonable excuse

¹⁵⁶ Explanatory notes, p 37.

¹⁵⁷ Explanatory notes, p 37.

¹⁵⁸ See Office of the Queensland Parliamentary Counsel, *Principles of good legislation: Reversal of onus of proof*, p 3, at legislation.qld.gov.au/file/Leg_Info_publications_FLP_Reversal_of_Onus1.pdf

rested with the defendant on the basis that the reasonable excuse was a statutory exception that existed as a separate matter to the general prohibition... That approach is consistent with the principles used to determine whether a provision contains an exception to the offence or whether negating the existence of the reasonable excuse is a matter to be proved by the prosecution once the excuse has been properly raised ...

... [It] is understood that in Queensland, 'reasonable excuse provisions' are drafted on the assumption that the Justices Act 1886, section 76 will apply and place both the evidential and legal onus on the defendant to raise and prove the existence of a reasonable excuse. On the other hand, ... departments have often taken the view in their Explanatory Notes that a provision containing an exemption where a reasonable excuse exists is an excuse for which only the evidential onus lies with the accused.¹⁵⁹

[There follows some examples where departments have disagreed with the view (expressed by the former Scrutiny of Legislation Committee) that reasonable excuse provisions involve a reversal of the onus of proof.]

The OQPC discussion concludes:

It seems likely that in most cases a reasonable excuse will constitute a statutory exception to be proved by the defendant. However, in the absence of an express statement as to the allocation of the onus, the question will ultimately need to be determined by a court having regard to the established rules of statutory interpretation.¹⁶⁰

Elsewhere, the OQPC has noted:

Generally, for a reversal to be justified, the relevant fact must be something inherently impractical to test by alternative evidential means and the defendant would be particularly well positioned to disprove guilt.

For example, if legislation prohibits a person from doing something 'without reasonable excuse', it is generally appropriate for a defendant to provide the necessary evidence of the reasonable excuse if evidence of the reasonable excuse does not appear in the case for the prosecution.¹⁶¹

In the present case, the explanatory notes for the Bill are silent on the issue. In considering the issue regarding similar provisions in other Bills, explanatory notes justify the reversal of the onus of proof on the basis that establishing the defence would involve matters which would be within the defendant's knowledge and/or on which evidence would be available to them.¹⁶²

Committee comment

These provisions may be seen to reverse the onus of proof. All these offences provide that a person does not commit an offence if the person has a reasonable excuse. The person bears the onus of proof to show that they had a reasonable excuse.

The committee considers any breach of fundamental legislative principle in the various 'reasonable excuse' provisions is sufficiently justified.

¹⁵⁹ See Office of the Queensland Parliamentary Counsel, *Principles of good legislation: Reversal of onus of proof*, p 25, at legislation.qld.gov.au/file/Leg_Info_publications_FLP_Reversal_of_Onus1.pdf

¹⁶⁰ Office of the Queensland Parliamentary Counsel, *Principles of good legislation: Reversal of onus of proof*, p 26.

¹⁶¹ See the Office of the Queensland Parliamentary Counsel, *Fundamental Legislative Principles: the OQPC Notebook*, p 36.

¹⁶² For a recent example, see Fisheries (Sustainable Fisheries Strategy) Amendment Bill 2018, explanatory notes, p17.

4.12 Power to enter premises

Summary of provisions

Chapter 5, parts 2 to 5, provide for a wide range of powers for inspectors.

Clause 140 is a power of entry provision. Entry can be by consent of the occupier or upon warrant but neither consent nor a warrant is required:

- if it is a public place, during times it is open to the public
- if it is a professional practice place of a person authorised under the Act, at times it is open for business or otherwise open for entry
- if it is an authorised place which is required to be open for inspection as a condition of that authorisation, or
- if entry is to check whether a compliance notice or a recall order has been complied with.

None of these listed situations authorise entry to premises used as a residence. The Bill provides that any consent must be an informed consent.

Clause 154 gives an inspector power to direct a person to stop, move, or not move a vehicle if the inspector reasonably suspects, or is aware, that a thing in or on a vehicle may provide evidence of the commission of an offence against the Act.

Inspectors have a range of powers which they can exercise after an entry which is made by consent, authorised under a warrant, to a professional practice place that is open for carrying on business or otherwise open for entry, or to an authorised place that is required to be open for inspection as a condition of the authorisation of the place.

Clause 158 provides that an inspector may search, inspect, examine, film, take a thing for examination, place an identifying mark, take an extract or copy from a document, produce an image from an electronic document and remain at the place for the time necessary to achieve the purpose of the entry.

If an inspector takes a document from the place to copy it, they must return it to the place as soon as practicable. If an inspector takes an article or device from the place that is reasonably capable of producing a document from an electronic document, they must produce the document and return the article or device to the place as soon as practicable.

Clause 159 provides that an inspector may make a ‘help requirement’ of an occupier or person at the place to give the inspector reasonable help to exercise a general power, including, for example, to produce a document or give information. (A failure to comply without a reasonable excuse carries a maximum penalty of 50 penalty units.)

Clause 161 empowers an inspector who enters a place without either consent or a warrant to seize a thing, based on a ‘reasonable suspicion’ that the thing is evidence of an offence against the Act.

Clause 162 allows an inspector who is authorised to enter a place with consent or by warrant to seize a thing if they reasonably suspect the thing is evidence of an offence against the Act and the seizure is consistent with the purpose of entry. The inspector may also seize anything else at the place if the inspector reasonably suspects the thing is evidence of an offence against the Act and the seizure is necessary to prevent the thing being hidden, lost or stolen, or if the inspector reasonably suspects the thing has just been used in committing an offence against the Act.

Clause 175 provides an inspector with the power to require a person to provide their name and residential address:

- if the inspector finds the person committing an offence against the Act

- in circumstances that lead the inspector to reasonably suspect the person has just committed an offence against the Act, or
- the inspector has information that leads the inspector to reasonably suspect an offence has just been committed.

The reasonable suspicion threshold is included for name and address powers across a range of Acts. Failure to comply with the requirement without a reasonable excuse carries a maximum penalty of 50 penalty units (clause 176). This power is justified as in order to effectively undertake compliance with the scheme, inspectors require correct information about persons found to be committing, or suspected of committing, an offence. Appropriate safeguards are included, with the inspector required to give the person an offence warning for the requirement.

Clause 177 empowers an inspector to require a person to make available for inspection or produce a document required to be kept by the person under the Act or a document given to the person under the Act. The inspector may copy the document, and require the person responsible for keeping the document to certify the copy as a true copy.

[The offences of contravention of a document production requirement and a document certification requirement, established by clauses 178 and 179 respectively, are considered in the next section, in the context of the privilege against self-incrimination.]

Clause 180 provides that an inspector may require a person to provide information to the inspector related to an offence by a stated reasonable time, if the inspector reasonably believes an offence against the Act has been committed and the person may be able to give information about the offence.

