

3 November 2022

Mr Shaun Drummond  
Director-General  
Department of Health

[Address redacted]



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**Subject: North Queensland Community Pharmacy Scope of Practice Pilot**

Dear Mr Drummond

We write in response to Queensland Health's *North Queensland Community Pharmacy Scope of Practice Pilot – Pilot Services* document, received 13 October 2022.

AMA Queensland remains steadfastly opposed to the implementation of the Urinary Tract Infection Pharmacy Pilot – Queensland (UTIPP-Q) and proposed North Queensland Scope of Practice Pilot (NQ Pilot) due to the inherent threats both pose to the health and safety of all Queenslanders.

Attached is a paper outlining AMA Queensland's specific concerns with the NQ Pilot (noting also our previous correspondence to you regarding the UTIPP-Q). We seek Queensland Health's response to all the identified concerns and questions in the paper and are happy to meet with you to discuss further.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Maria Boulton'.

Dr Maria Boulton  
**President**  
**AMA Queensland**

A handwritten signature in black ink, appearing to read 'Brett Dale'.

Dr Brett Dale  
**Chief Executive Officer**  
**AMA Queensland**

Enc: *AMA Queensland Identified Concerns: North Queensland Community Pharmacy Scope of Practice Pilot*

cc:  
Hon Yvette D'Ath MP  
Minister for Health and Ambulance Services

## AMA Queensland Identified Concerns

### North Queensland Community Pharmacy Scope of Practice Pilot

AMA Queensland is alarmed by the Queensland Government's proposed North Queensland Community Pharmacy Scope of Practice Pilot (the 'NQ Pilot'). AMA Queensland submits that the NQ Pilot contains the same failings as the Urinary Tract Infection Pharmacy Pilot – Queensland (the 'UTIPP-Q') identified in Dr Stephanie Dawson-Smith's Issues Paper.<sup>1</sup> The NQ Pilot also presents an even greater threat to patient safety than the UTIPP-Q given the broad scope of the NQ Pilot; range of conditions included; and vulnerable North Queensland communities targeted.

Given recent media reports about the harm suffered by Indigenous women and girls particularly, AMA Queensland submits it is highly inappropriate that treatment for these 17 common conditions be done by pharmacists. It is only doctors who are appropriately trained in responding to and treating patients suffering from or at risk of harm due to domestic and family violence who present with just such conditions as those included in the NQ Pilot. Removing this requirement for vulnerable patients to engage with a medical practitioner trained in differential diagnosis only serves to fragment the primary care model and will cause immediate harm to Queensland's vulnerable North Queensland Indigenous communities.

AMA Queensland's specific concerns and questions relating to Queensland Health's *North Queensland Community Pharmacy Scope of Practice Pilot – Pilot Services* document (the 'Pilot Paper') and cover letter are outlined below. AMA Queensland requests Queensland Health respond to each in turn and is prepared to meet with relevant departmental staff to discuss further.

#### Justification for NQ Pilot conditions

- AMA Queensland notes the confidential draft of the NQ Pilot contained 23 conditions but the Pilot Paper includes only 17 of these original 23 conditions. AMA Queensland requests Queensland Health provide the evidence-base and reasons for:
  - the inclusion of each of the 17 conditions in the current document; and
  - the deletion of the other six (6) conditions from the confidential draft (asthma and exercise induced bronchoconstriction; chronic obstructive pulmonary disease; uncomplicated urinary tract infections; dyslipidaemia; hypertension; type 2 diabetes).
- AMA Queensland requests Queensland Health advise if a cost-benefit analysis was undertaken of the NQ Pilot and each of the conditions included in the confidential draft and Pilot Paper and, if so, that Queensland Health publicly release any such analysis. If such cost-benefit analysis was not undertaken, AMA Queensland requests Queensland Health provide the reasons and justification for this decision.
- AMA Queensland also requests Queensland Health advise of the evidence-base and any cost-benefit analysis of the NQ Pilot compared with alternative policy responses, including increased investment in primary care services and collaborative primary care models. If such cost-benefit analyses and comparative evidence-based assessments were not undertaken,

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<sup>1</sup> Available at: <https://qld.ama.com.au/sites/default/files/QLD/images/Policy/220912-AMAQ-to-DG-Issues-Paper-UTIPPQ-QUT.pdf>

AMA Queensland requests Queensland Health provide the reasons and justification for this decision.

