QUEENSLAND COURTS

CORONERS COURT OF QUEENSLAND

FINDINGS OF INQUEST

CITATION:	**Inquest into the death of Alexandria Catherine Forrester**
TITLE OF COURT:	Coroners Court
JURISDICTION:	BRISBANE
FILE NO(s):	2021/4330
DELIVERED ON:	17 October 2025
DELIVERED AT:	Brisbane
HEARING DATE(s):	9 to 12 December 2024
FINDINGS OF:	Carol Lee, Coroner
CATCHWORDS:	Coroners: Inquest, Drugs of Dependence, Methadone, Opioid Treatment Program, Appropriateness of Care and Treatment within Clinical Guidelines, Regulatory Oversight.

REPRESENTATION:

Counsel Assisting:	Mr Mark Eade and Ms Carolyn McKeon
Ms Tanya Langhorne:	Ms Anna Crawford, instructed by Caxton Legal.
Metro North Hospital and Health Service (MNHHS):	Ms Prudence Fairlie, instructed by Metro North Hospital and Health Service (MNHHS).
Queensland Health:	Ms Jesika Franko, instructed by Queensland Health.
Mr Shahriar Kashani-Malaki:	Mr Joshua Sproule, instructed by Colin Biggers & Paisley.
Mr Steven Hancock:	Mr Joshua Liddle, instructed by Meridian Lawyers.
Ms Marissa Papacostas:	Mr George Williams, instructed by Colin Biggers & Paisley.
Dr Andrew Pluta:	Mr Ryan Nattrass, instructed by Avant Law[1].

[1] Confined to submissions after the Inquest had concluded. Otherwise, Dr Pluta was self-represented.

Contents

Introduction

1. Ms Alexandria Catherine Forrester[2] was a 39-year-old[3] single woman who resided in a unit in Albion. Alex had a complex and lengthy medical history, relevantly opioid dependency for which she was receiving longstanding treatment through the Queensland Opioid Treatment Program (**QOTP**). Throughout these challenges, she was supported by her sister Ms Tanya Langhorne.

2. On 20 September 2021, Alex was found unresponsive at her residence by a friend, after having taken an amount of her prescribed Methadone. Following the successful return of spontaneous circulation by first responder paramedics (twice), Alex was transferred for ongoing care and treatment to the Royal Brisbane and Woman's Hospital (**RBWH**). There, investigations revealed that she had sustained an unsurvivable severe hypoxic brain injury and tragically, she passed away in the Intensive Care Unit at 10:52 hours on 21 September 2021.

3. On 24 September 2021 an autopsy was undertaken. The attending Forensic Pathologist, Dr Nathan Milne, opined that the cause of death was:

    1(a) Hypoxic-ischaemic encephalopathy, *due to, or as a consequence of*

    1(b) Cardiorespiratory arrest, *due to, or as a consequence of*

    1 (c) Methadone toxicity.

4. Relevantly, the forensic pathologist found as follows:

    a. Toxicological analysis was performed on ante-mortem samples of blood collected at RBWH at 12:00 hours on 20 September 2021. These showed Methadone at a level that falls within the overlap of a non-toxic, toxic and potentially lethal ranges. Other medications were found to be present in non-toxic levels. Alcohol was not detected.

    b. External examination identified scarring over a vein, consistent with the history of drug abuse.

[2] At Ms Langhorn's request, Ms Forrester will be referred to throughout these findings as Alex.
[3] Having been born on 21 October 1981.

5. The coronial jurisdiction was enlivened because Alex's death was a '*reportable death'* under the *Coroners Act* 2003 (Queensland) (**CA**).

6. During the coronial investigation, Ms Langhorn expressed concerns about Alex's Methadone management.

7. The coronial investigation was undertaken by the Deputy State Coroner up until the end of May 2023, when I took over carriage of the matter. On 30 August 2024, formal notification was given that an Inquest was to be held and on 8 October 2024, a Pre- Inquest Conference (PIC) was held.

8. The role of the Coroner is limited to ascertaining what happened, not to ascribe guilt, attribute blame or apportion liability. A Coroner must not include in their findings any statement that a person is, or may be, guilty of an offence or civilly liable.

9. Additionally, a Coroner may, whenever appropriate, comment on matters connected with the death investigated at an Inquest and make preventative recommendations concerning public health or safety, the administration of justice or ways to prevent deaths from happening in similar circumstances in the future.

10. A Coroner may also give information about a person's conduct in a profession or trade to a disciplinary body for the person's profession or trade, if the Coroner reasonably believes the information might cause the body to inquire into, or take steps in relation to, the conduct.

11. I thank counsel assisting and the parties' representatives for their assistance during the investigation and Inquest, together with their helpful submissions following the hearing; the last of which was received on 30 April 2025. Except where indicated to the contrary, I largely accept and adopt the comprehensive 102-page submission provided by Counsel Assisting.

Coronial Issues

12. As identified at the PIC, the issues I have to determine are:

13. The findings required by s. 45(2) of the CA; namely the identity of the deceased, when, where and how she died and what caused her death; and:

    1. Whether the medical treatment afforded to Alex under the Queensland Opioid Treatment Program and the prescription of

Methadone was appropriate and in accordance with the Queensland Medication-Assisted Treatment of Opioid Dependence – Clinical Guidelines 2018 (**2018 Clinical Guidelines**).

2. Whether the dispensation of Methadone to Alex and her agent was appropriate and dispensed in accordance with the 2018 Clinical Guidelines.

3. Whether the Queensland Opioid Dependence Treatment Guidelines (**2023 Clinical Guidelines**) are adequate to minimise the risk of opioid overdose, in particular with respect to the prescribing of self-administered doses of Methadone, and the appointment of agents to collect those doses.

4. What Queensland Health measures are in place to communicate and address any potential concerns or non-compliance with the 2023 Clinical Guidelines amongst health services providers and between health services providers and pharmacists, and whether those measures are adequate.

5. Whether the actions of any person caused or contributed to Alex's death.

6. Whether any changes to the 2023 Clinical Guidelines could reduce the likelihood of death occurring in similar circumstances or otherwise contribute to public health and safety or the administration of justice.

14. The parties granted leave to appear were provided the opportunity to make submissions on the proposed issues. No party filed submissions in respect of the issues.

Evidence and Findings

15. To appreciate the context in which the issues have been determined, it is necessary to provide key details relevant to these findings.

Medical and Other History

16. The evidence reveals that Alex had a complex medical and psychosocial history, including:

a. A prejudicial childhood.

b. Domestic and Family Violence (**DFV**) and property damage.

c. Opioid Dependency, with a history of both illicit opioid and high dose prescription opioid use. With the aim of harm minimisation treatment and eventual abstinence, she was voluntarily registered on the Queensland Opioid Treatment Program (**QOTP**) on and off from approximately January 2005 until her death.

d. Concurrent misuse of other addictive substances including alcohol and sedatives.

e. Comorbid medical conditions including Hepatitis C, Anorexia Nervosa and risk behaviours including evidence of injecting and signs of intoxication or withdrawal.

f. At least in the year preceding her death, increasing numbers of attendances to the RBWH, with symptoms consistent with the effects of sedation including confusion.

g. In receipt of Government funded assistance including the Disability Support Pension, Department of Housing accommodation (in which she resided alone), transport, and cleaning.

Queensland Opioid Treatment Program

17. At the time of Alex's death, the prescription and dispensation of monitored medicines such as Methadone and Benzodiazepine was regulated by the now repealed *Health Act* 1937 (Queensland) (**HA**) and *Health (Drugs and Poisons) Regulations* 1966 (Queensland) (**HDPR**). They have been replaced by the *Medicines and Poisons Act* 2019 (Queensland) (**MPA**) and the *Medicines and Poisons (Medicines) Regulation* 2021 (Queensland) (**MPMR**).

18. These measures are complemented by the Monitored Medicine Standard (**MMS**) and relevantly, Queensland Health has produced the Queensland Medication- Assisted Treatment of Opioid Dependence Guidelines (the **Guidelines**).

19. **Attached** and marked "**A**" are key aspects about the QOTP Guidelines which are relevant to these findings.

20. Having considered the evidence available to me during the investigation and at the hearing, I accept and find as follows:

    a. The Guidelines are comprehensive, developed by a group of subject matter experts, are grounded upon the best available literature at the time and informed by the practical expertise of an experienced multidisciplinary team (**MDT**), including consultation with clinical, national policies and clinical guidelines and opioid treatment policies of other jurisdictions[4];

    b. Although not having legal force, the Guidelines are strong recommendations directed to clinicians for evidence-based management of these patients. They are not however, intended to replace professional judgement in individual cases;

    c. The broad goal of opioid dependence treatment (**ODT**) is reducing harm due to unsanctioned use of opioids. The QOTP can lead to psychological stability, improved control over drug use and eventual abstinence from opioid drugs;

    d. Participation in the QOTP is voluntary;

    e. The hazards associated with opioid treatment include overdose, accidental poisoning of someone other than the patient, and diversion to someone other than the prescribed patient; and

    f. Given the nature and extent of Alex's opioid dependence, her mortality risk, including for overdose, was lower whilst engaged with the QOTP when compared to the general opioid dependent population who are not so engaged. However, the overdose risk for Alex was probably higher compared to the population who are on the QOTP but in receipt of more regular supervised dosing[5].

Dr Andrew Pluta

21. Dr Andrew Pluta was the relevant provider involved in Alex's care under the QOTP between October 2014 until her death, over a 7-year period.

[4] Confirmed by the Executive Director, Mental Health Alcohol and Other Drugs Branch and Chief Psychiatrist of the Department of Health, Dr John Reilly.
[5] Dr Allan Pascoe, Addiction Psychiatrist and Addiction Medicine specialist.

22. Despite knowledge of the coronial Investigation through various requests for information early in the process, being notified of the PIC and Inquest and being called to give evidence as a witness, Dr Pluta attended the Inquest without legal representation and gave oral evidence in an argumentative, evasive, defensive and at times, self-serving fashion.

23. He is the subject of previous AHPRA notifications and disciplinary action and is currently the subject of publicly accessible conditions attaching to his registration[6].

24. Against that background, I found him to be an unimpressive witness and I approach the assessment of his evidence with caution, including not accepting his account on contentious issues unless corroborated by other evidence.

25. In fairness, I should add that following the Inquest, Dr Pluta obtained legal representation and was assisted with the preparation of submissions on his behalf. Those submissions contained an apology and, in part, an explanation for the manner in which he gave his evidence.

Issue 1: Was the Medical Treatment afforded to Alex appropriate and in accordance with the 2018 Guidelines?

26. Given that Dr Pluta was the medical practitioner who managed Alex's medical care and prescribed oral Methadone to her under the QOTP for 7 years before her death, it is his treatment and care that is to be examined on this issue. The evidence does not identify criticism against any other medical provider.

27. For at least one year prior to her death, Alex consumed her Methadone dose orally under in pharmacy supervision but otherwise took take away doses (**TAD's**) in her own home. As at the date of her death, Alex was authorised six TAD's of 120mg per week, with no more than four TAD's at any one time. The 'terminal' prescription collected on the morning of 20 September 2021 comprised three TAD's, each of 120mg and dilated to 100mls.

[6] https://www.ahpra.gov.au/Registration/Registers-of-Practitioners.aspx#search-results-anchor

The decision to prescribe Methadone.

28. Dr Pluta enrolled Alex onto the QOTP and prescribed her oral Methadone on 1 October 2014. He practices as a General Practitioner (**GP**) at Toombul Medical Centre.

29. Having considered the evidence, the Guidelines and the circumstances, I find as follows:

    a. Dr Pluta's contemporaneous entries in the clinical records of his initial assessment of Alex were suboptimal. At best they can be described as sparse and incomplete.

    b. Dr Pluta's attempts to supplement the nature and extent of his initial assessment in oral evidence at the Inquest was unconvincing. Perhaps unsurprisingly, he had no independent recollection of discussing these matters with Alex but that the medication choice was based upon what a patient will tolerate, will accept and turn up for treatment or, and what will work for the circumstances "*in front of you*".

    c. Dr Pluta's records did not contain the following factors necessary for an initial assessment pursuant to the Guidelines:

        i. Alex's drug use history, other than the prescribing by Dr Whittaker of slow-release Morphine tablets;

        ii. Alex's psychiatric or medical history, including any past attempts at suicide or self-harm;

        iii. Alex's risk behaviours, including any history of overdose and use of injecting paraphernalia;

        iv. Alex's family history;

        v. Alex's social history, apart from her reporting of being a victim of DFV;

        vi. Any physical examination undertaken by Dr Pluta, in particular whether Alex had the presence of needle track marks and signs of intoxication or withdrawal; and any psychiatric examination performed; and

vii. The decision to prescribe to Alex Methadone in lieu of Buprenorphine.

d. Specifically, Dr Pluta's records did not contain his rationale for prescribing Methadone over Buprenorphine, which appeared to be the more appropriate choice, given:

i. Alex had multiple unsuccessful Methadone treatment episodes;

ii. Alex had been prescribed Buprenorphine under the care of the Roma Street Clinic for many months prior to her attendance on Dr Pluta;

iii. Alex had overdose episodes in the past, and Buprenorphine presents less of a risk of fatal overdose than Methadone; and

iv. Buprenorphine would have avoided the need for daily dosing and permitted Alex flexible dosing arrangements.

30. Nevertheless, whilst Dr Pascoe's expert opinion was that it was unclear why Methadone was selected for Alex, the decision to prescribe Methadone was consistent with the Guidelines.

31. On behalf of Dr Pluta, it was submitted that there are difficulties and complexities associated with managing patients like Alex on the QOTP, which sometimes involve balancing strict compliance with the Guidelines with the overall aim of keeping the patient engaged and active on the program; a factor which was Dr Pluta's paramount consideration.

32. Ultimately, there is insufficient evidence to make a positive finding that Dr Pluta's decision to prescribe Methadone to Alex was inconsistent with and not in accordance with the Guidelines, in view of:

a. Dr Pascoe's evidence and expertise in this highly specialised field;

b. Sparse clinical records; and

c. The passage of time and absence of independent recollection on the part of Dr Pluta.

33. For completeness, I accept the submissions made on behalf of Metro North Health (**MNH**) and find that the actions on the part of the RBWH and The Prince Charles Hospital (**TPCH**) staff in respect of management of Alex's presentations and referrals were consistent with the Guidelines.