Issue of fundamental legislative principle

Whether legislation has sufficient regard to the rights and liberties of the individual depends on whether, for example, it confers power to enter premises and search for or seize documents or other property, only with a warrant issued by a judge or other judicial officer.¹⁶³

Comment

Power to enter premises should generally be permitted only with the occupier's consent or under a warrant issued by a judge or other judicial officer. Legislation should confer power to enter premises, and search for or seize documents or other property, only with a warrant issued by a judge. This principle supports a long established rule of common law that protects the property of citizens.¹⁶⁴

Strict adherence to the principle may not be required if the premises are business premises operating under a licence or premises of a public authority.

As already noted, the Bill provides that any consent must be an informed consent, and entry of premises used as a residence can only be by consent or upon warrant.

A possible concern in this context is the range of additional powers that can become exercisable after entry without a warrant or consent.¹⁶⁵ In this Bill, once a power of entry is exercised, many other powers flow, including search and seizure powers and provisions for possible forfeiture of property to the State.

¹⁶³ *Legislative Standards Act 1992*, s 4(3)(e).

¹⁶⁴ Office of the Queensland Parliamentary Counsel, *Fundamental Legislative Principles: The OQPC Notebook*, p 44.

¹⁶⁵ Alert Digest 2004/5, p 31, paras 30-36; Alert Digest 2004/1, pp 7-8, paras 49-54; Alert Digest 2003/11, pp 20-21, paras 14-19; Alert Digest 2003/9, p 4, para 23 and p 31, paras 21-24; Alert Digest 2003/7, pp 34-35, paras 24-27; cited in Office of the Queensland Parliamentary Counsel, *Fundamental Legislative Principles: The OQPC Notebook*, p 45.

One must be even more mindful of ensuring there is due regard for rights and liberties in such circumstances:

*Fundamental legislative principles are particularly important when powers of inspectors and similar officials are prescribed in legislation because these powers are very likely to interfere directly with the rights and liberties of individuals.*¹⁶⁶

*Residential premises should not be entered except with consent or under a warrant or in the most exceptional circumstances.*¹⁶⁷

The explanatory notes see the various powers as supporting an inspector's ability to undertake monitoring and compliance activities. They give this justification for the power to make a help requirement:

*This power is justified as it enables the inspector to carry out their duties. Appropriate safeguards have been included, as the inspector must give the person an offence warning for the help requirement ... and a person may have a reasonable excuse for not complying. It is a reasonable excuse not to comply with a help requirement if complying might tend to incriminate the individual or expose them to a penalty. However, the reasonable excuse does not apply if a document or information that is the subject of the help requirement is required to be held or kept by the person under the Act.*¹⁶⁸

The explanatory notes give this justification for the power to seize evidence or property:

*These powers are necessary to ensure enforcement of the scheme noting that these types of powers improve public health and safety by, for example, halting dangerous processes, securing dangerous substances, or ensuring evidence is not lost so that prosecutions may be undertaken. For example, if a retailer was selling a sports supplement containing a regulated substance that is harmful to human health, and the inspector was not able to seize the product, the retailer could continue to sell the product, exposing the public to health risks, or death, caused by the substance.*¹⁶⁹

The OQPC Notebook states:

*FLPs are particularly important when powers of inspectors and similar officials are prescribed in legislation because these powers are very likely to interfere directly with the rights and liberties of individuals.*¹⁷⁰

Clauses 161 and 162 regarding powers of seizure require a threshold of a 'reasonable suspicion' on the part of the inspector. The corresponding current provisions in the Health Act and the Pest Management Act require a higher threshold of a 'reasonable belief'.¹⁷¹ The explanatory notes address this reduced threshold at length:

It is considered that the threshold of 'reasonable suspicion' under the Bill is justified because it may be critical for public health and safety to seize evidence of an offence against the Act. For example, it may be vital that a dangerous substance is seized to prevent it from being distributed,

¹⁶⁶ Office of the Queensland Parliamentary Counsel, *Fundamental Legislative Principles: The OQPC Notebook*, p 45.

¹⁶⁷ Office of the Queensland Parliamentary Counsel, *Fundamental Legislative Principles: The OQPC Notebook*, p 46.

¹⁶⁸ Explanatory notes, p 42.

¹⁶⁹ Explanatory notes, p 42.

¹⁷⁰ Office of the Queensland Parliamentary Counsel, *Fundamental Legislative Principles: The OQPC Notebook*, p 45.

¹⁷¹ See sections 153A and 153B of the *Health Act 1937* and sections 72 and 73 of the *Pest Management Act 2001*.

or to prevent a person who is in illegal possession of a dangerous substance from disposing of that substance (for example a dangerous poison) so as to get rid of evidence, and the disposal method might prove dangerous to the environment and/or human health. An inspector may be unable to determine exactly what a substance is or contains on first inspection, with most substances requiring analysis before an inspector is able to reasonably believe it is or contains a particular substance. Therefore, at the time of seizure, it is generally only possible for an inspector to have a reasonable suspicion based on the ingredients listed on the label or information from similar products.

A threshold of reasonable belief requires the inspector to believe the thing is evidence of an offence on grounds that are reasonable in the circumstances. A reasonable belief requires knowledge of facts, although an inspector may not be in possession of all of the facts when monitoring compliance with the Bill information from similar products...

This causes practical difficulties for inspectors, as it is not possible to carry out testing of the evidence without first seizing it, as the facilities used to test these types of substances are not mobile. Without the ability to seize a thing based on reasonable suspicion, the potentially harmful substance would remain in the possession of its owner and potentially be available to the public.

Although the reasonable belief threshold requires a basis in fact, a threshold of reasonable suspicion allows an inspector to suspect the thing is evidence on grounds that are reasonable in the circumstances and that would also seem reasonable to others. This would enable an inspector to form a reasonable suspicion based on a range of factors.¹⁷²

In summary:

A reasonable suspicion threshold is appropriate in a medicines and poisons context because of the nature of the substances being regulated. Firstly, it is often impossible to gather facts required to hold a reasonable belief because the substances may not be identifiable by observation alone. Frequently, scientific analysis is required, and this can only be done through seizing the substance. Secondly, for regulated substances, there may be a danger of significant public or environmental harm if the suspected substance is not seized.¹⁷³

The justifications in the explanatory notes for the powers under clauses 175, 177, and 180 can be summed up as regarding the powers as necessary for inspectors to be able to ‘effectively undertake enforcement of the scheme’.¹⁷⁴

Committee comment

The Bill provides for powers of entry, and a wide range of consequential powers, including powers of search and seizure and potential forfeiture of property, which are not subject to consent or warrant.

The committee is concerned in regard to the reduced threshold of a ‘reasonable suspicion’.

However, the committee considers these powers (and the breach of fundamental legislative through the infringements on the rights and liberties of individuals that are involved) are justified in the effectively undertake enforcement of the scheme.

¹⁷² Explanatory notes, p 43.

¹⁷³ Explanatory notes, p 43.

¹⁷⁴ Explanatory notes, pp 46 and 47.

4.13 Protection against self-incrimination

Summary of provisions

Clause 178 (Offence to contravene document production requirement) and **clause 179** (Offence to contravene document certification requirement) provide that it is not a reasonable excuse for a person to fail to comply with a document production or document certification requirement on the basis that complying with the requirement might tend to incriminate the person or expose the person to a penalty.

These are penal provisions, with a maximum penalty of 50 penalty units in each case.