- AMA Queensland requests Queensland Health justify the reasons the NQ Pilot permits the prescribing of medicines by pharmacists which are prohibited by the Therapeutic Goods Administration (TGA), such as the oral contraceptive pill. AMA Queensland submits that Queensland Health's decision to go against the TGA demonstrates the NQ Pilot is a reckless and unacceptable risk to patient safety.
- AMA Queensland requests Queensland Health provide details of the chronic disease management programs set out under 'Category 3: Protocol based prescribing as part of a chronic disease management program' and an explanation as to why such detail has not been included in the Pilot Paper. AMA Queensland requests Queensland Health's response specifically explain how the safety concerns inherent in the diagnosis of these more complex conditions will be addressed and whether treatment of these complex conditions will be in consultation with the patient's regular medical practitioner.
- The Minister for Health and Ambulance Services stated in a media release on 13 October that "Deputy Director-General, Clinical Excellence Queensland, Dr Helen Brown said the pilot was designed to improve access to health care in North Queensland" and went on to quote Dr Brown as follows:

*The aim of this initiative is to supplement – not replace – existing services and give consumers in North Queensland greater access to the health care they need," Dr Brown said.*

*Pharmacists have always been an integral part of healthcare delivery.*

*I am confident in their ability to manage the additional responsibilities, given they are already highly trained and well-regulated health professionals and will undertake additional training as part of the pilot in order to safely offer these services to our community.*

*The pilot's progress will be closely monitored to ensure it is safe and effective, however I believe it will provide a wealth of benefits to health consumers in North Queensland.<sup>2</sup>*

AMA Queensland is aware Dr Brown is a neurologist and requests an explanation as to what involvement and influence Dr Brown had in the decision to exclude and include conditions.

- AMA Queensland submits many of the 17 proposed conditions already have suitable schedules that assist pharmacists to manage common illnesses for which patients present to community pharmacies (e.g. gastro-oesophageal reflux and gastro-oesophageal reflux disease; allergic and non-allergic rhinitis; atopic dermatitis). AMA Queensland requests Queensland Health advise:
  - the justification for the NQ Pilot and associated government expenditure in these circumstances; and
  - the justification for the extra cost burden which will be placed on patients under the NQ Pilot.

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<sup>2</sup> <https://statements.qld.gov.au/statements/96318>.

AMA Queensland submits there is no justification for the NQ Pilot, associated government expenditure and extra cost burden to patients other than to increase profits for pharmacy owners, and requests Queensland Health address this concern directly.

### Concerns identified in QH letter

*The Department of Health (the Department) will now undertake further development work to plan for the implementation and evaluation of [the] Pilot.*

- AMA Queensland notes the failings of this process during the UTIPP-Q (and identified in Dr Dawson-Smith's Issues Paper), including that multiple medical organisations withdrew their support and did not participate due to their dismay at the threat the program posed to patient safety. The secretive nature of this process was alarming and Queensland Health must ensure this is not repeated. AMA Queensland requests Queensland Health advise how it will ensure these failings are corrected in the NQ Pilot.
- The evaluation of the UTIPP-Q was riddled with failings, as noted in Dr Dawson-Smith's Issues Paper. AMA Queensland requests Queensland Health advise the measures it will take to ensure the evaluation is independent and conducted according to ethical, best-practice and rigorous evaluation methodologies. Will Queensland Health guarantee it will be a true evaluation of the NQ Pilot or only a sham 'service' evaluation as per the UTIPP-Q which merely assessed patient satisfaction with the service and not the health outcomes or associated harms?

*As you will be aware, the Department has undertaken significant scoping, planning and consultation work with key consumer, medical and pharmacy stakeholders to develop and refine the pharmacy services and prescribing models that will be included in the Pilot.*

- AMA Queensland is not aware of the medical stakeholders that were consulted to develop or refine the services and prescribing models. It requests Queensland Health advise what this process involved and who the stakeholders were.

*This has included review and consideration of pharmacist models of care in comparable countries for the management of common conditions and minor ailments, as well as the management of specified chronic conditions.*

- AMA Queensland rejects the assertion that the models of care relied upon by Queensland Health are comparable to that in Australia. The model in New Zealand does not occur in isolated community pharmacies but in an integrated model with doctors. Likewise, the United Kingdom does not permit the scope of pharmacist-prescribing permitted in the NQ Pilot. The model in Alberta, Canada lacks sufficient scientific evidence to be relied upon and incorporates far more stringent requirements for referral to a doctor and record-keeping than that included in the NQ Pilot.
- AMA Queensland requests Queensland Health provide the full details of the 'review and consideration' undertaken for each of the 17 conditions included in the NQ Pilot.

## General Concerns identified in QH Pilot Paper

### Misleading language

- AMA Queensland notes Queensland Health repeatedly refers to the NQ Pilot as involving pharmacists working to their ‘full scope of practice’, however, the pilot clearly represents *extended* scope of practice for pharmacists. In fact, Queensland Health’s letter and Pilot Paper contain significant information that demonstrates Queensland Health is aware the NQ Pilot will involve extended scope, including acknowledgement that legislative amendments are required.