Ongoing Reviews

34. There is no issue as to the frequency Dr Pluta undertook reviews of Alex, which the evidence reveals was on average every 4-6 weeks. That frequency is consistent with the Guidelines and confirmed as such by Dr Pascoe.

35. The issue to be determined is therefore confined to whether Dr Pluta's conduct at each review was consistent with the Guidelines.

36. Relevantly, the evidence reveals as follows:

    a. Dr Pluta's notes are poor and lacked any particularity. Entries were at times a 'copy and paste' exercise. At other times, the only written evidence that a review took place at all was the actual prescription for Methadone;

    b. Dr Pluta's rationale for this approach in oral evidence was broadly that "*no changes, good notes*". When clarification was sought, he said the mere fact that he prescribed medication constituted sufficient notetaking;

    c. None of the entries in the records explain:

        i. what was discussed between Dr Pluta and Alex;

        ii. whether Alex's dosage increased or decreased (and, if it did, why it did);

        iii. the continued appropriateness of TAD's of Methadone;

        iv. how Alex's appearance caused Dr Pluta to consider she was not intoxicated nor in withdrawal;

        v. how the program was benefiting Alex's health;

        vi. why the diversion risk seemed low or minimal;

        vii. how Alex presented psychologically;

        viii. what stressors or events had occurred to Alex relevant to her psychological health and drug dependency;

        ix. why Methadone remained clinically appropriate;

        x. the difference between being described as "*very well*", "*well*", "*OK*" and "*adequatley* [sic]"; and

xi. whether the method of taking Methadone was discussed.

d. Dr Pluta's explanation was that:

i. the most important factor to him was whether the patient could "*present in a reasonable fashion, not sedated, coherent, talking reasonably well, um, reasonably dressed, reasonable affect, reasonably looking after themselves*";

ii. he would ask questions about Alex's welfare and progress;

iii. he would assess for intoxication and withdrawal effects;

iv. he would discuss Alex' s social situation;

v. he would perform a physical examination if there was a report of trauma;

vi. he would consider the adequacy of the prescribed dose of Methadone; and

vii. he would consider her stability and adherence.

37. As to whether Dr Pluta ought reasonably to have been aware of the presence of track marks at these reviews (which would indicate Alex was injecting her Methadone), I note:

a. The evidence of Alex's friend (Mr Peter Morrow) that she injected her Methadone anywhere she could find a vein;

b. The findings documented at RBWH in 2019 and 2020, that Alex had visible track marks; and

c. That Dr Pluta says he did check her for same but that he did not ask that she roll up her sleeves or pants or remove her boots in order to check, because she did not appear to be sedated or appear as someone who was actively illicitly using and do so would have been damaging to the therapeutic relationship.

38. However, I am cautious about making a positive finding about the detection of track marks aspect given:

a. Alex's longstanding dispensing pharmacists who, over a significant period of time, also did not detect track marks on Alex on her regular attendances;

b. The absence of other cogent evidence that track marks were visible;

c. The evidence of Mr Morrow that Alex was careful to present as in the best possible light in order to obtain her Methadone; and

d. The sparse state of Dr Pluta's records.

39. For the balance of this issue however, for the above reasons, I do not accept Dr Pluta's explanations in the absence of a contemporaneous notes and find that his ongoing reviews were inconsistent with, and not in accordance with the Guidelines.

Urine Drug Screens

40. The evidence is such that in the 7-year period during which Alex was on the QOTP under Dr Pluta, at no time was urinary drug screening (**UDS**) undertaken on Alex. According to the expert evidence, had UDS been performed, it could have been a tool to assist in testing the validity of Alex's self-reported use of substances and in turn, inform on risk management including TAD's suitability.

41. I note the following evidence:

a. Dr Pluta's records contain no entries that he considered UDS but that he elected not to do it, and provides nothing about the rationale;

b. Dr Pluta became evasive and argumentative when questioned about this in oral evidence, stating that staffing arrangements at the medical centre where he worked were not conducive to performing UDS due to having to supervise patients whilst doing so. Further, he said that he did not consider UDS to be of much assistance nor would it help him make a management decision, despite accepting that such testing formed part of a patient's clinical presentation and was something that could be taken into account; and

c. Both Drs Pascoe and Reilly considered UDS to be a valid and useful tool in managing a patient on the QOTP regarding the determination of risk or adherence to the program.

42. I do not accept Dr Pluta's rationale for not undertaking UDS because:

a. The absence of contemporaneous entries in his records provides no basis for a consideration of his account;

b. His oral evidence was unconvincing and self-serving, especially given that supervision of UDS is not a requirement in the Guidelines; and

c. The expert evidence contends otherwise. Both Drs Pascoe and Reilly opined that UDS is a valid and useful tool in managing a patient on the QOTP with respect to determining risk or adherence to the program.

43. Whilst I find that the absence of the performance of UDS's was inconsistent with and not in accordance with the Guidelines, I find that there is insufficient basis to conclude it would have made any impact to the risk of Alex's death. The evidence of Mr Morrow was that Alex would not attend Dr Pluta when she was demonstrating signs and symptoms of withdrawal. That being so, any UDS performed, given the half-life of Methadone, would be unlikely to have yielded a positive result.

TAD Authorisation

44. The state of Dr Pluta's clinical records makes it difficult to determine when he first began prescribing TAD's to Alex.

45. In any event, I agree with Counsel Assisting that that the critical period for examination is between May 2020 (when Alex had her sixth presentation to the RBWH, when concerns were raised with Dr Pluta) through to her death in September 2021. At the time of her death, Alex was prescribed six TAD's.

46. I find that Dr Pluta's conduct in prescribing six TAD's to Alex was inconsistent with and not in accordance with the Guidelines, for the following reasons:

    a. *First,* the prescribing of five or six TAD's per week exceeded the maximum dose recommended in the Guidelines even for a patient of "low risk", which was for four TAD's doses per week. The Guidelines could not have been clearer: a coloured text box provided: "*The maximum quantity of Methadone take-away doses should never exceed four in a week*";

    b. *Second*, when one considers the risk assessment factors that were recommended to be considered and balanced in order to determine whether Alex was a "low", "moderate" or "high" risk, it is difficult to conclude Alex was anything other than a "high" risk. That is because:

        i. during 2019 to 2020, Alex presented to the RBWH with acute confusion, impaired memory, and reports of seizures on multiple

occasions. She was found to have Methadone and benzodiazepines on her person (which by that stage ought to have been consumed), she was unable to say when she last took her Methadone on various occasions, and she requested Methadone. Alex was also observed to have needle track marks which suggested either an alternate route of administration of Methadone or the use of other intravenous drugs. Relevantly, the discharge forms of those hospital attendances were provided to Dr Pluta;

ii. Alex was not the subject of UDS;

iii. Alex was prescribed the benzodiazepines Clonazepam and Oxazepam which increased her risk of overdose; and

iv. Alex reported ongoing DFV issues.

c. The presence of those factors suggested that Alex was a "higher risk" for TAD's during that period. The Guidelines were unambiguous in those circumstances. Alex should not have been prescribed any TAD's of Methadone except in special circumstances. And even if Alex was a "moderate" risk, she should not have been prescribed any more than two TAD's doses per week, and it should have been considered whether the TAD's were dispensed non-consecutively;

d. *Third*, the Guidelines were clear. Should a practitioner seek to prescribe more TAD's than was suggested within the Guidelines, they should "*seek specialist advice (or conduct a team consultation if in a clinic setting), and clearly document their decision making*". Dr Pluta did not seek specialist advice, nor did he conduct a team consultation. He did not document his decision-making (whether clearly or at all) which is of itself was contrary to the Guidelines;

e. *Fourth*, on 25 January 2021, Dr Pluta referred Alex to the TPCH psychiatry unit (the first such time he referred Alex for psychiatric care in over six years). He provided, in the referral, that Alex had "*extreme psychiatric upset*", was the subject of DFV, had considered self-harm, and that the situation was "*dangerous and fragile*" which he believed necessitated complex comprehensive assessment and ongoing monitoring and medication adjustments. The referral closed with the

words "*This is URGENT*". An urgent, dangerous and fragile psychiatric state with DFV and suggestion of self-harm elevated Alex's risk for TAD's.

f. It was against that background that Dr Pluta lessened the prescribing restrictions further and prescribed that Alex only required one supervised dose each week on and from July 2021;

g. *Fifth*, the Guidelines provided when TAD's were to be stopped (completely) with reintroduction to occur gradually based on an assessment of risk, albeit with at least 12 weeks of evident stability. A return to supervised daily dosing was stated to be an important measure to reduce risk;

h. Circumstances in which TAD's were to be stopped were if "*any of the higher risk factors*" are present, being those recorded in Table 13 of the Guidelines (**Attachment A**). Examples were also given of issues which demonstrate when a patient may need to return to supervised dosing. They included, relevantly, a deterioration in psychological, physical, or social well-being;

i. Alex did materially deteriorate throughout 2019 to 2021. She attended the RBWH on six occasions with similar symptomatology, including presentations with acute confusion and memory impairment during May 2019 to May 2020, and was referred to a Neurologist by Dr Pluta in February 2021. She also decompensated psychiatrically in the context of social and DFV stressors in late 2020 and throughout 2021 and was "*urgently*" referred to TPCH. These factors, consistent with the Guidelines, required a reassessment of the number of TAD's Alex was prescribed, and strongly suggested a need to return to supervised dosing or, at the very least, a reduction in the number of TAD's prescribed;

j. *Sixth*, Dr Pluta did not employ several risk mitigation strategies which were reasonably open to him consistent with the Guidelines, viz:

    i. he did not communicate with Mr Morrow regarding the conditions for TAD's, their responsible storage, and the use of medication;

    ii. he did not consider changing Alex to Buprenorphine;

iii. he did not prescribe Naloxone (considering it to be "*dangerous*" and "*immediately outweigh any benefit*");

iv. he did not limit the number of consecutive TAD's to, for example, every second day;

v. he did not employ UDS; and

vi. despite informing the Court that Alex had "*pharmacy delivery*" of Methadone (which she did not), he did not consider whether any pharmacy delivery could be made to Alex because he could not guarantee the quality of the people reliably delivering and dispensing to her.

k. *Seventh*, Registered Nurse (RN) Ms Backler (RBWH) contacted Dr Pluta directly on 20 May 2020 and advised him of her concerns in circumstances where Alex had been located with unused Methadone, Alex could not recall when she last took Methadone, Alex was acutely confused, and Alex had presented in a similar way on at least three occasions over the preceding 12 months. Despite being informed of those concerns from a practitioner specialising in alcohol and drugs, Dr Pluta's response was to add a second pick-up day to Alex's prescription. Despite Dr Pluta informing Ms Backler that he would add a second supervised dose, the prescription was ambiguous (it could be read to only add a second pick-up day) and further, Dr Pluta subsequently changed Alex's prescription back so that she only required one supervised dose each week;

l. *Eighth*, Dr Pascoe's expert opinion of 17 June 2022 addressing Dr Pluta's conduct in prescribing Alex TAD's is that various matters suggested deterioration in Alex's psychological, physical and social well-being which suggested removal of TAD's at that time, with reintroduction to occur gradually based on assessment of risk with a least 12 weeks of evident stability;

m. Dr Pluta was questioned about his decision to authorise up to six TAD's per week. His evidence was that he assessed Alex during 2020 and 2021 as being a "low" risk and provided reasoning as to his decision to prescribe the level of TAD's he did. He did however say that, clinically speaking, Alex should not have been prescribed the TAD's he did, and

that "*basically she is a person for whom that strict guideline or four takeaways a week is not meant to apply*".

47. In making the above finding, I have considered and rejected the oral evidence Dr Pluta gave in attempting to demonstrate the reasonableness of his conduct in prescribing six TAD's per week, as follows:

    a. He stated that Alex did not appear to be intoxicated or in withdrawal when repeatedly attending her appointments with him, and further that she appeared to adhere to her medication regime for a consistent period of time. This is in stark contrast to the findings of staff (who did not have the advantage of knowing Alex) at her various attendances at the RBWH, together with other factors detailed above including his referral to TPCH for urgent psychiatric review;

    b. He stated that in support of his response to increased risk, that once Alex had overdosed, he took immediate steps to cancel her treatment under the QOTP, stating that this was the "*first instance of major noncompliance*". This is not reflected in the further prescription he made on 20 September 2021, nor in the contemporaneous entry made by RBWH staff that "*Dr Pluta has documented events and will review takeaway doses and management";*

    c. He stated that Alex had carers residing with her who provided assistance with taking her medications. However, when questioned about this, he conceded he had no idea who the carers were, that they would know about medication doses because of the instructions on the containers and did not involve carers in conversations as to Alex's treatment nor provide them with any advice or guidance;

    d. He stated that Alex's financial limitations were such that more frequent supervised doses were not achievable. Although she was a recipient of welfare and support, the evidence does not bear this out (e.g. transport via BlueCare and Mr Morrow at no cost). As Mr Morrow stated, Alex would go to great lengths to get her Methadone, which she needed to "*survive*". She did not have any issues in attending historically. Consequently, I do not consider the state of Alex's finances to have been a major impediment to her attending for more supervised doses; and

e. He stated that Alex's mobility was an additional impediment to her attendance for more frequent supervised doses was inconsistent with his decision making at other times in support of more supervised doses.

48. I find that there was no sound reason for Dr Pluta to maintain Alex on six TAD's per week. Alex was motivated to do whatever it took to get her Methadone. If that meant more frequent attendances, then it is highly likely she would have done it, as she had done in the past. In view of her risk profile, Alex should have been the subject of increased supervision, not less.

49. Dr Pluta also advanced the proposition that prescribing six TAD's to Alex was the only way to voluntarily keep her engaged in the QOTP (which he said kept her "*alive*" for as long as she was). For the same reasons, I do not accept this. Alex had been subject to (and adhered to) variable and more stringent TAD arrangements before and had not rejected them.

50. Finally, Dr Pluta stated that the Guidelines are not always adhered to in practice and that they do not reflect industry standard. I reject this argument, based on the expert opinion of Drs Pascoe and Reilly to the contrary.

51. Ultimately, I find that Dr Pluta's decision to prescribe up to six TAD's to Alex on and from May 2020 was inconsistent with the Guidelines, was inappropriate and was done without specialist input and without written justification.