Issue of fundamental legislative principle

Section 4(3)(f) of the *Legislative Standards Act 1992* provides that whether legislation has sufficient regard to the rights and liberties of the individual depends on whether, for example, it provides appropriate protection against self-incrimination.

Comment

The principle that legislation should provide appropriate protection against self-incrimination:

... has as its source the long established and strong principle of common law that an individual accused of a criminal offence should not be obliged to incriminate himself or herself.¹⁷⁵

*Provisions denying the privilege [against self-incrimination] are rarely essential to the operation of legislation, although there is a perception that they are essential.*¹⁷⁶

Denial of the protection afforded by the privilege against self-incrimination is only potentially justifiable if:

- the questions posed concern matters that are peculiarly within the knowledge of the persons to whom they are directed and that would be difficult or impossible to establish by any alternative evidential means
- the legislation prohibits use of the information obtained in prosecutions against the person
- in order to secure this restriction on the use of the information obtained, the person should not be required to fulfil any conditions (such as formally claiming a right).¹⁷⁷

The explanatory notes state:

*The former Scrutiny of Legislation Committee considered that it may be easier to justify the abrogation of the privilege against self-incrimination if a person is required to produce documents required to be issued or kept under an Act. Similarly, the Queensland Law Reform Commission, in its 2004 report, *The Abrogation of the Privilege Against Self-Incrimination*, noted that by participating in a statutory scheme, such as through obtaining a licence or other form of registration, a person has, as a condition of participation, accepted the enforcement provisions and waived the benefit of the privilege against self-incrimination. The Commission also observed that to allow a claim of privilege in relation to records of this type would thwart the purpose of*

¹⁷⁵ Office of the Queensland Parliamentary Counsel, *Fundamental Legislative Principles: The OQPC Notebook*, p 52.

¹⁷⁶ Office of the Queensland Parliamentary Counsel, *Fundamental Legislative Principles: The OQPC Notebook*, p 52.

¹⁷⁷ Scrutiny of Legislation Committee, *Alert Digest* 1 of 2000, p 7, para 57; *Alert Digest* 13 of 1999, p 31; and *Alert Digest* 4 of 1999, p 9, para 1.60.

*the legislation, since it would facilitate a failure to keep the records, or their destruction or falsification, with little fear of detection.*¹⁷⁸

The reference in the explanatory notes to the Queensland Law Reform Commission's report 59 warrants some examination.¹⁷⁹ The QLRC observed:

Abrogation [of the privilege] ... may also be justified in a situation where an individual is required to co-operate with a legislative regulatory system to which the individual has voluntarily subjected himself or herself.

For example, some regulated activities require government authorisation in the form of a licence or permit in order to engage lawfully in that activity. There is a persuasive argument that society is entitled to insist on the provision of certain information from those who voluntarily submit themselves to such a regulatory scheme. The basis of the argument is that participation in the scheme is a matter of choice and, if undertaken, necessarily involves acceptance of submission to the requirements of the scheme, including compulsion to provide information. In other words, in some situations, participation in a regulated activity may be considered to amount to a waiver of privilege. This may be particularly so in the context of records that are required to be kept as part of a mechanism for ensuring compliance within a regulatory framework.

*A regulatory authority's need to secure compliance with the requirements of a legislative scheme is likely to be of particular relevance in relation to the abrogation of the penalty privilege.*¹⁸⁰

It should be noted that the QLRC continued:

*However, the Commission is concerned that the argument that voluntary submission to a regulatory scheme justifies abrogation should not be taken too far. There are many activities that are government regulated, and while, in theory, participation in these activities is voluntary, often they are activities that are an essential part of daily life.*¹⁸¹

In light of the content quoted in these extracts, the matters referred to in the explanatory notes are perhaps more accurately categorised as 'arguments' considered by the QLRC.

In any event, the committee considers the abrogation of the privilege in the Bill and the breach of fundamental legislative principle is justified in this instance. The explanatory notes give this justification:

The documents required to be produced under clauses 178 and 179 are documents given to the person under the Act or documents required to be kept under the Act ...

*Without cooperation by the person who has been given or is required to keep a document under the Act, it would not be possible for the inspector to gather relevant information by alternative means.*¹⁸²

...

This potential breach is considered justified as the provisions enable inspectors to enforce the framework - if they were not able to request documentation on the grounds it might incriminate, their enforcement capability would be compromised.

¹⁷⁸ Explanatory notes, p 47.

¹⁷⁹ On this aspect, see also the discussion by the Transport and Public Works Committee in its report *Plumbing and Drainage Bill 2018*, Report No. 3, 56th Parliament, April 2018, at pp 58-9.

¹⁸⁰ Queensland Law Reform Commission, report 59, *The Abrogation of the Privilege against Self-Incrimination*, December 2004, pp 54-55.

¹⁸¹ Queensland Law Reform Commission, report 59, *The Abrogation of the Privilege against Self-Incrimination*, December 2004, p 55.

¹⁸² Explanatory notes, p 47.

*If inspectors are not able to obtain such documents on the grounds that the authority holder may self-incriminate themselves, an inspector would not be able to identify and act on non-compliance with the person's conditions of authority.*¹⁸³

In this context, one can note the further commentary from the QLRC report:

It can also arise in the context of a legislative regulatory scheme, where one of the requirements of participation in the regulated activity is the keeping of specified records. In such a situation, it might be argued that the keeping and production on demand of the records are conditions of authorisation to participate in the activity in question, and that participation therefore involves the waiver of the right to refuse to produce the records on the grounds of self-incrimination or self-exposure to a penalty. It might also be argued that to allow a claim of privilege in relation to such records would thwart the purpose of the legislation, since it would facilitate a failure to keep the records, or their destruction or falsification, with little fear of detection. These considerations have given rise to an argument that there may be a case for abrogating the privileges in relation to certain documents:

*Plainly enough the case for protecting a person from compulsion to make an admission of guilt is much stronger than the case for protecting a person from compulsion to produce books or documents which are in the nature of real evidence of guilt and not testimonial in character.*¹⁸⁴

One can also note the provisions of clause 188, referred to in the explanatory notes:

*An appropriate safeguard is provided in clause 188 (Evidential immunity for individuals complying with particular requirements), which states that evidence of the information or document given under clauses 159 (Power to require reasonable help) or 177 (Power to require production of document), and other evidence directly or indirectly derived from the information or document, is not admissible against the individual in any proceeding to the extent it tends to incriminate the individual, or expose the individual to a penalty, in the proceeding.*¹⁸⁵

Committee comment

The committee considers the breach of fundamental legislative principle occasioned by the abrogation of the privilege against self-incrimination is justified.

4.14 Institution of Parliament

4.14.1 Scrutiny of the Legislative Assembly

Pursuant to section 4(4)(b) *Legislative Standards Act 1992* the committee considered whether the Bill sufficiently subject the exercise of a proposed delegated legislative power (instrument) to the scrutiny of the Legislative Assembly.

Summary of provisions

The Bill includes numerous references to a range of external documents such as codes, guidelines, protocols or standards.

¹⁸³ Explanatory notes, p 48.