AMA Queensland also submits that the scope proposed under the NQ Pilot is not recognised by the Pharmacy Board of Australia (PBA) and requests what consultation, if any, Queensland Health has undertaken with the PBA to ensure the NQ Pilot aligns with best practice.

Based on the above, AMA Queensland submits that Queensland Health must be honest with the Queensland public and patients that the NQ Pilot represents a pilot of pharmacists working to an ‘extended scope’, not their ‘full scope’, and must correct the public record accordingly.

### ‘Background’, page 2

*Internationally, the pharmacy profession has undergone significant changes over recent decades with community pharmacists becoming involved in the provision of collaborative patient care and the incorporation of prescribing activities into pharmacists’ scope of practice in a range of comparable countries including the United Kingdom, Canada and New Zealand.*

- AMA Queensland supports “community pharmacists becoming involved in the provision of collaborative patient care” and would welcome such a proposal, however, this is not what is contemplated under the NQ Pilot. AMA Queensland requests an explanation as to why an extended scope model was chosen over more clinically-appropriate and proven collaborative models, or greater investment in primary care which would also protect patient safety and health outcomes.
- AMA Queensland does not support “the incorporation of prescribing activities into pharmacists’ scope of practice” outside collaborative and rejects the assertion that the practice in the United Kingdom, Canada and New Zealand is comparable to that in Australia (please also refer to comments in the above section).

*The aim of the North Queensland Community Pharmacy Scope of Practice Pilot (the Pilot) is to increase access to high-quality, integrated and cost-effective primary health care services for North Queensland communities.*

- What aspects of the NQ Pilot does Queensland Health regard as representing an ‘integrated’ primary health care service? AMA Queensland submits the service is not at all integrated with other health services and is a stand-alone, autonomous prescribing model. AMA Queensland requests Queensland Health’s justification for this misleading statement.

'Clinical protocols and Pilot Handbook', page 3

*Clinical practice guidelines and/or clinical protocols for each condition and/or program will be developed*

- AMA Queensland requests Queensland Health advise who will be responsible for developing these guidelines and/or clinical protocols, noting the significant failings associated with the process under the UTIPP-Q as identified in Dr Dawson-Smith's Issues Paper.

*The clinical practice guidelines/protocols will detail the parameters of the pharmacist intervention or service, including requirements for:... Referral to other health practitioners.*

- AMA Queensland notes the significant failures of the UTIPP-Q to refer patients to other health practitioners, particularly doctors. AMA Queensland requests Queensland Health demonstrate how these failures will not be repeated under the NQ Pilot and the precise process involved in ensuring patients are referred to doctors.

*Patient encounters during the Pilot will be communicated to the patient's usual medical practitioner.*

- AMA Queensland requests Queensland Health explain what mechanism will be used to communicate this information to the patient as well as the patient's usual medical practitioner. AMA Queensland again notes the significant failings of the UTIPP-Q in reporting patient information to doctors as identified in Dr Dawson-Smith's Issues Paper and requests Queensland Health explain how will these failures will be addressed in the NQ Pilot.

*... a Pilot Handbook will be developed that will detail eligibility for participation, enrolment, training and approval processes, along with the rules and requirements that govern the implementation of the Pilot and the individual interventions/services provided within the Pilot, by participating pharmacists and pharmacies.*

- AMA Queensland requests Queensland Health explain how and by whom the Pilot Handbook will be developed. Given the significant failings of the Guildcare Workflow during the UTIPP-Q, as demonstrated in Dr Dawson-Smith's Issues Paper, AMA Queensland requests Queensland health explain how these failures will be avoided in the NQ Pilot.

'Conditions of participation', page 4

- 'Pharmacists'

*"During the Pilot, the pharmacist must only provide the Pilot services:... In accordance with the clinical practice guidelines/clinical protocols for the Pilot"*

- AMA Queensland notes multiple instances were identified in QUT's own evaluation of the UTIPP-Q and set out in Dr Dawson-Smith's Issues Paper where pharmacists failed to follow the relevant protocol. AMA Queensland requests Queensland Health demonstrate how it will ensure compliance by pharmacists with any guideline/protocols and what action will be taken where pharmacists fail to comply, including monitoring and reporting mechanism and any associated penalties.

- 'Pharmacies'

*Being accredited by the Quality Care Pharmacy Program (QCPP) including having the infrastructure and facilities to enable private consultation, and examination and vaccination, specifically, a screened or private consulting area...*

- Patient privacy is paramount in consultations. AMA Queensland submits that a 'screened' area is wholly inadequate to ensure the privacy of patients when answering very sensitive and personal health questions. Queensland Health must mandate that a private, closed consultation room must be used for all services provided under the NQ Pilot.