52. Also relevant to this issue is the terminal amount of Methadone taken by Alex on 20 September 2021. Counsel Assisting submits I should find that Alex took all three 120mg TAD's intravenously. Having closely reviewed the available evidence, I am persuaded by the submissions made on behalf of the family that Alex injected a quantity of Methadone (in excess of one dose) rather than all three doses, and I find accordingly, because:

    a. The notes made by QAS officers about the scene findings (repeated in the RBWH notes), were based on information given by Mr Morrow at the scene; there being no suggestion that this was based upon their own observations;

    b. This issue was not explored with the QAS officers, who were not asked to provide statements during the investigation nor were they called to give oral evidence at the Inquest;

c. Mr Morrow's evidence about the scene should be viewed in the context that he was likely in shock, having unexpectedly found his friend in the state she was in, having to urgently contact Emergency Services and having to commence CPR pending QAS arrival;

d. Mr Morrow's evidence was that Alex would tend to take her dose daily and would often have half and full bottles of Methadone around the house, depending upon how close she was to her next pick-up dose. She would not take the entirety of her dose when she would not pick up more Methadone for a number of days but that she would sometimes take more than she was supposed to, resulting in massive withdrawals. On the day of the incident, the TAD collection had just occurred;

e. Alex was an experienced Methadone user. I agree her use could at times be best described as haphazard, sometimes taking more that the daily amount in response to withdrawal symptoms. However, there is no evidence that suggests that Alex would ever take all doses of Methadone available to her immediately upon receipt; and

f. The state of the toxicology evidence is that Methadone was detected at a level that falls within the overlap of a non-toxic, toxic and potentially lethal ranges. Relevantly, in the absence of expert opinion from a Forensic/Clinical Pharmacologist, I am reluctant to make a positive finding on this issue, if that is indeed possible.

53. In my view, the evidence is insufficient to conclude that Alex injected all three doses immediately following collection. Rather, on the available evidence, I find that Alex injected a quantity of Methadone in excess of one dose.

54. I also reject the suggestion by Dr Pluta that there was a deliberate or intentional element to Alex's death, for the same reasons. Alex was voluntarily on the QOTP to manage her chronic opioid dependency, presumably with the ultimate aim of achieving abstinence, not because she was intent on ending her life. Having been on the QOTP for some time, she was likely acutely aware of the dangers associated with overdose.

Agent Authorisation

55. The terms of Dr Pluta's prescriptions were that an agent was authorised to collect Alex's Methadone, as follows:

a. From August 2020 to January 2021- "*Carer or patient herself may pick up*".

b. From February 2021 until Alex's death- "*Blue Care Carer or patient herself may pick up*".

56. At no time was an agent named.

57. I reject Dr Pluta's evidence that the prescription he provided did not authorise any person to collect Alex's Methadone but rather facilitated the lawful temporary "*holding*" of that medication if Alex was herself unable to hold it in the pharmacy, and while walking from the pharmacy to a vehicle, for the following reasons:

    a. *Firstly*, in an earlier statement to this Court[7], Dr Pluta advised that Alex had been stable on the QOTP program with a regular pick-up either herself or "*through the agency of a carer*". And, earlier in his oral evidence, Dr Pluta said (unprompted) that:

        i. it was his understanding that Alex had a carer because "*she is unable to pick up her medications herself, and somebody else needed to pick them up*"; and

        ii. *"[h]er carers would fetch her medications for her for part of that period of, what was it, 15 years*".

    b. It was only when Dr Pluta was questioned as to BlueCare's policies[8] and it was suggested that his prescriptions were ambiguous that Dr Pluta gave evidence that he "*never intended to authorise*" the collection of TAD's of Methadone by anyone other than Alex, but that he was aware that had "*happened in the past time*". I accept that the most reliable evidence is that contained in the early statement which Dr Pluta provided to this Court and his unprompted oral evidence;

    c. *Secondly*, as a matter of common sense and reality, if Dr Pluta did not intend for an agent to collect TAD's for Alex but intended Alex to collect the TAD's herself (albeit that an agent could "*hold*" the medication for her), there would be no reason why Alex would not be prescribed a

[7] Dated 21 October 2021, in response to a Form 25 issued 27 September 2021.
[8] To the effect that they do not provide a medication collection service, rather they provide transport for the patient to collect.

supervised dose on that collection day. Alex would have been present in the pharmacy. But Dr Pluta prescribed, for some months, one supervised dose a week minimum with two pick-up days; and

d. *Thirdly*, the prescription is clear and unambiguous. There were to be two "*pick-ups*" per week of Methadone. Alex or a "*Blue Care carer*" were authorised to "pick up" the medication.

58. I find that Dr Pluta's authorising of an agent to collect Alex's TAD's of Methadone did not comply with the Guidelines, as follows:

    a. The authorisation did not include the name of the agent but rather adopted the generalised phrase "*carer*" (so that it could be any person Alex trusted) and subsequently "*Blue Care carer*" (being someone who may be "*more reliable*" and "*less prone to cause problems than a simple acquaintance or friend");*

    b. The authorisation was not for a brief, specified, period but rather extended at least for 14 months;

    c. The authorisation did not occur in the context of any acute medical issue, but rather was said by Dr Pluta to be in reference to Alex's chronic medical issues;

    d. Dr Pluta's deviation from the Guidelines was not the subject of any documentation in Alex's records; and

    e. During August 2020 to January 2021, the authorisation of an agent to collect was superfluous and apt to confuse because Alex was only permitted five TAD's per week and so did not require an agent to collect them given she had two supervised doses each week and could collect sufficient TAD's from those attendances.

59. I find that Dr Pluta's decision to authorise an agent to collect Alex's TAD's of Methadone on and from (at least) August 2020 was inconsistent with the Guidelines, was done without specialist input and without any written justification.

60. It was fortuitous that did not have any impact upon Alex's care and treatment or diverted, because:

a. Blue Care, despite being authorised by Dr Pluta to collect TAD's medications for Alex, did not do so in accordance with their own policies and procedures; and

b. Mr Morrow, who did collect TAD's for Alex, appears to have been a person who genuinely and altruistically sought to assist her. There is no suggestion that Mr Morrow did anything other than collect Alex's medications and provide them directly to her.

Prescriptions

61. During August 2020 to September 2021, there were essentially two forms of Methadone prescriptions issued by Dr Pluta:

    a. The first was in these terms:

    Pick Up Days Are: 2 pickup per week TUES +
    other,,, non consecutive,
    prefer well spaced
    as per hosp advice after admission
    dispense meds with meth only: clonazepam,
    dilantin antenex,
    Carer or patient herself may pick up
    TAD Days Are: 5 per week, non consecutive

    b. The second was in these terms:

    Pick Up Days Are: 2 pickup per week MON +
    other,,, non consecutive, ,, prefer well spaced
    2nd pickup day is flexible if needed by patient
    Dispense meds with meth only: clonazepam,
    dilantin antenex
    One witnessed dose per week Minimum
    BLUE CARE Carer or patient herself may pick up
    TAD Days Are: 5 per week, non consecutive

62. I find that Dr Pluta's written instructions for Methadone during August 2020 to September 2021 were unclear and ambiguous and inconsistent with the Guidelines, for the following reasons:

a. Dr Pluta was responsible for "*clearly documenting dosing instructions on the Written Instruction*". Neither form of prescription is clear nor unambiguous;

b. The first form of prescription did not provide for the number of supervised doses per week. While one could attempt to deduce from the number of TAD's (being "*5 per week*") that there were to be two supervised doses per week, that could have been stated in unambiguous terms, rather than the words "*2 pickup per week*". That ambiguity is then compounded by the authorisation that a "*Carer or patient herself may pick up*" the medication. If Alex was prescribed two supervised doses per week, and five TAD's, there would be no need for an agent to collect any doses as Alex would simply collect her TAD's on the two days she attended for a supervised dose;

c. The second form of prescription instructed "*One witnessed dose per week Minimum*" whilst only prescribing five TAD's per week. Methadone is a daily dosed drug. If, on any given week, Alex only had one supervised dose, there would be insufficient TAD's prescribed. It is therefore unclear whether Dr Pluta intended to prescribe five or six TAD's per week;

d. The use of the phrase "*2nd pickup day is flexible if needed by patient*" increases the ambiguity. The prescription instructs two pick up days per week, and five non-consecutive TAD's. The second pick up day will always be needed by the patient if those instructions are followed; and

e. Contrary to Dr Pluta's evidence, the use of the word "*Minimum*" in the phrase "*One witnessed dose per week Minimum*" did not instruct that there must be more than one supervised dose per week. Read literally, the prescription means what is says. Alex could, in any given week, decide to have one supervised dose, conformably with the prescription, which is what she did. The effect was that Alex was regularly provided six TAD's of Methadone.

Benzodiazepine

63. Dr Pluta commenced prescribing Alex benzodiazepines as follows:

a. Clonazepam from 17 June 2015. The reasoning for him doing so is not expressly recorded in the clinical records. His evidence was that he prescribed Clonazepam for Alex's epilepsy.

b. Diazepam from 8 October 2015. The reasoning for him doing so is not expressly recorded in the clinical records. Diazepam was changed to Oxazepam during the course of his treatment of Alex. Dr Pluta's evidence was that he prescribed both for Alex's anxiety.

64. Benzodiazepines are sedatives. Additional safety concerns arise with the concurrent prescribing of benzodiazepines with Methadone. There is an increased risk of overdose and an increased risk of impaired memory and impaired cognition. As the Guidelines provide:

> *Extreme caution should be taken if a decision is made to prescribe benzodiazepines in combination with methadone or buprenorphine, particularly during the first two weeks of treatment. Generally, benzodiazepine prescribing is discouraged outside the context of an agreed withdrawal plan.*

65. The Guidelines provide detailed information and guidance to practitioners in such circumstances. A benzodiazepine withdrawal regimen is recommended.

66. Dr Pluta was questioned about his benzodiazepine prescribing for Alex. He initially said he was prescribing benzodiazepines to Alex because they had been commenced by other practitioners and, although he was not taking over management of that part of Alex's healthcare, he was continuing drugs prescribed by others.

67. When it was highlighted to Dr Pluta that it was he who commenced prescribing Diazepam (and did not take it over from someone else) he defended his decision on the basis that Alex presented with anxiety such that "*there were different circumstances active in this case*". He said he was "*most comfortable*" with using that drug than others with respect to side-effects, effects, and overdose, despite the fact it was a benzodiazepine.

68. Ultimately, there is insufficient evidence that Dr Pluta's decision to prescribe those medications was contrary to the Guidelines. However, I find that his conduct in prescribing same was inappropriate, because:

a. Dr Pluta's evidence was to the effect that he never treated Alex's epilepsy but only took over the prescribing of Clonazepam (and other medications) for her epilepsy for over six years. He could not say who was looking after Alex's epilepsy. The concern with that conduct is:

    i. on the available evidence, it is unclear whether Alex actually had epilepsy;

    ii. Alex's broader medical history referred to Alex having benzodiazepine dependence;

    iii. Alex was not seen by any other practitioner for her epilepsy for over six years. It is difficult to conclude (objectively) anything other than Dr Pluta was responsible as her GP and within the limits of his expertise for managing and treating Alex's epilepsy;

    iv. Dr Pluta did not refer Alex for specialist review of her possible epilepsy until 10 July 2020 (the RBWH Neurology Clinic); and

    v. Alex was reviewed by Professor O'Sullivan, a Neurologist, on 11 January 2021 by telephone. Professor O'Sullivan wrote to Dr Pluta and advised that it was most likely her symptoms were psychogenic in nature, and he recommended referring her to a Psychiatrist.

b. It was in that context that Dr Pascoe gave expert evidence that:

    i. Clonazepam is not a first-line treatment for epilepsy;

    ii. there is a risk of developing dependence on Clonazepam (in addition to the risk of taking benzodiazepines with Methadone);

    iii. there were first-line treatments for epilepsy available that were not benzodiazepines;

    iv. if Dr Pluta was to prescribe Clonazepam as an adjunctive therapy for epilepsy, he ought to have done so with caution;

    v. it would have been reasonable and appropriate for Dr Pluta to have sought specialist advice from a Neurologist as to what medication to prescribe for Alex; and

    vi. it would have been preferable for specialist advice from a Neurologist to have been sought earlier than it had been.

c. With respect to the prescribing of Diazepam and subsequently Oxazepam, the evidence of Dr Pascoe was similar. In his report, Dr Pascoe explained:

    i. Diazepam (and Oxazepam) are not first-line treatments for anxiety or depression associated anxiety;

    ii. Oxazepam can be used as for short-term relief of anxiety symptoms; and

    iii. there is a risk of developing dependence on each of Diazepam and Oxazepam.

d. In his oral evidence, Dr Pascoe opined that introducing Diazepam would want to be done cautiously with "*a plan to try not use it in… the longer term*" and it would have been preferable for Alex to be referred to a specialist Psychiatrist earlier than she had been.

e. This is reflective of a larger issue with Dr Pluta's conduct, namely his contention that he was really only treating Alex's opioid dependency and others were managing the myriad of her other medical concerns.

69. I also find that Dr Pluta did not have the required regulatory approval to prescribe benzodiazepines to Alex based on an erroneous understanding of his legal obligations, having regard to the following:

a. During the period Dr Pluta was treating Alex, the HDPR r 213(1) provided that a "*relevant practitioner*" must not, without an approval, prescribe a "*restricted drug of dependency*" for a person the relevant practitioner reasonably believes is a drug dependent person. In order to obtain an approval, r 213(2) provided that a relevant practitioner was required to give to the Chief Executive, a report in the approved form, as to the circumstances of the person's treatment if the practitioner reasonably believes it is necessary to treat them with the drug;

b. A "*relevant practitioner*" was defined to be a "*doctor, endorsed midwife, nurse practitioner, surgical podiatrist or endorsed podiatrist*";

c. Dr Pluta was a relevant practitioner. Alex was a "*drug dependent person*" who was on the QOTP. Dr Pluta must have reasonably believed Alex was a drug dependent person, because he admitted her onto the QOTP and was managing her care and treatment. A "*restricted*

drug of dependency" included Diazepam, Oxazepam, and Clonazepam;

d. Dr Pluta did not obtain or receive an approval under r 213(1) of the HDPR to prescribe to Alex Diazepam, Oxazepam or Clonazepam at any time during his treatment of her. That conduct contravened the Regulations. This was not identified until after Alex's death;

e. Dr Pluta was questioned about his lack of approval under the regulation 213. His responses demonstrate a flawed and erroneous understanding of his legal obligations. He contended that he did not require an approval because the drugs were therapeutic, and not for benzodiazepine dependency. That Alex did not have benzodiazepine dependency is doubtful. But irrespective, that understanding was not correct; and

f. Dr Pluta also sought to buttress his understanding as being correct by saying that specialists, such as Psychiatrists and Neurologists, did not require an approval. He is correct that such specialists did not require an approval. That is because they are not "*relevant practitioners*". As a GP, Dr Pluta was a "*relevant practitioner*", and the requirement to seek and obtain approval extended to him.