¹⁸⁴ Queensland Law Reform Commission, report 59, *The Abrogation of the Privilege against Self-Incrimination*, December 2004, pp 37, quoting from *Environment Protection Authority v Caltex Refining Co Pty Ltd* (1993) 178 CLR 477 (per Mason CJ and Toohey J at 503).

¹⁸⁵ Explanatory notes, p 48.

Clause	External document referenced
10, 11, 12, 13, 15, 16	Standard for the Uniform Scheduling of Medicines and Poisons (Poisons Standard)
14	Meaning of fumigant and pesticide are substances approved for use by the APVMA
52	Clinical trials approved by a Human Research Ethics Committee (HREC)
10 – meaning of substance	A substance may be described by reference to the Poisons Standard, as well as to codes, guidelines, protocols or other standards.
54 – authorisation of prescribed classes of persons	Requirements for approved persons can be prescribed by regulation. These requirements may include that an approved person complies with an EPA, code, guideline, protocol or standard.
70 - conditions	A regulation may prescribe standard conditions for a substance authority by reference to a code, guideline, protocol or standard, including departmental standard.
232 – making extended practice authorities	The chief executive may make an EPA stating the places and circumstances in which an approved person may deal with a regulated substance, imposing conditions on dealing with a regulated substance or requiring an approved person to hold particular qualifications or training to deal with a regulated substance.
233 – making departmental standards	The chief executive may make a standard about carry out a regulated activity with a regulated substance and other matters relating to the purposes and administration of the Act.
76 – deciding initial application	Sets out the matters the chief executive may have regard to when deciding whether or not to grant an application for a substance authority.

Issue of fundamental legislative principle

Whether subordinate legislation has sufficient regard to the institution of parliament depends on whether the subordinate legislation allows the sub-delegation of a power delegated by an Act only:

- if authorised by an Act, and
- in appropriate cases and to appropriate persons.¹⁸⁶

The significance of dealing with such matters other than by subordinate legislation is that, since the relevant document is not 'subordinate legislation', it is not subject to the tabling and disallowance provisions in Part 6 of the *Statutory Instruments Act 1992*.

Where there is, incorporated into the legislative framework of the State, an extrinsic document that is not reproduced in full in subordinate legislation, and where changes to that document can be made without the content of those changes coming to the attention of the House, it may be argued that the

¹⁸⁶ Section 4(5)(e) of the *Legislative Standards Act 1992*.

document (and the process by which it is incorporated into the legislative framework) has insufficient regard to the institution of Parliament.

Comment

In considering whether it is appropriate for matters to be dealt with by an instrument that was not subordinate legislation, and therefore not subject to parliamentary scrutiny, committees have considered the importance of the subject dealt with, the commercial or technical nature of the subject-matter, and the practicality or otherwise of including those matters entirely in subordinate legislation.¹⁸⁷

The explanatory notes provide the following general justification:

*Reference to external documents throughout the framework is considered justified noting the detailed, technical and clinical nature of the matters contained in the external documents, and the flexibility this provides the scheme to remain up to date with current practices and requirements. If the matters referenced in external documents were contained in the Bill or regulations, they would regularly be out of date and not reflect changing practices, substances and activities.*¹⁸⁸

In relation to the schedule 1 definitions being prescribed by regulation, the explanatory notes state:

It is considered necessary to define monitored medicines and diversion-risk medicines in regulation because the evolutionary nature of drug development means that new substances with a potential for diversion for illicit use are regularly developed or identified. In addition, the process of drug use evaluation frequently identifies new risks with existing medicines. For example, quetiapine, an anti-psychotic medicine, has recently been identified as a drug of potential misuse or abuse, a characteristic that was not known at the time this medicine was originally marketed.

*It is necessary to define pest by reference to the regulation to provide flexibility to add additional classes of pests that become a problem to health, agriculture and industry in a timely manner.*¹⁸⁹

It can be seen that the main thrust of the justifications given is a need for flexibility.

4.14.2 Delegation of legislative power

4.14.2.1 Retrospectivity - section 4(3)(g) of the Legislative Standards Act 1992

Clause 282 contains a transitional regulation-making power. The clause allows a transitional regulation to make:

Provision of a saving or transitional nature about any matter for which it is necessary to make provision to allow or facilitate the doing of anything to achieve the transition from the Health Act or the Pest Management Act to the new Act, and for which the new Act does not already make provision or sufficient provision.

A transitional regulation must declare it is a transitional regulation, may have retrospective operation to a day that is not earlier than the day on which clause 282 commences, and expires 2 years after this clause commences. The power to make a transitional regulation also expires at that time.

¹⁸⁷ See the Office of the Queensland Parliamentary Counsel, *Fundamental Legislative Principles: the OQPC Notebook*, pp 155-156, and Scrutiny of Legislation Committee, *Alert Digest 1999/04*, p.10, paras 1.65-1.67.

¹⁸⁸ Explanatory notes, p 67.

¹⁸⁹ Explanatory notes, p 88.

Issue of fundamental legislative principle

Section 4(4) of the *Legislative Standards Act 1992* states:

Whether a Bill has sufficient regard to the institution of Parliament depends on whether, for example, the Bill –

- (a) allows for the delegation of legislative power only in appropriate cases and to appropriate persons; and*
- (b) sufficiently subjects the exercise of a delegated legislative power to the scrutiny of the Legislative Assembly; and*
- (c) authorises the amendment of an Act only by another Act.*

Transitional regulation-making powers are discussed in the OQPC handbook, based on comments by the former Scrutiny of Legislation Committee. That committee regarded it as an inappropriate delegation to provide that a regulation may be made about any matter of a savings, transitional or validating nature 'for which this part does not make provision or enough provision' because this anticipates that the Bill may be inadequate and that a matter which otherwise would have been of sufficient importance to be dealt with in the Act will now be dealt with by regulation.

The form of transitional regulation-making power regarded as most objectionable has the following aspects:

- (a) it is expressed to allow for a regulation that can override an Act
- (b) it is so general as to allow for a provision about any subject matter, including those that should be dealt with by Act as opposed to subordinate legislation
- (c) it is not subject to any other control, for example, a sunset clause.¹⁹⁰

Comment

Here, the clause is very broad in scope, especially noting the wording of clause 282(1). Moreover, the clauses have retrospective effect.

The explanatory notes provide the following justification:

*Although the Bill provides for a range of transitional issues, it is possible that unanticipated matters may arise given the complexity of transitioning to the new Bill. The inclusion of such a power will ensure that any transitional issues that have not been identified during the drafting of the provisions can be quickly addressed to ensure individuals' rights are not adversely affected.*¹⁹¹

It is noted that the clause does include the following sunset provisions:

- A transitional regulation may only be made within 2 years after the commencement of the section (subsection 4).
- The relevant section and any transitional regulation made under it will expire 2 years after that commencement (subsection 5).

These periods are longer than some. For example, the Plumbing Bill 2018 provided for a sunset clause of 1 year in each case.

¹⁹⁰ Office of the Queensland Parliamentary Counsel, *Fundamental Legislative Principles: The OQPC Notebook*, p 160.

¹⁹¹ Explanatory notes, p 87.