*Having access to the software to enable data recording, clinical record keeping and follow-up.*

- AMA Queensland submits that each and every patient treated under the NQ Pilot must have a record of the treatment added to the patient's MyHealth Record. In addition, records must align with the Medical Board of Australia's 'Good Medical Practice' and be kept for a minimum of eight (8) years for adults and a minimum of 18 + 8 years for children.
- AMA Queensland further submits that all patients must be followed up by an independent evaluator and not the treating pharmacist or pharmacy as under the UTIPP-Q.

*Ensuring only authorised pharmacists provide services as part of the Pilot and only at authorised sites.*

- QUT's evaluation of the UTIPP-Q and Dr Dawson-Smith's Issues Paper showed this requirement was regularly breached during the UTIPP-Q, with pharmacy assistants and other pharmacy employees providing services. AMA Queensland requests Queensland Health demonstrate how it will ensure compliance with this requirement including monitoring and reporting mechanism and any associated penalties.

- 'Patients'

*In order to receive a service as part of the Pilot, patients (or parents/guardians) must:... Consent for the pharmacist to advise their usual medical practitioner of their participation in the service and treatment plan.*

- A major failing of the UTIPP-Q, as demonstrated in Dr Dawson-Smith's Issues Paper, was the requirement for pharmacists to advise patients' medical practitioners of their participation in the UTIPP-Q and treatment plan. AMA Queensland requests Queensland Health demonstrate how it will ensure compliance with this requirement including monitoring and reporting mechanism and any associated penalties.
- AMA Queensland further requests Queensland Health explain how this referral mechanism will be communicated to both patients and doctors.

*In order to receive a service as part of the Pilot, patients (or parents/guardians) must... Consent to participate in the service evaluation for the Pilot, including being contacted by the authorised pharmacist/pharmacy, Queensland Health and/or the Pilot evaluator for the purposes of the monitoring and evaluation for the Pilot.*

- AMA Queensland notes the complete failure of the requirement for follow-up under the UTIPP-Q as identified in Dr Dawson-Smith's Issues Paper, as well as the multiple and egregious inadequacies of the QUT evaluation and associated report. It is also highly inappropriate that Queensland Health are again assigning the treating pharmacist or pharmacy with responsibility to undertake patient monitoring and evaluation given the inherent conflict of interest.

AMA Queensland requests Queensland Health immediately remove the treating pharmacist or pharmacy as authorised to monitor or evaluate services under the NQ Pilot. It also requests Queensland Health demonstrate how it will address the monitoring and evaluation failings of the UTIPP-Q in the NQ Pilot.

- In addition, Queensland Health must demonstrate what independent feedback mechanism will be provided to patients to report harms they experience as a result of participating in the NQ Pilot, including to their medical practitioner, and how this feedback mechanism will be communicated to both patients and doctors.

#### 'Education and training', page 5

*Pharmacists who participate in the Pilot will be required to undertake an education program delivered by higher education institution(s)...*

- AMA Queensland requests Queensland Health advise which institution(s) will be delivering this program and the process to be undertaken to develop this program, including bodies/persons involved, in the development, review and implementation.
- AMA Queensland notes the proposed program will include "120 hours of learning in practice" and will cover "clinical assessment, diagnosis and management of the conditions included in the Pilot". AMA Queensland submits that 120 hours is completely inadequate to undertake these tasks which doctors train for over 10 years to perform.

#### 'Legislative approval', page 5

*The activities included in the Pilot that are not already authorised under the Medicines and Poisons Regulation 2021 will be authorised through a temporary legislative approval.*

- AMA Queensland submits that the statement that legislative amendments to the Regulation are required to authorise the activities under the NQ Pilot demonstrates that the NQ Pilot is not "a trial of pharmacists working to their full scope of practice" but a trial of *extended* scope of practice for pharmacists. AMA Queensland submits that this is highly inappropriate and evidence that the NQ Pilot should be



immediately abandoned until it has undergone and obtained human research ethics approval.

'Evaluation', page 31

*The Department will engage an independent external provider to undertake a service evaluation of the Pilot, aligned to the Australian Institute of Health and Welfare dimensions of system performance (accessibility, continuity, effectiveness, efficiency and sustainability, appropriateness and safety).*

- AMA Queensland submits it is highly inappropriate that the evaluation of the NQ Pilot be a 'service evaluation' and notes the multiple and serious failings identified with the UTIPP-Q in Dr Dawson-Smith's Issues Paper as a result of this approach. AMA Queensland again submits that the NQ Pilot should be registered as a clinical trial and be dependent on human research ethics approval and associated research evaluation standards.