70. I have considered submissions made on behalf of Alex's family to the effect that clear findings should be made that Dr Pluta's conduct in Alex's care more generally, in particular with respect to management of her epilepsy and ongoing prescription of benzodiazepines, was inappropriate.

71. Respectfully, I reject that submission on the following basis:

a. It is outside the scope of the coronial issues and was not the subject of sufficient investigation, beyond the impact such treatment would or should have had upon Alex's treatment under the QOTP; and

b. There is no evidence that suggests that Alex's epilepsy or other medical conditions had any causal nexus to her death.

Medical Care generally

72. Dr Pluta gave evidence to the effect that he was only treating Alex in relation to her opioid dependency and matters that pertained to that. To the extent there were other medical issues facing Alex, he appeared to take the position

that he was not her treating practitioner or that those other medical issues were not his responsibility to treat or care. He also said that as a medical practitioner he did not consider he "*was in a position to determine whether* [Alex] *required specialist review*".

73. I do not accept that evidence for the following reasons:

    a. Alex was a complex patient. She had other medical conditions, some of which were intertwined with her opioid dependency, and which necessitated a comprehensive/holistic approach;

    b. The evidence shows that Alex did in fact attend Dr Pluta for a range of medical issues other than her opioid dependency, which resulted in at least some management on Dr Pluta's part, as follows;

        i. the referral of Alex for neurology and psychiatry review in the year before her death); and

        ii. the prescription of medication for Alex's other conditions; at times commencing same without specialist input (see paragraphs 63-68 above); and

    c. Whilst there were at times other medical practitioners who were intermittently involved in Alex's care, they were predominantly for discrete issues for a limited period of time, and it was ultimately identified that Alex needed to have one treatment provider for all her concerns (Dr Pluta).

74. Dr Pluta's care can be contrasted with that of GP Dr McAlister, who treated Alex in the context of a shoulder impaction fracture from February to June 2021. Dr McAlister recognised Alex needed psychiatric review and referred her on more than one occasion. Dr McAlister also recognised that Alex had other medical needs, including epilepsy, but did not get to the point of being able to treat them given the few consults Alex attended on her for. In her words:

> *Normally with our patients once a year, we do epilepsy plans and we, you know, go through and look – do seizure reviews and things like that. I don't think we'd got to the stage when we were able to talk about those sorts of things because there was always a lot of other issues that we were dealing in those – just those few*

consults. But with a female of her age, we would obviously be looking at sort of normal sexual screening, pap smears – um – you know, general sort of nutrition status, bone density, because she fractured – um – you know, epilepsy management, all those sorts of things. …

It would have just been normal, general screening and management that we would have got to. … which we do with all our chronic health patients.

75. Against that background, I find that Dr Pluta was Alex's sole treatment provider from about October 2015 until 8 February 2021, and from June 2021 until the date of her death. And when other practitioners were treating Alex, I find that Dr Pluta had little or no engagement with them. Dr Pluta acted as Alex's ODT provider and otherwise had taken over the balance of Alex's medical issues save for in acute circumstances.

76. Dr Pluta said, in his evidence, that he would only spend 10 to 15 minutes with Alex on each review. GP Dr Williams, by contrast, considered that "*endless*" time would be needed for someone like Alex, and that it required a "*team*"; a "*multidisciplinary approach*".

77. In a broader context, Dr Pluta has been the subject of a number of investigations of the Australian Health Practitioner Regulation Agency (AHPRA). He was the subject of a performance assessment on 22 July 2020. A report was produced on 4 August 2020. The report identified:

    a. Dr Pluta elected to have a large number of "*very challenging*" patients with complex needs, which includes managing patients on drugs of dependence programs and HIV and Hepatitis C positive patients;

    b. Dr Pluta's insistence of seeing patients for 10-minute consultations did not allow him much time to address the complex medical needs for such patients, other than providing them with repeat prescriptions, and his inflexible approach of "*one issue per consultation*" would make it difficult for him to provide adequate care to complex patients; and

    c. Dr Pluta did not have a plan with how to deal with multiple prescribers for the one patient, however he believed in one prescriber for drugs of dependence. But drug dependent patients would find it hard to get

routine medical care for other medical issues due to Dr Pluta's one issue per consultation policy.

78. This does not place Dr Pluta's account of his treatment of Alex in a good light, when viewed in the context of the circumstances of this inquest.

79. For the above reasons, I find that Dr Pluta's conduct in not referring Alex for specialist review by a Neurologist and Psychiatrist earlier than 2020 and 2021 respectively, was, insofar as it is relevant to her care under the QOTP, not appropriate, particularly in circumstances where he prescribed benzodiazepines to Alex on and from 2015.

Record Keeping

80. As identified above, Dr Pluta's record-keeping was poor. And, where the Guidelines provide that any deviation from their recommendations be recorded, Dr Pluta's practice of record-keeping is contradictory to those Guidelines.

81. Dr Pluta, when questioned about his record-keeping, was defensive and argumentative. That is perhaps best demonstrated when Dr Pluta said in his evidence: "*We kept Alex … alive for that period of time, and although you might like the notes, you might like more notes, you might like to second guess what I've done, you might like to add your professional legal judgment to judge my medical judgment as inadequate because your legal judgment obviously knows more about the medical judgment than mine*".

82. The various reasoning given by Dr Pluta for his record-keeping can be categorised as follows:

    a. *First*, Dr Pluta sought to contend that there were clinical notes (when there were no notes recorded) because the fact that he had issued prescriptions with specific doses was information. His reasoning was that the writing of a script constitutes a *de facto* assessment and judgment of Alex's status;

    b. *Second*, it was Dr Pluta's view that a patient's notes are an "*aide memoire*" for him, and they were adequate for that purpose;

    c. *Third*, Dr Pluta sought to justify his practice on the basis that it "*takes a substantial amount of clinical time to write and would bog the file up so much that no-one would want to read it*", such that it "*actually hides*

clinical information rather than makes it visible, and it's not a practical thing to do". He termed it "*sterile data*";

d. *Fourth*, Dr Pluta sought to reason his conduct on the basis that the records are "*quite damaging to people if you start preparing those sort of levels of detail. Anybody can get hold of their history, it can ruin their ability to get a job. You have to be very careful what you say and how you say it… You don't have too much descriptive detail … you don't add anything which might poison someone as well*"; and

e. *Fifth*, and finally, Dr Pluta said that the notes were adequate to keep Alex from dying.

83. The entries of Dr Pluta stand in stark contrast to an entry of Dr Peter Dunne, another GP at that practice, made on 24 February 2016. On that day, Alex had attended at Toombul Medical Centre seeking replacement Methadone doses as she claimed to have left her TAD's at another location. Dr Dunne's entry is far more fulsome than any of Dr Pluta's entries, and Dr Dunne (in prescribing three replacement Methadone doses) recorded that:

    a. each of the doses were to be witnessed; and

    b. Alex claimed she was in too much pain to attend the pharmacy each day and needed "*takeaways*" to which Dr Dunne advised that Alex should "*stay in a hotel near her pharmacy to ease her difficulty*". That is, he did not authorise TAD's. And there is no suggestion that Alex was unable to attend on the pharmacy for three consecutive supervised doses.

84. Contrary to Dr Pluta's assertions, clinical records are not just an *aide-memoire* to himself. The clinical records are a record of Alex's medical care and treatment including Dr Pluta's decision-making and his process of reasoning. In particular, clinical records serve several essential purposes, especially in clinical, legal and administrative contexts. It has been most difficult to identify why Dr Pluta made the decisions he did, and deviated from the Guidelines in numerous respects, because there is nothing recorded which allows those facts to be comprehended and analysed.

85. What is more concerning is that many of the entries for Alex made by Dr Pluta in the clinical records were entered *after*:

a. Dr Pluta had been informed by AHPRA – following a performance assessment conducted on 22 July 2020 – that his record keeping was unsatisfactory in that:

    i. a patient's health summary, medication lists and past patient history were not adequately documented, and

    ii. Dr Pluta's progress notes were often brief and did not contain enough clinical detail;

b. Dr Pluta provided a statement to AHPRA that, on reflection, there could have been greater detail included in the clinical records, and he accepted the importance of maintaining accurate clinical records; and

c. Dr Pluta underwent education with respect to medical record keeping with his professional indemnity insurer.

86. When questioned, Dr Pluta insisted that his record-keeping had improved, yet his entry of Alex's attendance on him on 8 September 2021 containing no progress notes whatsoever. That conduct, and the evidence of Dr Pluta, is concerning.

87. I find that Dr Pluta's record-keeping of his medical care and treatment of Alex was inconsistent with the Guidelines and inadequate and insufficient for any patient on the QOTP.

88. Ultimately, the deficiencies identified above are professional conduct issues on the part of Dr Pluta and are not confined to straight non-compliance with the Guidelines. In this respect, a referral is made below.

Issue 2: Was Methadone Dispensed in Accordance with the 2018 Clinical Guidelines?

89. All three pharmacists who gave evidence in these proceedings (namely Mr Steven Hancock, Mr Shahriar Kashani-Malaki and Ms Maria Papacostas) (**the pharmacists**) worked at Brisbane Compounding Pharmacy (**BCP**) and dispensed Methadone to Alex. It is therefore their conduct that is to be examined under this issue.

90. In considering whether their conduct was consistent with the Guidelines and was otherwise appropriate, the following is to be examined:

    a. communication with the OTD prescriber, Dr Pluta;

b. the dilution of Methadone;

c. the dispensation of Methadone;

d. the dispensation of Methadone to an agent; and

e. the dissemination of information.

QOTP Guidelines

91. Like Issue 1, the 2018 Guidelines are relevant to determination of this Issue as they provide recommendations to pharmacists who dispense Methadone to a patient on the QOTP.

92. **Attached** and marked "**B**" are key aspects of the QOTP Guidelines which are relevant to this aspect of these findings.

93. Each of the three pharmacists confirmed that they were aware of and familiar with the 2018 Guidelines.

Pharmacy Systems and Processes

94. Relevant to determination of this issue were the systems and processes available to the dispensing pharmacists at the BCP at the relevant time.

95. There were two software systems that were employed at BCP during 2020 and 2021 for dispensing, namely Rx One and MethDA; the latter of which was used solely for the dispensation of Methadone and Buprenorphine.

96. MethDA functioned by permitting a pharmacist to manually enter in the details of a prescription in MethDA against a patient record for the month the prescription pertained. Once that was done, MethDA would inform the dispensing pharmacist on any given day:

    a. The prescribed dose of Methadone;

    b. How many TAD's were authorised to be dispensed;

    c. The recent history of dispensation events; and

    d. The balance of the terms of the prescription, for example, whether an agent was permitted to collect TAD's.

97. The accuracy of the MethDA system for future dispensing events of Methadone was therefore solely dependent upon the accuracy of the

pharmacist manually inputting the prescription, and any other information from the prescription that they chose to insert.

98. The pharmacist who loaded the written instruction into the MethDA system, the pharmacist who dispensed, and the pharmacist who supplied the dispensed Methadone to the patient or agent, may not necessarily be the same person.

99. BCP also kept a hardcopy file for each patient. Located on that hardcopy file would be hard copy prescriptions, correspondence, relevant hospital documentation, and notes.

100. Between January and June 2022, BCP migrated data on both dispensing systems; with the effect that some historical data was lost. The consequence of this is that the current dispensing record pertaining to Alex[9] is not a comprehensive record of everything that existed in 2020 and 2021 at the pharmacy. I draw no adverse inference about this. Software updates are an invariable part of practice management improvements.

101. All three pharmacists provided statements to this Court and gave oral evidence about the systems and processes at the BCP, and their professional practice.

102. The assessment and determination of Issue 2 is inherently limited having regard to the period of time that has lapsed since the events the subject of the coronial investigation, given:

    a. That naturally, the pharmacists' independent recollections are limited; and
    b. That any contemporaneous documentation that might otherwise have been available on the part of the pharmacists in the dispensing software, that might assist in what did/did not occur, has been lost with the passage of time, in this case, through software updates and access limitations through for example, expired licensing.

103. In this context, therefore, I approach determination on this issue with some caution, before drawing positive conclusions about compliance with the

[9] Exhibit C1.

Guidelines and conduct on the part of the pharmacists, particularly having regard to the requisite standard of proof.[10]

Communication

122. The Guidelines provide that there ought to be communication between the prescriber and pharmacists for matters of concern. In particular, a pharmacist who receives a prescription "*that is incomplete, unclear or ambiguous*" must contact the prescriber to clarify the prescription.

104. In this context, Counsel Assisting raised a preliminary issue which informs on the nature and extent of communications between the pharmacists and Dr Pluta when discrepancy in his prescriptions arose, in considering whether the pharmacists conduct was consistent with the Guidelines and was otherwise appropriate. This impacts on all areas under consideration under this Issue.

105. To that end, Counsel Assisting submitted that various questions were asked of the pharmacists which suggested that:

    a. Electronic notes were made by pharmacists in one or more software systems used at BCP, and that those notes had not been produced;

    b. Those notes may have possibly recorded conversations with Dr Pluta as to Alex's Methadone prescription where there had been demonstrable deviation from his prescription by a pharmacist, or to seek clarification as to the terms of the prescription where it was ambiguous; and

    c. Those possible conversations with Dr Pluta may have resulted in verbal authorisation by Dr Pluta to deviate from his prescription and clarification as to any ambiguity in what Dr Pluta authorised.