On this aspect, the explanatory notes state:

Transitional regulation-making powers and transitional regulations often expire after one year. However, for this Bill, two years is considered necessary to accommodate the phased implementation of the monitored medicines program of work. It may take more than 12 months before the monitored medicines database becomes operational. Operationalising the database is also affected by the timing of national real-time prescription data sharing, following agreement at the COAG Health Council meeting on 13 April 2018 to a new, federated model... The federated model involves the establishment of a National Data Exchange (NDE), which will use prescribing and dispensing information and other information from jurisdictional regulatory systems to provide information to support clinical decision-making. It is proposed under the federated model that each jurisdiction integrates with the NDE, to form a national real-time reporting solution. Transitional provisions may be needed that factor in the timeframes required for integrating the database into the NDE.

Some other provisions in the Bill may not take effect until 12 months after the commencement of the Act. For example, entities that hold a current licence will have 12 months from commencement to develop a substance management plan. If any implementation issues are identified that require changes to the scheme, these may need to be made during a period of up to two years after the commencement of the Act, to provide sufficient time for affected stakeholders to implement any transitional arrangements.¹⁹²

Committee comment

Given the complexity of this legislation and of the Health portfolio the committee considers that the sunset periods are appropriate, and, more broadly, that the clause has sufficient regard to the institution of Parliament.

4.14.3 Amendment of an Act only by another Act

The Bill contains numerous provisions allowing for various matters to be prescribed by regulation

Clauses	Matters prescribed by regulation
Clause 240 – regulation making power	This is a general regulation-making power, listing various matters that may be the subject of regulation, including imposing penalties of up to 100 penalty units.
Clause 7 – exemption for low risk activities	A regulation may prescribe that a type of activity with a substance is exempt from the operation of the Act.
Clauses 11, 12 and 13 – meaning of medicine, poison and prohibited substance	A regulation may prescribe another substance as a medicine, poison or prohibited substance.
Clause 14 – meaning of fumigant and pesticide	In addition to substances approved for use by the APVMA, a regulation may prescribe another substance as a fumigant or pesticide.
Clause 19 – meaning of pest management activity, fumigation activity and pest control activity	A regulation may prescribe carrying out another activity a fumigation activity.

¹⁹² Explanatory notes, p 87.

Clauses	Matters prescribed by regulation
Clause 40 – offences for self-prescribing or self-administering high-risk medicines	A regulation prescribes what is a high-risk medicine.
Clause 41 – restrictions for monitored medicines	The requirement to check the monitored medicines database does not apply if the proposed action happens in a situation prescribed by regulation to be exempt.
Clause 224 - chief executive to keep database	This provision sets out the purposes of keeping the monitored medicines database, including any other purpose prescribed by regulation.
Clause 226 – giving information	An information provider must give the chief executive information at the time, and in the way, prescribed by regulation, unless they have a reasonable excuse.
Clause 227 – use of information	The chief executive may prescribe an entity by regulation to be a user of the database, and may disclose information in the database to a user by giving them the information or giving the user electronic access to the database.
Clause 281 – procedure until monitored medicines database operational	Provides that the transitional provision applies between the transitional period, which ends on a day prescribed by regulation as the day the database becomes fully operational.
Clause 51 – agents and carers	The regulation provides an exemption to an offence to a person prescribed by regulation.
Clause 54 – authorisation of prescribed classes of persons	Provides that a regulation may prescribe a class of persons to be authorised to carry out a regulated activity with a regulated substance.
Clause 60 – authorisation for persons subject to work health and safety laws	This provision relates to S7 poisons at a place. Clause 60 does not apply if the buying, possession or application of a poison at the place relates to a type of industry prescribed by regulation.
Clause 68 – what is a general approval	A regulation may prescribe different classes of general approval for carrying out different types of activities.
Clause 70 – conditions	A regulation may prescribe standard conditions that apply to a substance authority.
Clause 75, 78, 82 – requirements for making initial application, amending application, renewal application	A regulation may prescribe the fee for making, amending or renewing an application.

Clauses	Matters prescribed by regulation
Clause 76 – deciding initial application	The chief executive may decide to impose additional conditions or vary a standard condition if they reasonably believe it is necessary. This provision enables the chief executive to vary a standard condition under the regulations.
Clause 91 – requirements may be prescribed	A regulation may prescribe requirements for a person, or a class of persons in relation to carrying out a type of regulated activity with a regulated substance.
Clauses 92 and 93 – substance management plans	A regulation may prescribe a place to be a regulated place and a person to be the responsible person for a regulated place. Also, matters to be addressed in substance management plans may be prescribed by regulation and that the plan should be reviewed at the time prescribed by regulation.
Clause 131 – appointment and qualifications	A regulation may prescribe persons that may be appointed as inspectors.
Clause 132 – appointment conditions and limit on powers	An inspector holds office on conditions, which may be stated in regulation.
Clause 232 – making extended practice authorities	A regulation may prescribe the matters the chief executive must consider before making an extended practice authority. The EPA will not take effect until it is approved by regulation, and it is intended that the name and date of the relevant EPA will be prescribed by regulation. Each time an EPA is updated, including any changes to the conditions, a regulation amendment will prescribe the new name and date.
Schedule 1 - definitions	The definitions of diversion-risk medicine and monitored medicine are to be prescribed in regulation. The definition of ‘pest’ also involves prescription by regulation.

Issue of fundamental legislative principle

An Act should only be amended by another Act

A Bill should only authorise the amendment of an Act by another Act.¹⁹³ A clause in an Act, which enables the Act to be expressly or impliedly amended by subordinate legislation or executive action is defined as a Henry VIII clause.

Appropriate delegation of legislation

A Bill should sufficiently subject the exercise of a delegated legislative power to the scrutiny of the Legislative Assembly.¹⁹⁴

¹⁹³ *Legislative Standards Act 1992*, section 4(4)(c).

¹⁹⁴ *Legislative Standards Act 1992*, section 4(4)(b).

*For Parliament to confer on someone other than Parliament the power to legislate as the delegate of Parliament, without a mechanism being in place to monitor the use of the power, raises obvious issues about the safe and satisfactory nature of the delegation.*¹⁹⁵

Section 4(4)(a) of the *Legislative Standards Act 1992* provides that whether a Bill has sufficient regard to the institution of parliament depends on whether the Bill, for example, allows the delegation of legislative power only in appropriate cases and to appropriate persons. This question is concerned with the level at which delegated legislative power is used.

Generally, the greater the level of political interference with individual rights and liberties, or the institution of Parliament, the greater the likelihood that the power should be prescribed in an Act of Parliament and not delegated below Parliament.

Comment

The Bill provides that a number of topics may be prescribed by regulation.

Clause 240

In relation to the imposition, by regulation, of penalties up to 100 penalty units, provided for in clause 240, the explanatory notes state:

*Although permitting a regulation to impose a maximum penalty of 100 penalty units could be considered enabling the inclusion of significant penalties, the health and safety benefits outweigh any potential breach of this fundamental legislative principle. It is appropriate for legislation with a purpose of minimising public health and safety risks for the use of substances, carries maximum penalties to reflect the seriousness of offences and, importantly, to act as a deterrent.*¹⁹⁶

There can be no argument that offences that might result in considerable risks to public health and safety ought to have appropriately high penalties. The issue here though is whether such offences and penalties are appropriate for inclusion in regulation rather than in a primary Act.

The principal means for creating offences should always be through Acts of Parliament, rather than in delegated legislation:

*In relation to a power to create offences and impose penalties under subordinate legislation, the more serious the consequences, the more likely it is that an offence or penalty should be imposed only by an Act of Parliament.*¹⁹⁷

The former Scrutiny of Legislation Committee had a policy that maximum penalties in regulations should be limited, generally, to 20 penalty units.¹⁹⁸

Note that section 181B of the *Penalties and Sentences Act 1992* applies to any provision prescribing a maximum fine for an offence but not expressly prescribing a maximum fine for a body corporate different from the maximum fine for an individual. In any such case:

¹⁹⁵ Office of the Queensland Parliamentary Counsel, *Fundamental Legislative Principles: The OQPC Notebook*, p 154.

¹⁹⁶ Explanatory notes, p 77.

¹⁹⁷ Office of the Queensland Parliamentary Counsel, *Fundamental Legislative Principles: The OQPC Notebook*, p 150.

¹⁹⁸ In *Alert Digest* No.4 of 1996, the former Scrutiny of Legislation Committee adopted a formal policy (Policy No. 2 of 1996) on the question of delegation of legislative power to create offences and prescribe penalties. The committee accepted that legislative power to create offences and prescribe penalties may be delegated in limited circumstances, provided certain safeguards were observed. These included that maximum penalties in regulations should be limited, generally, to 20 penalty units.

- The maximum fine is taken only to be the maximum fine for an individual.
- If a body corporate is found guilty of the offence, the court may impose a maximum fine of an amount equal to 5 times the maximum fine for an individual.

More generally regarding clause 240 and the various other provisions for regulation listed above, the explanatory notes state:

These provisions are considered to have sufficient regard to the institution of Parliament because:

- *the matters to be prescribed are consistent with the policy objectives and purpose of the authorising law;*
- *the matters to be prescribed are technical and clinical in nature;*
- *this approach will allow the Government to respond promptly and flexibly if changes are needed to the framework in future, ensuring the scheme can be managed appropriately. Some flexibility for Queensland Health to be able to respond rapidly and decisively to matters that pose a risk to public health and safety, such as addressing an outbreak of a highly pathogenic disease, is considered appropriate; and*
- *any changes to regulations will be tabled in the Legislative Assembly and subject to parliamentary scrutiny and disallowance.*¹⁹⁹

Committee comment

Given the complexity of this legislation and of the Health portfolio the committee considers the use of regulations necessary and appropriate. The committee notes that the regulations will be tabled in the Legislative Assembly and subject to parliamentary scrutiny and disallowance.

4.15 Explanatory notes

Part 4 of the *Legislative Standards Act 1992* requires that an explanatory note be circulated when a Bill is introduced into the Legislative Assembly, and sets out the information an explanatory note should contain.

Explanatory notes were tabled with the introduction of the Bill. The notes are fairly detailed and contain the information required by Part 4 and a sufficient level of background information and commentary to facilitate understanding of the Bill's aims and origins.

The committee commends Queensland Health for the detail provided in the explanatory notes.

¹⁹⁹ Explanatory notes, p 77.

Table 1 – proposed NEW OR AMENDED OFFENCE provisions

[NOTE: ONE PENALTY UNIT = \$133.45 AS OF 1 JULY 2019]

Clause	Offence	Proposed maximum penalty
32	<p>Offence to deal with prohibited substances</p> <p>A person must not deal with a prohibited substance unless the person—</p> <p>(a) deals with the substance in the authorised way; or</p> <p>(b) as a reasonable excuse.</p> <p>Maximum penalty—750 penalty units</p>	\$100,087.50
33	<p>Offence to manufacture medicines or hazardous poisons</p> <p>A person must not manufacture a medicine or hazardous poison unless the person—</p> <p>(a) manufactures the medicine or poison in the authorised way; or</p> <p>(b) has a reasonable excuse.</p> <p>Maximum penalty—750 penalty units.</p>	\$100,087.50
34	<p>Offence to buy or possess S4 or S8 medicines or hazardous poisons</p> <p>(1) A person must not buy or possess an S4 or S8 medicine or hazardous poison unless the person—</p> <p>(a) buys or possesses the medicine or poison in the authorised way; or</p> <p>(b) has a reasonable excuse.</p> <p>Maximum penalty—200 penalty units</p>	\$26,690
35	<p>Offence to supply medicines or hazardous poisons</p> <p>(2) A person (the <i>supplier</i>) must not supply a medicine or hazardous poison to someone else (the <i>recipient</i>) unless the supplier—</p> <p>(a) lawfully possesses the medicine or poison and supplies the medicine or poison in the authorised way; or</p> <p>(b) has a reasonable excuse.</p> <p>Maximum penalty—500 penalty units.</p>	\$66,725
36	<p>Offence to administer medicines</p> <p>A person must not administer a medicine to someone else or an animal unless the person—</p> <p>(a) administers the medicine in the authorised way; or</p> <p>(b) has a reasonable excuse.</p> <p>Maximum penalty—200 penalty units.</p>	\$26,690

Clause	Offence	Proposed maximum penalty
37	<p>Offence to supply or administer animal medicines to humans</p> <p>(2) A person must not deal with an animal medicine as mentioned in subsection (1) unless the person has a reasonable excuse.</p> <p>Maximum penalty—100 penalty units</p>	\$13,345
38	<p>Offence to prescribe or make standing orders</p> <p>A person must not prescribe, or make a standing order for, a medicine unless the person—</p> <p>(a) prescribes, or makes the standing order, for the medicine in the authorised way; or</p> <p>(b) has a reasonable excuse. Maximum penalty—200 penalty units.</p> <p>Maximum penalty—200 penalty units.</p>	\$26,690
39	<p>Unlawfully buying diversion-risk medicines</p> <p>(1) A person must not use a document the person has unlawfully prepared, or knows has been unlawfully prepared, for buying a diversion-risk medicine.</p> <p>Maximum penalty—100 penalty units.</p> <p>(2) A person must not, for buying a diversion-risk medicine, give someone who is authorised to prescribe or supply the medicine—</p> <p>(a) a statement the person knows is false or misleading in any way; or</p> <p>(b) a statement that omits anything without which it is false or misleading.</p> <p>Maximum penalty—100 penalty units</p>	\$13,345
40	<p>Offences for self-prescribing or self-administering high-risk medicines</p> <p>(1) A person who is authorised to prescribe a high-risk medicine must not self-prescribe the medicine unless the person has a reasonable excuse.</p> <p>Maximum penalty—100 penalty units</p> <p>(2) A person who is authorised to deal with a high-risk medicine must not self-administer a dose of the medicine unless—</p> <p>(a) someone else who is authorised to prescribe the medicine has prescribed the medicine for the person's treatment; or</p>	\$13,345