106. Ultimately, Counsel Assisting submitted that the preponderance of evidence supports a positive conclusion that it is unlikely any such notes (and conversations), either authorising deviation from the prescription or providing clarity, were made by the attending pharmacists. The implication is that the pharmacists departed from the Guidelines or failed to follow Dr Pluta's instructions.

[10] *Briginshaw v Briginshaw* (1938) 60 CLR 336, 361.

107. I respectfully decline to arrive at such a positive conclusion, in the following context:

a. There were approximately 100 patients on the QOTP at the BCP. Dr Pluta had the most patients of any single provider seen at the pharmacy;

b. The passage of time impacts on the reliability and weight to be attached to the evidence;

c. The deviations identified by Counsel Assisting which were said to render it unlikely that each and every one of such variations was authorised by Dr Pluta, have to be seen in context. They comprise eight occasions over a course of 16 months and represent potential deviations over all three pharmacists. This is not systemic in nature as it represents a small deviation rate overall, considering some degree of human error is inevitable in any human undertaking. Having assessed all three pharmacists giving oral evidence, I found them to be professional and caring clinicians, and that any deviations or errors were unintentional. In any case, I accept and find that none of these deviations caused or contributed to Alex's death;

d. Where the pharmacists did have an independent recollection about the existence of documents that are no longer available in the pharmacy record, it was to the effect that various documents *were* contained in Alex's record. For example:

i. patient photos;

ii. client agreement; and

iii. identity of a nominated carer in the notes in the patient profile.

e. The absence of records on Dr Pluta's part and absence of independent recollection of specific conversations cannot be taken as support of the contention that the conversations with pharmacists about his prescriptions did not occur. He agreed in evidence that he did have conversations with pharmacists and that he probably would not record it[11]. In any case, as detailed above, I approach Dr Pluta's evidence with

[11] Transcript 3, page 47.

some caution particularly in circumstances where there is other available evidence to the contrary. Examples are:

i. Ms Papacostas who says she did have an independent recollection of speaking with Dr Pluta, albeit about issues more generally, but which did not exclude issues about his prescriptions for Alex[12]. It would be difficult to appreciate why else she would call him, if not about the prescription; and

ii. whilst Dr Pluta's record making is generally poor, there is an example, however, where he did make a note in the Toombul Medical Centre records about a discussion he had with Mr Kashani- Malaki, following which dispensation occurred to Alex.[13]

108. For these reasons, I decline to positively conclude that no records were made and that no conversations took place with Dr Pluta. Rather, the state of the evidence is more consistent with a finding that:

a. Any notes made in the software about conversations between the pharmacists and Dr Pluta regarding deviations from prescriptions or providing clarity, are no longer available; and

b. In the absence of any such notes, and on other available evidence, it cannot be inferred that such conversations did not take place.

109. In my view, this provides an insufficient basis to conclude that there was inconsistency with the Guidelines in this respect, on the part of the pharmacists.

Dilution of Methadone

110. Section 6.6.14 of the Guidelines provides that it is "*recommended*" that each TAD of Methadone is diluted to 200mL with purified water. That is repeated in section 9.4.1 (instructions to pharmacist) through the text it is "*recommended*" each TAD of Methadone "*is made **up to** 200mL with purified water*". That recommendation is repeated in section 9.4.7.

[12] Transcript 1, page 97.
[13] "*d/w Shaz*" in his note on 29 May 2020 (Exhibit B3.1.1).

111. The rationale given for the recommendation is that dilution of Methadone lowers the concentration of the Methadone dose, which reduces *the chance* of an entire dose being accidentally swallowed by, say, a child, it discourages injection (due to volume), and reduces the value of diverted Methadone.

112. The evidence of the pharmacists was that Alex's TAD's of Methadone were diluted to 100mL. Doing the best they could given the passage of time, various general explanations were offered by the pharmacists, as follows:

    a. That some patient's experience nausea and vomiting, by reason of the taste and the volume having to be consumed. There is no suggestion that Alex fell into this category;

    b. That carrying a 200 mL bottle would be "*quite a lot for some people*". There is no evidence Alex could not carry a 200 mL bottle, let alone a carer;

    c. That smaller patients (physically) or those with eating disorders may benefit from a reduced quantity of liquid. Although Alex would appear to fall into that category by reason of her low body weight[14], there was no evidence that was the reasoning employed. And there was a suggestion that the higher the dose of Methadone, the more important that it be diluted to 200mL over 100mL. Alex's dose fell into that category; and

    d. That the storage bottles available to be used at BCP included 100 mL bottles. As to the use of 200mL bottles, it was left to the discretion of the pharmacist given how well the patient tolerated the volume.

113. Ultimately, Alex's TAD's were diluted to half of what was recommended, and half of what Dr Pluta considered the pharmacists were diluting to as "*standard protocol*".

114. It is easy in hindsight to be critical of the decision made to dilute Alex's Methadone to 100 mL, not 200 mL But any criticism overlooks the 2018 Guidelines couching it as a "*recommendation*", and the ambiguity in the words employed in the Guidelines, namely dilution "***up*** *to*" 200mL which on one reading suggests the recommended dilution could be to something less than 200 mL. It would have been better expressed as each dose be "*made*

[14] 49kg with a body mass index of 17.4kg/m2, and a height of 168cm (Autopsy Report: Exhibit A4).

to 200mL with purified water". It should also not be overlooked that the Guidelines are advisory only; albeit founded upon best practice, and that departure is permitted.

115. On that basis, I find that there is an insufficient basis to find that the dilution of Methadone by the pharmacists at BCP was inconsistent with the Guidelines.

116. Further, there is no cogent evidence (including expert evidence) that dilution of Alex's TAD's of Methadone to 100mL likely made it easier for her to inject Methadone on 20 September 2021, such that her death could have been avoided. It is speculative to reach such a conclusion. At its highest, dilution to 200 mL may have reduced the risk of Alex injecting a quantity of it and therefore her suffering Methadone toxicity and ultimately death. In my view, there is insufficient basis to conclude that it contributed to Alex's death.

Dispensation of Methadone

117. The determinations relevant to this issue have already been made, namely:

    a. That Dr Pluta's prescriptions for Alex were unclear and ambiguous and inconsistent with the Guidelines, which had the effect of creating ambiguity for the attending pharmacists in the dispensation of same;

    b. That the passage of time has had an impact on the evidence that might otherwise have been available on this issue, which might have explained their attempts to seek clarification; and

    c. That any dispensing variances on the part of the pharmacists are to be kept in perspective.

118. Critically, I also note the pharmacist evidence that at no time did Alex appear to be intoxicated, nor were they aware of any psychosocial stressors going on in her life, or that she was injecting. I accept that evidence. There was no reason for the pharmacists to be untruthful about this, particularly given they appeared to be on good terms with Alex and would likely be concerned about her welfare had she presented like this.

119. In that context, and consistent with the findings arrived at above, there is an insufficient basis to conclude that there was inconsistency with the Guidelines in this respect, on the part of the pharmacists. Equally, I find that

none of the discrepancies identified on the part of the pharmacists caused or contributed to Alex's death.

120. In this respect, it is worth noting that the terminal TAD's dispensed on 20 September 2021 *were* in accordance with Dr Pluta's prescription for the month of September 2021, namely three 120mg TAD's.

Dispensation to an Agent

121. Alex's Methadone prescription for August 2020 to January 2021 included the instruction "*Carer or patient herself many pick up*" and, from February 2021, the instruction "*BLUE CARE Carer or patient herself may pick up*".

123. Mr Morrow collected TAD's for Alex from time to time in the capacity of carer. Mr Morrow was neither a paid carer nor a Blue Care worker. Nevertheless, Alex herself introduced him to the pharmacists as her carer and regularly called the pharmacy to let them know he was attending to collect TAD's for her.

124. Counsel Assisting submits that there are two concerns with the dispensing of TAD's to an agent on Alex's behalf:

    a. That the dispensing of Methadone was given to a carer without Dr Pluta's prescriptions specifying the particular person to collect, when the Guidelines required this; and

    b. That Mr Morrow collect the TAD's during the period when Dr Pluta's prescriptions authorised collection by a "BLUE CARE Carer".

125. It is relevant to view this issue in the context of my previous determination, that Dr Pluta's *authorisation* of an agent to collect Alex's TAD's of Methadone did not comply with the Guidelines. Pharmacists played no role in such authorisation.

126. I agree with counsel for Mr Hancock that the concerns raised in paragraph 124 above rest on a false premise that the naming of a particular person on the prescription was a *legal* requirement. As noted elsewhere, the Guidelines are recommendations, and have no legal force.

127. In any event, and acknowledging that recommendations are nevertheless based on best practice, the dispensing of TAD's to an agent (whether Blue

Care or otherwise) must be viewed in context, with the following mitigating circumstances:

a. Dr Pluta was a well-known QOTP prescriber who had the lion's share of patients at the BCP, which was a busy inner urban pharmacy with about 100 patients registered on the QOTP;

b. The obligation for agent authorisation ultimately rests with the QOTP prescriber, for the prescriptions to be consistent with the Guidelines, namely Dr Pluta;

c. The central obligation of the dispensing pharmacist under the Guidelines is to dispense in accordance with the prescriber's written instructions. It is not the role of the pharmacist to determine the appropriateness of the prescription;

d. To the extent that any such obligation shifted to the pharmacists by reason of ambiguity in Dr Pluta's prescriptions, the passage of time on any communications they may have had with Dr Pluta to evidence clarification of agent authorisation, invariably affects the reliability and weight to be attached to such evidence. In any case, it is unknown what clarification or instruction Dr Pluta might have given, although given the overall tone of his evidence of flexibility to keep patients engaged on the QOTP to keep them "*alive*", it might not be unreasonable to conclude he would have authorised dispensation to Mr Morrow;

e. It is also likely that the change from 'carer' to 'Blue Care carer' in Dr Pluta's prescriptions might not have been perceived by the pharmacists as something different;

f. The pharmacists were unaware of Alex's other stressors, that she was at times intoxicated or that she was injecting, such that would have otherwise given rise to an appreciation of heightened risk, associated with dispensing TAD's to an agent; and

g. To the extent that there were instances identified where the pharmacists were unaware of specific recommendations under the Guidelines, they are not in my view sufficient for a positive conclusion to be drawn that they were generally lax in their approach in ensuring compliance with the Guidelines overall. For example, it is not a recommendation to check ID *on each occasion*. When considering the period of time over

which Mr Morrow attended the pharmacy to collect TAD's for Alex, I consider it was not unreasonable for the attending pharmacists to have developed a level of collective familiarity with him such that ID was not routinely required. Rather, in those circumstances, it would in my view be damaging to the therapeutic relationship to routinely require the production of ID when the pharmacists well knew who they were dispensing to.

128. Ultimately, for the above reasons, I find that there is an insufficient basis to conclude that the actions of the pharmacists in dispensing to an agent was inconsistent with the Guidelines. In my view, the root cause of strict non-compliance with the dispensing recommendations in the Guidelines, lay with Dr Pluta in respect of his ambiguous prescriptions. This placed them in a difficult position.

129. Finally, as was the case with Dr Pluta, I find that the dispensing to Mr Morrow had no causal link to Alex's death. He did appear to genuinely and altruistically care for Alex, and he did provide the medication to her after collecting TAD's over a period of time. Fortuitously, no risk of harm arose from that conduct.

Dissemination of Information

130. Mr Morrow's evidence was that he was provided no guidance or advice from pharmacists when he collected Alex's medication. He was not told:

    a. That it was only for oral consumption;

    b. About the risks or hazards of using Methadone in combination with other drugs; and

    c. About how it was to be stored or what to do with empty bottles.

131. That is consistent with the evidence of Mr Hancock and Ms Papacostas.

132. Whilst the Guidelines provided for advice to be given to patients about TAD's of Methadone, they provided no recommendations for advice, guidance or assistance to be provided to an agent collecting TAD's. On that basis it cannot follow that not providing Mr Morrow advice or guidance was inconsistent with the Guidelines.

133. In reaching this conclusion, I note the submissions made on behalf of the Queensland Health that logically, the advice given to patients ought to extend to agents given the medication is intended for self-administration, noting the intention in the overview at 5.3:

Medication intended for self-administration of the 2023 Guidelines

"Advice should be given about the dangers of misuse, the hazards of using BPN and methadone in combination with other drugs, and the toxic potential if taken by a child or a person not tolerant to opioids.

Pharmacists should advise patients about secure storage of medication out of reach of children. The refrigerator is not an appropriate place (condensation may affect stability of the medication, and the medication may be accessible to others). Patients are solely responsible for the care and proper consumption of each medication once they have taken possession of it. Patients should be reminded to remove the labels and rinse single use take-away methadone containers after use and before disposal."

Determination

134. For the above reasons, I have ultimately found that there is an insufficient basis to conclude:

    a. That the conduct on the part of the pharmacists were inconsistent with the Guidelines; and

    b. That any act or omission of the pharmacists caused or contributed to Alex's death.

135. The evidence did highlight however, that although they impressed me as being dedicated to their patients and the profession, the pharmacists did not at times appear to be fully aware of the important role they play in the QOTP, in the dispensation of Methadone under the Guidelines, to minimise the risks to participating patients.

136. Recommendations relevant to this issue are addressed below.

Issues 3 & 6: Are the 2023 Guidelines adequate and whether changes are required?

137. It is appropriate to deal with these two issues together.

138. The 2023 Guidelines, published in June 2023, update the 2018 Guidelines:

    a. To reflect the requirements of the MPA and the MPMR, which came into effect on 27 September 2021;

    b. To reflect contemporary treatment approaches;

    c. To use less stigmatising and more appropriate language; and

    d. Is informed by evidence derived from research literature, consultation with clinical, national policies and clinical guidelines and other jurisdictional consultation and opioid treatment policy documents.

139. Relevantly, there have been several changes from the 2018 Guidelines to the 2023 Guidelines with respect to:

    a. the prescribing of Methadone;

    b. the prescribing of Naloxone;

    c. the authorising of "*self-administered doses*";

    d. the appointment of an agent to collect "*self-administered doses*"; and

    e. the dispensation of Methadone.

Are those changes adequate to reduce similar deaths to that of Alex?

The prescribing of Methadone

140. The ODT medication options have changed from the 2018 Guidelines due to the introduction of long-acting injectable Buprenorphine. That drug is expressed to be the "*recommended treatment*" due to regimen simplicity. Advantages include:

    a. Buprenorphine is long-acting and injectable;

    b. Buprenorphine requires a patient to attend for an injection by an authorised clinician of Buprenorphine weekly or monthly, depending upon the product used;

    c. It avoids the need for a patient to be prescribed any self-administered oral doses;

    d. It avoids the need to attend a pharmacy each day or multiple times per week; and

e. It negates the need for an agent to collect the medication even in extreme circumstances.

141. Methadone is still authorised to be prescribed. The 2023 Guidelines provide that it may be appropriate to consider a trial of Methadone if Buprenorphine (whether long-acting injectable, or sublingual) is ineffective or produces significant side effects. That is, Methadone is essentially recommended as the alternative. It ultimately remains a matter of clinical judgment.

142. Dr Reilly gave evidence that the most recent data shows Queensland has about 25% of QOTP patients on long-acting injectable Buprenorphine, which is well ahead of the other Australian jurisdictions.

143. The introduction of long-acting injectable Buprenorphine, and the preference for Buprenorphine over Methadone, may of itself have the effect of reducing the likelihood of similar deaths to Alex in the future. It minimises the risk of overdose.

144. Additionally, the recommended upper dose of Methadone has changed from 120mg to 150mg (in the 2018 Guidelines) to 100 mg (in the 2023 Guidelines). That was done to encourage practitioners to be aware of the risks of higher dose Methadone. That too minimises the risk of overdose.

145. I accept these changes appropriately manage the risk under this issue and find accordingly.

Naloxone

146. Naloxone is a drug that can temporarily reverse the effects of an opioid overdose or an adverse reaction. It works by blocking opioid drugs from attaching to opioid receptors in the brain.

147. In 2022, the Australian Commonwealth Government established the "*Take Home Naloxone program*", to make Naloxone available for free with no prescription to any person who may experience, or witness, an opioid overdose or adverse reaction.

148. Conformably with the "*Take Home Naloxone program*", the 2023 Guidelines recommend that:

a. Any patient receiving treatment for opioid dependency treatment be provided with Naloxone, particularly when self-administration of Methadone is commenced; and

b. Patients and their family members or carers, and other relevant persons, should be advised how to recognise and respond to an opioid overdose and how to use Naloxone.

149. Whilst Naloxone does not reduce the risk of opioid overdose, it reduces the risk of mortality from opioid overdose.

150. Dr Pluta's evidence at the inquest was to the contrary. He considered it was *more* dangerous to provide Naloxone to Alex, or any relevant carer or family member, because it could send her into immediate withdrawal. Dr Pluta's view is contradictory to a Commonwealth Government initiative, the 2023 Guidelines, and the evidence of Drs Pascoe and Reilly to this Court. Indeed, Dr Reilly's evidence was that Naloxone may have assisted to reverse the effects of acute opioid overdose in Alex on 20 September 2021.

151. I accept the views of Drs Pascoe and Reilly over that of Dr Pluta, who I consider is not an objective yardstick to measure industry knowledge against on this issue, given the matters detailed at length above about his professional practice, and find accordingly.

152. Finally, there is no evidence that other prescribers hold a similar view to Dr Pluta about Naloxone, hence I do not consider that it is a widespread held view.

Self-administered doses

153. There are two fundamental differences between the 2018 and 2023 Guidelines with respect to TAD's (what is now termed "*self-administered doses*"), regarding:

a. The risk assessment process; and

b. The recommended number of self-administered doses each week.

154. Similar to the 2018 Guidelines, the 2023 Guidelines provide that a risk assessment should be undertaken to inform the number of supervised and self-administered doses. The difference, however, is that risk assessment is said to be "*treated less categorically*" in the 2023 Guidelines as compared

to the 2018 Guidelines, "*with clinicians encouraged to make an overall clinical judgement based on assessment of higher risk behaviours, settings or situations*".

155. The 2023 Guidelines:

    a. Provide that Methadone requires a closely supervised regimen, with all doses initially supervised other than in special circumstances, following which, during the maintenance phase, consideration can be given to authorise the prescribing of self-administered doses;

    b. Split a patient's risk profile into either "*Higher risk*" or "*Lower risk*" (as opposed to high, moderate, and low risks in the 2018 Guidelines) when determining the recommended number of self-administered doses each week; and

    c. Provides, with respect to the risk assessment to be undertaken:

        Risk assessment is an overall clinical judgement based on assessment of higher risk behaviours. See sections 1.2 and 4 together with appendix 3 for further information that may help guide risk assessment.

156. Ultimately, Counsel Assisting submits that it is open for me to find that that the changes to the 2023 Guidelines in terms of the prescribing of self-administered doses and the move away from providing a list of various factors to guide decision making may have *heightened the risk of opioid overdose* as compared with the 2018 Guidelines given the less restrictive approach. Respectfully, I am unable to accept that submission primarily because it lacks proper evidentiary basis and is otherwise speculative, having regard to the following:

    a. Dr Reilly's evidence to the effect that:

        i. there is a lack of evidence base with the more categorical judgements being made about risk;

        ii. there was not really any good reason to think that higher, moderate and lower risks have any basis in reality and the changes in recommending self-administered dosing was to give more flexibility. In his words, it was trying to say "*Listen, we need to be a bit smarter, have a – a little bit more clinical*

sense and be working with the patient around how we could safely do this"; and

iii. the experience arising out of the health care response to the COVID pandemic led to a dramatic reconsideration of the need to supervise medication around the world. What it demonstrated was that when the restrictions were lifted, from a public health perspective, nothing changed and there were no major problems with regard to it.

b. There is no other expert evidence in these proceedings that the amendments to the 2023 Guidelines may have heightened the risk of opioid overdose compared with the more prescriptive approach in the 2018 Guidelines.

Appointment of agents

157. The 2018 Guidelines were prescriptive and strict as to the appropriateness of authorising agents to collect TAD's of Methadone.

158. That remains the case in the 2023 Guidelines, save that the circumstances in which agents are to be appointed has been changed from in "*rare*" circumstances, to in "*extreme*" circumstances, where "*pharmacy attendance is not possible and other options for ODT are not available*".

159. The issue with the authorisation of agents for Alex was not the terms of the 2018 Guidelines. It was a matter of non-compliance.

160. I consider the 2023 Guidelines are adequate in this respect to minimise the risk of opioid overdose, if followed.

161. As outlined above, the 2018 Guidelines contained no express recommendation to provide guidance or advice to agents who collected TAD's of Methadone on behalf of a patient. That continues to be the case in the 2023 Guidelines.

162. I accept and find that it is appropriate for the same advice given to a patient ought to be given to an agent who collects self-administered medication for a patient, such that it ought to be reflected in the 2023 Guidelines. Queensland Health accepts that this could be considered for amendment in the 2023 Guidelines. A recommendation about this is made below.

Dilution of Methadone

163. I have dealt with this at paragraphs 110 to 116 above.

164. I accept and find that any ambiguity that existed in the 2018 Guidelines regarding the "*recommendation*" for dilution of Methadone has been rectified in the 2023 Guidelines, by now specifying it is a *direction* to dilute to 200mL[15].

165. To the extent that one section remains in the 2023 Guidelines, that uses the word's dilution "*up to*" 200mLs, Queensland Health accepts this could be considered for amendment.

166. A recommendation about this is made below.

Benzodiazepines

167. The 2023 Guidelines provide that benzodiazepines in combination with ODT should be avoided and, if necessary, should be closely monitored and wherever possible a plan developed for reduction and cessation. That reflects that the combination of various sedative medications poses a greater risk, and when people do overdose, it is not uncommon for benzodiazepines to be a contributing factor.

168. I accept that this stronger guidance assists to reduce the risk of overdose.

Other matters

Training

169. Counsel Assisting also submits that the evidence in this inquest raised other matters which predominantly relates to training for medical and pharmaceutical clinicians for apparent knowledge gaps in respect of the QOTP. This led to a submission that it should be the subject of recommendations aimed at Queensland Health to provide training to both disciplines.

170. Whilst I can appreciate why this submission was made in the context of the specific circumstances of this case:

[15] 5.3.1

a. There is insufficient evidence to find that this exists more widely on the part of prescribers or pharmacists;

b. Dr Pluta is not a reliable yardstick at least insofar as OTP prescribers are concerned;

c. The evidence is insufficient to conclude it is a systemic issue for pharmacists; and

d. There is no expert evidence to the effect that the current training is inadequate.

171. I also do not accept that it is overly onerous for diligent clinicians (including medical practitioners and pharmacists) who are involved with the QOTP to manage their own learning if they elect to practice in this specialised field, having regard to:

a. Their own professional obligations of maintaining skill level and competence, in the exercise of reasonable care, skill and diligence, which inherently requires keeping up to date with relevant knowledge, advancements and best practice relevant to their field of expertise[16]; and

b. The following training that is already available for a level 1 QOTP prescriber:

i. e-learning packages; and

ii. requirements for individual clinical placements in consultation with an approved and practising level 1 QOTP prescriber, and supervision periods depending upon the level of prescriber type[17].

172. It is also relevant to note the following:

a. For prescribers:

i. the 2018 Guidelines were distributed widely across Queensland Health Mental Health and Other Drug services,

[16] Leaving aside that it is also an expectation of all medical practitioners registered to practice in Australia- Section 9, Good Medical Practice: A Code of Conduct for Australian Doctors, October 2020. https://www.medicalboard.gov.au/Codes-Guidelines-Policies/Code-of-conduct.aspx

[17] https://www.health.qld.gov.au/__data/assets/pdf_file/0018/1211544/fs-qotp-prescriber-types.pdf

the Australian College of Nurse Practitioners, the Australian Medical Association Queensland, The Australasian Chapter of Addiction Medicine, Queensland Network of Alcohol and Other Drug Agencies, Queensland Aboriginal and Islander Health Council, Royal Australian and New Zealand College of Psychiatrists, the Royal Australian College of General Practitioners, Australian College of Rural and Remote Medicine, Private Hospitals Association of Queensland, and each of the Primary Health Networks in Queensland; and

ii. Queensland Health submits it will, where appropriate, consult with relevant professional bodies regarding any clinical best practice recommendations/suggestions relevant to the QOTP.

b. For pharmacists:

i. Queensland pharmacists have as- of- right authority to administer ODT medicines ("*approved opioids*") if it is administered on a prescription[18]. Queensland Health does not provide approval for them to supply ODT and consequentially, has limited oversight in this respect; and

ii. nevertheless, Queensland Health:

i. provided the 2018 Guidelines to The Pharmacy Guild of Australia and the Pharmaceutical Society of Australia, noting that the latter provides information on its website about QOTP for all States and Territories, with the Queensland section including a link to the updated 2023 Guidelines; and

2. will continue to work in partnership with key pharmacy group stakeholders to support the ongoing provision of information and training to pharmacists about QOTP.

173. In my view, any education directed to pharmacists is best given by their respective governing bodies, rather than Queensland Health.

174. Having regard to the above, I do not consider that the training recommendations proposed by Counsel Assisting beyond training upon

[18] Schedule 9, Division 1 of the MPMR.

prescriber renewal and dispensing approval, are required and decline to do so.

Second Opinion

175. I have considered the submission made on behalf of the family that a recommendation is open on the evidence, that in the course of its review of the 2023 Guidelines, Queensland Heath consider an amendment to the effect that practitioners utilise specialist review along with multidisciplinary case conferences, as a 'check opinion' for the prescription of Methadone to both new and long-term Methadone users. I respectfully decline to do so, having regard to the matters raised by Queensland Health in its submissions, which I accept, including:

    a. The benefits of same are already identified in the 2023 Guidelines;

    b. They are already advised or recommended on a number of occasions;

    c. To mandate a second opinion may risk the unintended consequence of reducing access to ODT, with the wider public health implications of raising the barrier to entry into QOTP treatment;

    d. To do so will have significant implications in relation to access to medical addiction specialists and the use of Methadone, contrary to the policy intent of increasing system wide capacity; and

    e. Methadone is no longer the preferred ODT, with the transition to Buprenorphine use increasing.

Catchment/Referral Process

176. Equally, I reject the submission made on behalf of the family that it is open to make a recommendation that the referral process by MNH between catchments for mental health treatment be reviewed, because it is outside of the scope of coronial issues and not the subject of sufficient investigation. To the extent that it may be peripherally relevant, I accept the submissions of MNH in this respect, relevantly:

    a. Alex resided in the RBWH catchment area. Geographical areas are used by a number of entities (including health services) to determine boundaries within which (in this case) health care resources are distributed based on population;

b. The RBWH and TPCH are facilities which are both within the wider health service, namely MNH;

c. In respect of the initial 2021 referral to TPCH, the referral was correctly referred to the appropriate catchment at the RBWH. The clinical record evidences that every effort was made to action/triage the referral from Dr Pluta. Tragically, despite every effort, Alex failed to engage with the Service. Alex did not voice concerns about past engagement with RBWH. MNH did not decline to provide care. Rather, Alex chose to refuse care in the exercise of her rights of self-determination. In accordance with usual process, Alex was then closed to the Service and referred back to her GP;

d. In the absence of evidence of impaired or absent capacity, MNH had no legal basis to force Alex to engage and undertake a mental health assessment; and

e. In respect of the second 2021 referral to TPCH, the referral was correctly referred to the RBWH catchment. However, in view of the information contained in the referral (namely past trauma at RBWH), a home visit was arranged. However, despite repeat attempts to reach Alex, she again refused to engage and following an MDT meeting she was closed to the Service and referred back to her GP.

Issue 4: What Measures are in Place to Communicate Concerns?

177. Over the period Dr Pluta was treating and managing Alex and prescribing her Methadone, Alex was also being treated by other clinicians (GP's and in a public hospital setting).

178. It was contended that better avenues of communication between those providers may have raised issues such as non-compliance with the 2018 Guidelines and identified high risk factors impacting on OTP management such as:

a. Doctor shopping e.g., medication seeking behaviour including benzodiazepine prescription in circumstances where the regulatory systems in place at that time did not identify the doubling up of prescription and dispensation of same; and

b. Psychosocial stressors, deterioration of mental health and presentations to Emergency Departments (**ED**) with acute confusion and evidence of track marks.