Clause	Offence	Proposed maximum penalty
	<p>(b) someone else who is authorised to give a treatment dose of the medicine has given the medicine to the person for the person's treatment; or</p> <p>(c) the person has a reasonable excuse.</p> <p>Maximum penalty—100 penalty units.</p>	\$13,345
41	<p>Restrictions for monitored medicines</p> <p>(2) Before taking the proposed action, the prescriber or dispenser must check the monitored medicines database to see whether the person has previously been prescribed or supplied any monitored medicine.</p> <p>Maximum penalty—20 penalty units.</p>	\$2,669
42	<p>Offence to dispose of waste from S8 medicine</p> <p>(1) A person must not dispose of waste from an S8 medicine unless the person—</p> <p>(a) disposes of the waste by giving it to an appropriate person; or</p> <p>(b) disposes of the waste in the authorised way; or</p> <p>(c) has a reasonable excuse. Maximum penalty—200 penalty units.</p> <p>Maximum penalty—200 penalty units.</p>	\$26,690
43	<p>Offence to apply poisons</p> <p>(2) A person must not apply a poison unless the poison is lawfully supplied to the person and the person—</p> <p>(a) applies the poison in the authorised way; or</p> <p>(b) applies the poison in accordance with the poison's approved label; or</p> <p>(c) has a reasonable excuse.</p> <p>Maximum penalty—200 penalty units.</p>	\$26,690
44	<p>Offence to carry out pest management activities</p> <p>(1) A person must not carry out a pest management activity unless the person carries out the activity in the authorised way or has a reasonable excuse.</p> <p>Maximum penalty—200 penalty units.</p>	\$26,690
45	<p>Offence to offer to carry out pest management activities if unauthorised</p> <p>A person must not offer to carry out a pest management activity for a pest management business unless—</p> <p>(a) the person has a pest management licence; or</p>	

Clause	Offence	Proposed maximum penalty
	<p>(b) the person employs someone else with a pest management licence to carry out the pest management activity.</p> <p>Maximum penalty—200 penalty units.</p>	\$26,690
46	<p>Offence to require or permit unauthorised persons to carry out pest management activities</p> <p>(2) The manager must not permit or require another person to carry out a pest management activity for the manager if the manager knows the other person is not authorised to carry out the activity, unless the manager has a reasonable excuse.</p> <p>Maximum penalty—200 penalty units</p>	\$26,690
47	<p>Offence to dispose of waste from hazardous poison, pesticide or fumigant</p> <p>A person must not dispose of waste from a hazardous poison, pesticide or fumigant unless the person—</p> <p>(a) disposes of the waste in the authorised way; or</p> <p>(b) has a reasonable excuse.</p> <p>Maximum penalty—200 penalty units</p>	\$26,690
48	<p>Offence for giving or keeping false, misleading or incomplete information and records</p> <p>The person must not—</p> <p>(a) give the chief executive information the person knows is false or misleading in a material particular; or</p> <p>(b) make or keep a record the person knows is false or misleading in a material particular; or</p> <p>(c) make or keep a record the person knows is incomplete in a material particular.</p> <p>Maximum penalty—50 penalty units.</p>	\$6,672.50
71	<p>Failure to comply with substance authority conditions</p> <p>A person to whom a substance authority applies must comply with the conditions of the authority unless the person has a reasonable excuse.</p> <p>Maximum penalty—200 penalty units.</p>	\$26,690
93	<p>Requirements for substance management plan</p> <p>(1) The responsible person for a regulated place must make a substance management plan for the place that complies with subsection (2) before any dealing happens with a</p>	

Clause	Offence	Proposed maximum penalty
	<p>regulated substance at the place, unless the person has a reasonable excuse.</p> <p>Maximum penalty—250 penalty units.</p> <p>(3) The responsible person must ensure the substance management plan—</p> <p>(a) is made available to staff when it is made; and</p> <p>(b) is reviewed at the time prescribed by regulation.</p> <p>Maximum penalty—250 penalty units</p>	<p>\$33,362.50</p> <p>\$33,362.50</p>
94	<p>Compliance with substance management plan</p> <p>A person stated in a substance management plan under section 93(2)(a)(iv) must comply with the plan, unless the person has a reasonable excuse.</p> <p>Maximum penalty—200 penalty units.</p>	\$26,690
110	<p>Failure to comply with compliance notice</p> <p>A person given a compliance notice must comply with the notice unless the person has a reasonable excuse.</p> <p>Maximum penalty—200 penalty units.</p>	\$26,690
116	<p>Failure to comply with emerging risk declaration</p> <p>A person must comply with the emerging risk declaration unless the person has a reasonable excuse.</p> <p>Maximum penalty—500 penalty units.</p>	\$66,725
125	<p>Failure to comply with recall order</p> <p>The responsible person for a recall order must comply with the order unless the person has a reasonable excuse.</p> <p>Maximum penalty—500 penalty units.</p>	\$66,725
137	<p>Return of identity card</p> <p>If the office of a person as an inspector ends, the person must return the person's identity card to the chief executive within 21 days after the office ends unless the person has a reasonable excuse.</p> <p>Maximum penalty—20 penalty units.</p>	\$2,669
160	<p>Offence to contravene help requirement</p> <p>(1) A person of whom a help requirement has been made must comply with the requirement unless the person has a reasonable excuse.</p> <p>Maximum penalty—50 penalty units.</p>	\$6,672.50

Clause	Offence	Proposed maximum penalty
165	<p>Offence to contravene other seizure requirement</p> <p>A person must comply with a requirement made of the person under section 164(2)(c) unless the person has a reasonable excuse.</p> <p>Maximum penalty—50 penalty units.</p>	\$6,672.50
166	<p>Offence to interfere</p> <p>(1) If access to a seized thing is restricted under section 164, a person must not tamper with the thing or with anything used to restrict access to the thing without—</p> <p>(a) an inspector’s approval; or</p> <p>(b) a reasonable excuse.</p> <p>Maximum penalty—100 penalty units</p> <p>(2) If access to a place is restricted under section 164, a person must not enter the place in contravention of the restriction or tamper with anything used to restrict access to the place without—</p> <p>(a) an inspector’s approval; or</p> <p>(b) a reasonable excuse.</p> <p>Maximum penalty—100 penalty units.</p>	\$13,345
176	<p>Offence to contravene personal details requirement</p> <p>(1) A person of whom a personal details requirement has been made must comply with the requirement unless the person has a reasonable excuse.</p> <p>Maximum penalty—50 penalty units.</p>	\$6,672.50
178	<p>Offence to contravene document production requirement</p> <p>(1) A person of whom a document production requirement has been made must comply with the requirement unless the person has a reasonable excuse.</p> <p>Maximum penalty—50 penalty units.</p>	\$6,672.50
179	<p>Offence to contravene document certification requirement</p> <p>(1) A person of whom a document certification requirement has been made must comply with the requirement unless the person has a reasonable excuse.</p> <p>Maximum penalty—50 penalty units.</p>	\$6,672.50

Clause	Offence	Proposed maximum penalty
181	<p>Offence to contravene information requirement</p> <p>(1) A person of whom a requirement is made under section 180(2) must comply with the requirement unless the person has a reasonable excuse.</p> <p>Maximum penalty—50 penalty units.</p>	\$6,672.50
185	<p>Giving inspector false or misleading information</p> <p>(1) A person must not, in relation to the administration of this Act, give an inspector information the person knows is false or misleading in a material particular.</p> <p>Maximum penalty—50 penalty units.</p>	\$6,672.50
186	<p>Obstructing inspector</p> <p>(1) A person must not obstruct an inspector exercising a power, or someone helping an inspector exercising a power, unless the person has a reasonable excuse.</p> <p>Maximum penalty—100 penalty units.</p>	\$13,345
187	<p>Impersonating inspector</p> <p>A person must not impersonate an inspector.</p> <p>Maximum penalty—100 penalty units.</p>	\$13,345
217	<p>Changes in criminal history must be disclosed</p> <p>(2) The person must, within 14 days after the conviction, give notice of the conviction to the chief executive, unless the person has a reasonable excuse.</p> <p>Maximum penalty—100 penalty units.</p>	\$13,345
220	<p>Confidentiality of information</p> <p>(1) An administrator must not, directly or indirectly, disclose confidential information or criminal history information to another person unless the disclosure is permitted under subsection (2).</p> <p>Maximum penalty—50 penalty units.</p>	\$6,672.50
226	<p>Giving information</p> <p>(1) An information provider must give the chief executive the information mentioned in section 225 at the time, and in the way, prescribed by regulation, unless the information provider has a reasonable excuse.</p> <p>Maximum penalty—100 penalty units.</p>	\$13,345

Appendix A – Submitters

Sub #	Submitter
001	Australian Pest Managers Association Ltd
002	Professor Jane Hocking and Dr Jane Goller, University of Melbourne, Melbourne School of Population and Global Health
003	Southern Downs Regional Council
004	Local Government Association of Queensland
005	GrainCorp Limited
006	Queensland Nurses and Midwives' Union
007	Anglicare Southern Queensland
008	The Pharmacy Guild of Australia, Queensland Branch
009	Australian Medical Association Queensland
010	Mr Andrew Calabro and Mr Daniel Calabro
011	Directors of Physiotherapy Services Queensland
012	Garrards Pty Ltd
013	AgForce Queensland
014	Australian Veterinary Association
015	The Royal Australian College of General Practitioners
016	Pharmaceutical Society of Australia
017	Sexual Health Society of Queensland
018	MIGA (Medical Insurance Group Australia)
019	Australian College of Nurse Practitioners
020	Mary McLean
021	Australian Physiotherapy Association
022	Orthoptics Australia
023	Queensland Catholic Education Commission
024	Royal Australian and New Zealand College of Psychiatrists
025	Stuart Plant

Appendix B – Officials at public departmental briefing

Queensland Health

- Dr Jeannette Young, Chief Health Officer and Deputy Director-General, Prevention Division
- Mr David Harmer, Senior Director, Strategic Policy and Legislation Branch, Strategy Policy and Planning Division
- Ms Eve Gibson, Acting Manager, Legislative Policy Unit, Strategy Policy and Planning Division

Appendix C – Witnesses at public hearing

Australian Medical Association Queensland

- Dr Richard Kidd, AMA Queensland Member and Past President

Queensland Nurses and Midwives' Union

- Mr Jamie Shepherd, Professional Officer – Team Leader
- Mr Daniel Prentice, Professional Research Officer
- Dr Elizabeth Todhunter, Research and Policy Officer
- Ms Deborah Twigg, Research and Policy Officer

Royal Australian College of General Practitioners

- Dr Bruce Willet, Chair, RACGP Queensland
- Dr Chris Ifediora, RACGP Queensland Council Member

Pharmaceutical Society of Australia

- Mr Chris Campbell, Queensland President
- Mr Mark Lock, State Manager - Queensland

MIGA (Medical Insurance Group Australia) *(by teleconference)*

- Mr Timothy Bowen, Senior Solicitor – Advocacy, Claims & Education

AgForce

- Ms Marie Vitelli, Policy Officer

Australian Environmental Pest Managers Association

- Mr John Graham, Queensland Representative

Garrards Pty Ltd *(by teleconference)*

- Mr Philip Sayer, Technical and Training Manager

Queensland Health

- Dr Jeannette Young, Chief Health Officer and Deputy Director-General, Prevention Division
- Ms Sophie Dwyer, Executive Director, Health Protection Branch, Prevention Division
- Ms Eve Gibson, A/Manager, Legislative Policy Unit, Strategy Policy and Planning Division

Statement of Reservation

The non-government members of the State Development, Natural Resources and Agricultural Industry Development Committee do not oppose the intent of the Medicines and Poisons Bill 2019, however have concerns with some elements seeming to be incomplete, with references to subordinate legislation and standards needed to fill in more detail.

This is a significant piece of legislation, noting that it will repeal and replace existing legislation with a new regulatory framework that has greater alignment with national regulations.

There is strong support for the introduction of real-time prescription monitoring and the potential to prevent death or serious injury from a practice known as doctor shopping from people who are addicted to prescription medicines. We also understand the concerns raised by doctors in relation to the implementation of the new system and the need to have an integrated model that avoids duplication of tasks or unnecessary additional bureaucracy for medical practitioners and pharmacists.

There are also concerns for the need to check the history of patients who have lived in other states. Cross-border system integration will be an important next step that will enhance real-time prescription monitoring.

There has been further concerns raised about increased assaults against general practitioners, which is something that needs to be monitored closely. The Royal Australian College of General Practitioners also raised the issue of the need to transition to the new real-time reporting arrangements and we would encourage the Health Minister to consult thoroughly on the implementation process. In that regard, we note comments from Queensland Health that:

“A comprehensive implementation and communication plan about the system and expected commencement is being prepared, with further communication with stakeholders to follow debate of the Bill.”

In relation to other elements in the Bill, there was considerable concern regarding the lack of oversight of substance management plans – which may be a role for the Medicines Regulation and Quality Unit, as raised by the Queensland Nurses and Midwives Union. Any consideration of that oversight role would also need to determine whether any additional resources were needed.

There is furthermore a lack of detail about the specified requirements for a substance management plan, noting that it will be outlined by regulation and included in the relevant departmental standard. Schedule 1 of the draft Medicines and Poisons (Medicines) Regulation 2019 that was tabled refers to a number of departmental standards that are yet to be made – including standard 6 regarding substance management plans. We believe the detail of these plans should be provided in legislation, or at the very least in regulation and should already have been completed.

Concerns were raised by pest management companies in relation to the dual licensing requirements – from the Queensland Building and Construction Commission (QBCC) and Queensland Health. While we understand the different purposes, there is no reason why this model can't be integrated. This is just another example of the Palaszczuk Labor Government increasing red tape and regulation on small

business operators. Government departments and agencies shouldn't operate as silos – it is all under the umbrella of the Queensland Government.

There are concerns from agricultural groups regarding the public register of schedule 7 poisons. While we note the advice from Queensland Health about discretion from the chief executive, we would urge caution in any publication, given the well documented illegal protest activities from animal extremists.

The non-government members do not oppose the bill however do express concern at the amount of detail that will be required in the regulations to underpin the bill that are not yet available for scrutiny.



Pat Weir MP
Member for Condamine
Deputy Chair of the SDNRAIDC



David Batt MP
Member for Bundaberg
Shadow Assistant Minister for State Development



Brent Mickelberg MP
Member for Buderim
Shadow Assistant Minister for Tourism Industry Development