179. Despite this, there is evidence that informal pathways were employed[19]. By way of example, in May 2020, RBWH Registered Nurse Ms Backler was so concerned as to the appropriateness of Dr Pluta's prescribing of Methadone for Alex, that she contacted the Drug Dependency Unit (**DDU**), believing that it could provide advice or assistance by contacting Dr Pluta. It could not, as it was not their role at the time. She was told to contact Dr Pluta directly which, to her credit, she did[20]. It does not appear that the DDU passed on those concerns to the Queensland Health compliance division despite Ms Backler (correctly) identifying non-compliance by Dr Pluta with the 2018 Guidelines. Ms Backler's evidence was that the pathway of contacting DDU (with its limitations) is not open anymore.

180. The evidence obtained during the Inquest was to the effect that there are now various supports in place for patients, the public, health practitioners, and pharmacists, as follows:

QScript

181. QScript is a major development which now gives oversight over monitored medicines. Relevantly:

a. Health practitioner access to QScript came into effect on 27 September 2021[21];

b. It provides real-time information to health practitioners about certain monitored medicines (including opioids and benzodiazepines). It can provide real-time information to health practitioners about monitored medicines which have been prescribed for patients (whether or not dispensed) depending upon whether the practitioner's clinical software is connected to QScript. If it is, QScript provides alerts and notifications of circumstances which a patient may be at risk of monitored medicine-

[19] For example, Queensland Health's '13S8INFO' number, and access to the Viewer by public hospital staff.
[20] By telephone and email.
[21] Tragically, 6 days after Alex's death.

related harm. That assists in the early identification and mitigation of opioid-related risks and informs clinical decision-making;

c. From 27 October 2021, it became mandatory for all "*relevant practitioners*" (medical practitioners, pharmacists, nurse practitioners, endorsed midwives, dentists, podiatric surgeons and endorsed podiatrists) to check QScript before:

    i. prescribing a monitored medicine;

    ii. dispensing a monitored medicine; and

    iii. giving a treatment dose of a monitored medicine.

d. It also has the following functionality:

    i. Medication history: where a prescribing/dispensing record has been uploaded to QScript, users can identify the prescribing/dispensing practitioner by viewing the patient's medication history. Expanding individual medication events displays additional information about the prescriber/dispenser, including practice name, address, email and phone number (where this information is supplied);

    ii. View Access History: users can click the 'View Access History' button at the top right of a patient's profile to see details of other health practitioners who have viewed the patient's profile; and

    iii. Regulatory information: if there is regulatory information associated with a patient (e.g. prescribing approvals or QOTP episodes), users can view these details by clicking the 'Patient Profile' button at the top right of the patient's profile. Details of prescribing approval holders and QOTP prescribers can be viewed by expanding the 'Approvals and QOTP Episodes' section and clicking on individual approvals/episodes displayed.

e. Following its rollout in Queensland, Queensland Health's compliance oversight of practitioner's checking QScript has been (not inappropriately) focussed upon education, awareness and assistance. Queensland Health may also undertake a reactive review of a

practitioner's QScript usage in response to triggers such as a complaint or a coronial information request; or a proactive "top down" approach focussing on the highest risk prescribers and dispensers. Queensland Health is now turning to a more proactive approach of identifying practitioners who are not complying with the mandatory obligations to check QScript.

f. QScript is a read only system. It does not permit the entry of any information manually by a practitioner.

g. Thus, through its functionality, QScript provides for the automatic sharing of a subset of information amongst practitioners. That subset of information comprises:

    i. the prescribing of monitored medicines (if a practitioner's clinical software is connected to QScript);

    ii. the dispensation of monitored medicines; and

    iii. a patient's risk profile for monitored medicine-related harm.

Monitored Medicines Standard

182. The MMS is a standard made under the MPA, section 233. It is required to be complied with by all practitioners when prescribing a monitored medicine to be dispensed a patient, when prescribing a monitored medicine for giving a treatment dose to a patient; and dispensing a monitored medicine for a patient: regulations 93 and 126 of the MPMR.

183. The current version of the MMS, Version 2, commenced on 1 July 2024.

184. Relevantly, Part 1 provides that a prescriber must not prescribe a monitored medicine for a patient registered on the QOTP unless:

    a. They are in fact the QOTP service provider;

    b. They believe it is urgent and essential for the patient's wellbeing, and they cannot contact the QOTP service provider (and even then, it is limited to three days' supply); or

    c. Most pertinently, the prescriber has agreement from the QOTP service provider and documents the details of that agreement.

185. That mandatory process requires a coordinated approach to a patient's care and mandates the prescriber to communicate with the QOTP prescriber and reach agreement.

186. Part 2 provides that a dispenser, such as a pharmacist, who holds significant concerns about the clinical appropriateness of dispensing a monitored medicine for a patient on the QOTP, must:

    a. Attempt to communicate with the prescriber regarding their concerns; and

    b. Document the details of their concerns and the details and outcome of their attempts to communicate with the prescriber.

187. That process provides for the sharing of concerns by a dispenser to a prescriber and a document trail of the communications.

Other avenues

188. The existence of various not for profit organisations, for example:

    a. ADIS (Alcohol and Drug Information Support) is a free, anonymous and confidential 24-hour, 7 day a week support for anyone for concerns about their own or somebody else's alcohol and other drugs use. ADIS offers telephone and online counselling and can help patient's friend a local treatment service that meets their needs; and

    b. ADCAS (Alcohol and Drug Clinical Advisory Service) is a specialist telephone support service for health professionals in Queensland, providing clinical advice regarding the management of patient's with alcohol and other drug concerns. Initial inquiries are taken by alcohol and drug counsellors who can provide alcohol and drug information, relevant local agency information, and referral options. Calls will be transferred to an on-call medical additional specialist where the enquiry specifically relates to medical management.

189. Otherwise, the available options for a practitioner to report serious concerns they may have as to a fellow practitioner's professional conduct are:

    a. Queensland Health has established a process by which a medical professional is able to "*report or inform*" the Chief Executive of a matter that relates to the MPA and MPMR via an online form. A relevant matter

might involve concerns relating to another health practitioner's regulatory compliance; and

b. There are also appropriate regulatory or supervisory bodies that deal with professional practice or conduct concerns, such as the Office of the Health Ombudsman (**OHO**), the Queensland Police Service, the Commonwealth Department of Health and Aged Care and the Therapeutic Goods Administration.

190. Counsel Assisting submits that gaps remain in these processes which impact on effective communication, such that it is open for me to recommend that, in the course of its review into the QOTP, Queensland Health:

a. Consider whether any add-on to an existing information system, such as QScript, would be feasible to enable the sharing of notes between GP's and pharmacists caring for patients on the QOTP;

b. Consider whether any guidance documentation or processes could be drafted (whether in a new version of the Guidelines or otherwise) and disseminated to health service providers and pharmacists that addresses:

i. the types of communication amongst GP's and between GP's and pharmacists that may be recommended to take place for a patient on the QOTP, for example the sharing of progress notes, changes or additions to prescriptions, and referrals to specialists and diagnostic imaging, and the recording of notes of any such communications;

ii. the sharing or raising of possible concerns as to the treatment of a patient who is on the QOTP and the recording of notes of any such communications; and

iii. the various means available to GP's and pharmacists to report concerns of non-compliance with the 2023 Guidelines, where to report such concerns, and the circumstances when reporting may be appropriate.

c. Consider whether any guidance documentation or processes could be drafted and disseminated to health service providers that addresses

what a health service provider should do if a patient attends upon them who is a patient admitted onto the QOTP under the care of another practitioner.

191. Having carefully considered the available evidence, I am satisfied that the extensive systems now in place are reasonable and sufficient to ensure effective communication between clinicians such that no specific recommendations about this are necessary to ensure the delivery of safe care for patients on the QOTP. In reaching this conclusion, I have taken into account and accept the following submissions of Queensland Health:

    a. In respect of potential enhancement to any add on capability to QScript as proposed above in paragraph 190 (a), the feasibility of any possible enhancements would require careful consideration of the risks, benefits and complexities, taking into account numerous factors including (but not limited to):

        i. Contractual arrangements: QScript is operated under contractual arrangements between the Australian Digital Health Agency ('ADHA') and the national real-time prescription monitoring ('RTPM') national data exchange vendor, and a related jurisdictional deed of agreement between Queensland Health and the ADHA. Any updates to the design or functionality of QScript would need to be managed in accordance with those contractual arrangements. A contract variation or separate contract/change request could potentially be required. Whilst Queensland Health may exercise some rights in relation to the contract (including entering into a separate contract with the QScript vendor for Queensland-specific changes), any changes must undergo an assessment through nationally established change management processes;

        ii. Patient safety: a consideration of what risks (if any) may present to patient safety if introducing clinical notes. For example:

            1. Are there risks for user's misinterpreting a practitioner's notes;

2. Could patient safety be at risk as a result of fragmented record keeping;
3. Is there a risk that practitioners may view the absence of clinical notes on a patient's profile as a sign there are no concerns or risks for that patient; and
4. Might the inclusion of clinical notes result in some practitioners simply relying on any notes rather than communicating / collaborating with other practitioners involved in a patient's care.

iii. Privacy and human rights implications:

1. The mandatory look up of QScript pursuant to s 41 of the MPA applies to some practitioners in certain circumstances. Because of this requirement, from a privacy / human rights perspective, it is critical that only the minimum amount of information necessary is recorded and displayed to users. Not all clinical notes for a patient would be relevant to all practitioners. If Queensland Health were to enable practitioners to record and share clinical notes in QScript, this information may be accessed by any/all users, whether it is relevant to them or not. Given the look-up requirements in s 41 of the MPA, it could be argued that Queensland Health was compelling users to view this information. These privacy/human rights issues would have to be carefully considered if such a recommendation was made by the Court;

2. Currently, health practitioners who use QScript can view only objective information about a patient's care e.g. prescribing and dispensing records, prescribing approval information, QOTP admission/discharge details. If Queensland Health were to enable practitioners to record and share clinical notes in QScript, swathes of subjective information would be displayed to the 37,000+ users e.g. practitioner's assessments, opinions and beliefs, potential allegations

of criminal activities (such as suspicions of diversion by a patient etc.) This would substantially change the nature of the system, and careful consideration of the risks and benefits would be required if such a recommendation was made by the Court; and

3. Consideration would need to be given to whether clinical notes saved in QScript should be made visible to practitioners in other states/territories and consequently the enhancement of the national RTPM system to enable cross-border data sharing.

iv. Interjurisdictional consistency: As previously outlined, QScript is Queensland's component of a national RTPM system. In general (and to the extent possible), national consistency in RTPM system design/functionality is preferred and would need to be considered if such a recommendation was made by the Court;

v. Funding availability and mechanisms: Any upfront and ongoing costs for making the change would need to be considered, and funding sources identified and secured. Although some national RTPM system enhancements may be funded under the Intergovernmental Agreement on National Digital Health, a system change such as this would likely need to be funded separately by Queensland if such a recommendation was made by the Court;

vi. Regulatory implications would need to be considered. For example, whether the MPA or MPMR provisions ought be amended and whether that would compel practitioners to record clinical notes. Further, whether Section 41 of the MPA ought to be amended to compel relevant practitioners to review any clinical notes saved on a patient's profile. If that look up was made mandatory, considerations such as the time frame for practitioners to read clinical notes is a relevant consideration. Whether that would add an additional burden on health practitioners who are already pressed for time and whether that additional burden is reasonable and justified.

Further, if the review of such notes was not made mandatory, would the less thorough practitioners choose to not read these, impacting the utility of recording them;

vii. RTPM records management: Introducing clinical notes to the system may change the classification of QScript data to 'clinical records' (instead of 'administrative records'). The impact of which would need to be assessed and considered from a records management and data custodianship perspective;

viii. Technical capability and system usability: Proposed enhancements must be feasible from a technical perspective and may be limited by technical constraints within the national RTPM software architecture and data model. Whether inclusion of clinical notes complicate system usability and deter voluntary system use would have to be considered if such a recommendation was made by the Court;

ix. Clinical workflows and burden: whether the inclusion of clinical notes functionality unreasonably and unjustifiably increases the burden on health practitioners and regulators by providing them with more information to record, and more information to review would have to be considered if such a recommendation was made by the Court; and

x. Strategic priorities: where such an enhancement sits within the context of Queensland's existing strategic priorities for QScript, and whether it aligns with national priorities for the broader (national) RTPM solution, would need to be considered if such a recommendation was made by the Court.

192. In respect of drafting and disseminating the information proposed at paragraph 190 (b) and (c) above, guidance could potentially cover QOTP best practice/clinical elements and legislative guidance on general record-keeping requirements under the MPA (e.g. Section 224 of the MPMR);

193. With respect to proposed recommendation at paragraph 190 (b)(iii), guidance about reporting patient safety/professional

practice concerns to the OHO or Queensland Health could be drafted and disseminated by Queensland Health. Although it must be remembered that there is there is no offence under the legislation for non-compliance with the 2023 Clinical Guidelines; and

194. With respect to proposed recommendation at paragraph 190 (c), Queensland Health could consider drafting and disseminating this information. Existing resources could be reviewed and, if appropriate, updated to provide relevant guidance.

195. Insofar as QScript in particular is concerned, having regard to the reasons articulated by Queensland Health above and having regard to its primary purpose, I consider that an 'add on' function to QScript for communication purposes is likely to be problematic and, in my view, not tenable.

Issue 5: Did the Actions of any Person Cause or Contribute to Death?

196. The following persons are to be considered under this issue:

a. Dr Andrew Pluta;

b. Mr Steven Hancock, Mr Shahriar Kashani Malaki and Ms Marisa Papacostas (the pharmacists); and

c. Mr Peter Morrow.

197. I find that the actions of the pharmacists and Mr Morrow neither caused nor contributed to Alex's death, because:

a. There is no cogent evidence that the conduct of any of the pharmacists caused or contributed to Alex's death, as detailed at length above;

b. Methadone is an oral medication and is not meant to be injected. The fact that Alex chose to inject it was not in fairness something the pharmacists could control, particularly in the absence of any evidence or indicia to indicate such use on the part of Alex; and

c. Mr Morrow impressed me as a caring and kind person, who was seeking to assist his drug dependent friend on an altruistic basis. This included collection of Alex's Methadone from the pharmacy and providing it to her, when she asked. Whilst he was aware that Methadone should be orally consumed, and that Alex was not doing so but rather was at times,

injecting it, he frankly conceded he did not tell anyone that she was doing so despite pleading with her not to inject it. Not being a trained clinician or a paid carer, and otherwise not being responsible for dispensation, it is in my view unreasonable to assess his conduct in such light. In my view, he did not act inappropriately in his handling of Alex's Methadone.

198. Conversely, I find that Dr Pluta's conduct did contribute to Alex's death. In summary:

    a. Dr Pluta's decision to prescribe to Alex's TAD's of up to five or six per week on and from May 2020 was inconsistent with the Guidelines and was inappropriate. The preponderance of evidence is to the effect that Alex should have had her TAD's ceased on and from May 2020 and gradually introduced upon stability being achieved, but no earlier than 12 weeks. At the very least, the TAD's should have been prescribed to be non-consecutive;

    b. Dr Pluta's decision to prescribe six TAD's for the month of September 2021 armed Alex with three TAD's of 120 mg of Methadone on 20 September 2021; a quantity of which she proceeded to inject into herself, causing or contributing to cardiac arrest. Had she been on supervised doses, or non-consecutive TAD's, she would have either had no Methadone to inject, or alternatively had one TAD available to her after having orally consumed a dose earlier that morning. As Dr Pluta said in his evidence, an additional dose of 120 mg is potentially dangerous. An additional two doses of 120 mg "*is definitely dangerous*"; and

    c. Dr Pascoe was asked whether that was likely to have contributed to Alex's death. In his expert opinion of 4 August 2022, he opined that Alex may have been more susceptible to harm (injecting and taking medication whilst intoxicated) which could contribute to a heightened risk of overdose. He was asked further questions during his oral evidence. The relevant exchange provides:

        And if you assume for me that Alex injected those three takeaway doses of methadone on the 20th of September 2021, and the cause of her death was a cardiac arrest as a result of or as a consequence of methadone toxicity, do you agree that

the decision to permit Alex to have takeaway doses of methadone was likely to have contributed to her death?---Uh – yes, probably. Yep.

And that her risk would have been lower, potentially avoiding the risk of her – sorry – avoiding her death had she been on supervised doses? At least her death as at 20 September 2021 … --- Yep. Yeah. I guess if we assume that she took three days' worth of – um – methadone – um – if she was on daily supervised dosing – um – she wouldn't have had the same access to that amount of methadone.

199. In those circumstances, bearing in mind the gravity of the finding and the need for cogent evidence commensurate to that in accordance with the requisite standard of proof, I find that Dr Pluta's conduct and decision to deviate from the Guidelines contributed to Alex's death at that time, being her cardiac arrest on 20 September 2021, the development of brain injury and her death on 21 September 2021.

200. The above conclusion was reached having regard to the broader context, namely the following unchallenged evidence:

    a. That based on the available literature, Alex's mortality risk, including for overdose, was lower whilst engaged with the QOTP when compared to the general opioid dependent population who are not so engaged. However, the overdose risk for Alex was probably higher compared to the population who are on the QOTP but in receipt of more regular supervised dosing; and

    b. Dr Pascoe, who reviewed such literature, opines that the studies provide "*supportive evidence that Ms Forrester's mortality risk, including for overdose, was lower with being engaged with QOTP in the form of methadone compared to if she was not engaged with QOTP*".

201. However, the evidence is insufficient to support a finding that Alex was safer on the QOTP *under Dr Pluta*.

202. Alex was vulnerable opioid dependent person who was voluntarily on the QOTP under a harm minimisation framework, with the administration of opioid agonist treatment in a controlled manner. The principles under which

the Guidelines operate are for the delivery of safe, evidence-based care, with the broad goal of reducing medication related harm and avoiding hazards such as overdose. The ultimate aim is to achieve abstinence. Particularly against the background of other psychosocial stressors Alex was experiencing in the lead up to her death together with unstable use, it was my view inappropriate for such a vulnerable person to have been provided with the terminal TAD's of Methadone on 20 September 2021 in accordance with the terms of Dr Pluta's prescription. It is for this reason that I reject any suggestion of 'blame' or 'intention' on Alex's part, for electing to inject a quantity of her Methadone.

Recommendations in accordance with Section 46 CA

203. Counsel Assisting submits that it is open for me to make various recommendations that relate to public health and safety, and to prevent deaths from happening in similar circumstances in the future. Those recommendations were aimed at Queensland Health, in respect of consideration of a range of changes to the QOTP framework, in the following areas:

    a. Amendments to the QOTP 2023 Guidelines;

    b. Addressing knowledge gaps by:

        i. the delivery of targeted training to QOTP clinicians; and

        ii. the dissemination of information.

    c. Systems in support of communication between providers about patients on the QOTP.

204. In the context of the Guidelines not having legal force, I agree that any changes to matters such as authorised agents, collection of TAD's and the like, are best achieved through regulatory change. Whilst I acknowledge Queensland Health is prepared to consider the provision of specific advice in support of regulatory change, however given the issues the subject of the Inquest predominantly relates to professional practice, I consider the better approach to achieve this is by:

    a. Amending the 2023 Guidelines; and

b. Consulting with relevant professional bodies regarding any clinical best practice recommendations/suggestions and guidance documentation and processes relevant to clinicians who practice in the QOTP.

205. Queensland Health is willing to consider these measures.

206. In my view, addressing any potential knowledge gaps and dissemination of information to QOTP clinicians must also be seen in this light, namely in the professional practice space, having regard to the following:

a. Insufficient evidence that any such knowledge gaps are systemic;

b. Individual responsibility of maintaining clinical competence, in alignment with professional standards;

c. The training already available;

d. Insufficient evidence that the existing training is lacking;

e. The widely accessible Guidelines; and

f. The systems now available in support of the delivery of safe care of patients under the QOTP framework, as detailed above.

207. In terms of pharmacists, I find that the delivery of any training about professional practice and workflow, preparation of guidance documents or processes, and the dissemination of information are best aimed at peak industry bodies such as The Pharmacy Guild, The Pharmaceutical Society of Australia and The Society of Hospital Pharmacists of Australia, targeting their members.

208. More widely, I acknowledge that through a plan known as “Better Care Together”, a plan for Queensland’s state funded Mental Health, Alcohol, and Other Drug Services, additional funding has been provided to invest in the alcohol and other drug service capacity and capability in Queensland. Part of that funding is allocated for specific opioid dependence treatment to be delivered in public, private, and non-government services. Statewide consultation is being undertaken by Queensland Health as to the current, emergent, and future needs for service providers and people accessing ODT and harm reduction, which will ultimately inform the identification of redesign options and actions to improve the ODT system. The Consultation Paper was released to key stakeholders.

209. Overall, I find that the issues identified in this case have largely been addressed by the 2023 Guidelines together with the other system measures and improvements now in place. To the extent that they have not, and in the above context, I make the following recommendations:

Amendment of the 2023 Guidelines

I recommend that Queensland Health consider how best to amend the 2023 Guidelines:

a. To clarify that Methadone be diluted to 200 mL, by removal of the reference to dilution of Methadone up to 200mL;

b. To extend the provision of advice to authorised agents who collect self-administered medications for patients;

c. That in the extreme circumstances where and agent is appointed by a prescriber to collect medication for a patient, to the extent that a generic term such as "carer" is insufficient, that the description of the agent be narrowed; and

d. To the extent that the 2023 Guidelines take a less prescriptive approach to matters informing on risk assessment than what appeared in the 2018 Guidelines:

   i. provide a non-exhaustive list of high-risk behaviours and circumstances which may impact on medication adherence to be considered by a prescriber when deciding whether to prescribe self-administered doses and the number to be prescribed; and

   ii. reduce the recommended number of self-administrated doses of Methadone in circumstances where a patient presents with high-risk behaviours or in high-risk circumstances, to non-consecutive self-administrated doses.

Training, Dissemination of Information and Communication

I recommend that Queensland Health consider how best to:

a. Offer refresher training as part of the renewal process for prescribers, particularly with respect to the recommendation for injectable Buprenorphine, the risks of Methadone overdose, polypharmacy and in particular benzodiazepines, the authorising of self-administered Methadone doses and the appointment of agents;

b. Disseminate the 2023 Guidelines (and any subsequent iteration) to key stakeholders of the QOTP;

c. Through its Monitored Medicines and Compliance Unit, Medicines Approvals and Regulation Unit or Mental Health Alcohol and Other Drugs Branch, issue an e-alert regarding the specific risks associated with this case;

d. Consult with relevant professional bodies, where appropriate, regarding any clinical best practice recommendations/suggestions/guidance documentation or processes relevant to the QOTP; and

e. Continue to work in partnership with key pharmacy group stakeholders to support the ongoing provision of information and training to pharmacists about the QOTP.

I recommend that entities such as The Pharmacy Guild, The Pharmaceutical Society of Australia or The Society of Hospital Pharmacists of Australia:

a. Disseminate information (including the 2023 Guidelines) to remind and educate their members of their obligations under the QOTP (using this tragic case as an example) through targeted publications;

b. Consider how best to offer training to their members in consultation with Queensland Health, as appropriate, when they apply for approval to be authorised to dispense ODT; and

c. Consult with Queensland Health, as appropriate, regarding any clinical best practice recommendations/suggestions/guidance documentation or processes relevant to the QOTP.

210. Beyond the above, I consider there are no matters which could be meaningfully addressed by the making of further recommendations. To the extent that they haven't already given the tragic circumstances of this case, I encourage clinicians involved in Alex's care to take the opportunity to reflect on their professional practices generally.

211. Finally, in making the above recommendations, I have considered the submission made on behalf of the family that the recommendations should be framed more strongly, as a direction rather than a consideration. My view is that the better approach is to empower the respective entities to consider how best to progress the identified operational improvements, acknowledging they know their core business best, rather than to impose actions that might not achieve the desired outcomes.

Referral in accordance with Section 48 CA

212. Section 48 of the CA states:

> **Reporting offences, corrupt conduct or police misconduct**
>
> (4) A coroner may give information about a person's conduct in a profession or trade, obtained while investigating a death, to a disciplinary body for the person's profession or trade if the coroner reasonably believes the information might cause the body to inquire into, or take steps in relation to, the conduct.
>
> (5) In this section—
>
> ***disciplinary body*** for a person's profession or trade means a body that—
>
> (a) licenses, registers or otherwise approves the carrying on of the profession or trade; or
>
> (b) can sanction, or recommend sanctions for, the person's conduct in the profession or trade.

213. Counsel Assisting submitted that it is open to me to refer Dr Pluta to the relevant disciplinary body with respect to:

    a. His conduct in treating and managing Alex on the QOTP;

    b. His record keeping practices; and

c. The appropriateness of Dr Pluta remaining authorised as a treatment provider for patients with drug dependency issues.

214. Although unrepresented during the coronial investigation and Inquest, Dr Pluta was given every opportunity to seek legal advice but chose not to. After the Inquest concluded, he was sent correspondence to the effect that on the available evidence it was open to me to make adverse comments about his conduct in his treatment of Alex, such to make a referral under Section 48 CA to the relevant disciplinary body. To that end he was supplied with the brief of evidence together with submissions from Counsel Assisting and the parties who were granted leave to appear. He was given 28 days to provide any submissions he wished to make together with any material he relied upon.

215. Ultimately, Dr Pluta did obtain legal advice. It was submitted on his behalf that he acknowledges the issues the subject of the Inquest warrant consideration by AHPRA and does not dispute the making of a referral as proposed by Counsel Assisting, and supported by the family and MNH, and would engage with AHPRA in its consideration of the issues.

216. I have decided that there will be a referral under that provision of Dr Pluta to the relevant disciplinary body.

Findings required by s. 45

Identity of the deceased – Alexandria Catherine Forrester

How she died – Between 9:30am and 10:00am on 20 September 2021, whilst alone in her home, Alex injected a quantity of Methadone from the three take away oral 120mg doses (diluted to 100mls) that had been prescribed for her by her treating General Practitioner (Dr Pluta) under the Queensland Opioid Treatment Program. Those doses had been collected that morning for Alex from the Brisbane Compounding Pharmacy by a friend. The quantity of Methadone taken caused Alex to go into cardiac arrest and despite efforts of emergency responders,

	the oxygen deprivation to her brain caused her to sustain an unsurvivable hypoxic ischaemic encephalopathy and she died at 10:52am the following day.
Place of death –	Royal Brisbane and Women's Hospital HERSTON QLD 4006 AUSTRALIA
Date of death–	21 September 2021
Cause of death –	1(a) Hypoxic-ischaemic encephalopathy, *due to or as a consequence of* 1(b) Cardiorespiratory arrest, *due to or as a consequence of* 1(c) Methadone toxicity.

Concluding Comments

217. Leaving aside the professional conduct issues on the part of an individual prescriber, this tragic case highlights the competing challenges involved in managing complex patients like Alex under a regulatory scheme which treats opioid dependency in a harm minimisation framework, by the use of controlled opioid agonist therapy, with the ultimate aim at achieving opioid abstinence. It is hoped that the changes that have already occurred to support the safe delivery of care under the QOTP framework together with publication of this case with the above recommendations, will have the effect of preventing a similar death in the future.

218. In memory of Alex, a collage of photos was displayed whilst Ms Langhorne read out a family statement on the last day of the Inquest. Testament to Alex's desire to seek acceptance, acknowledgement and freedom from judgement throughout her challenging life, her sister shared a favourite song of Alex's by Amy Shark- '*I said Hi*'.[22] Suffice to say that these sentiments were heartfelt and sincere. It is clear that the loss of Alex has had a profound impact on those that loved and cherished her.

[22] https://www.youtube.com/watch?v=1K4KwuV2l4s

219. I offer my sincere condolences to Alex's loved ones. To the extent that it is able, it is hoped that these proceedings have addressed any concerns and assists in bringing a measure of healing.

220. I close the inquest.

Carol Lee
Coroner
BRISBANE

Annexure A

122. The Queensland Medication-Assisted Treatment of Opioid Dependence: Clinical Guidelines 2018 were published in June 2018. They superseded the Queensland Opioid Treatment Program: Clinical Guidelines 2012 (2012 Guidelines).

123. The 2018 Guidelines do not have legal force. Rather, they sought to give clinicians the information they require to give optimal care to patients. The foreword to the 2018 Guidelines provided:

> *These guidelines align with national directions and recommendations and incorporate the latest clinical evidence for treatment of opioid dependence. The clinical guidelines cannot provide detailed direction for managing every client in every situation. In some circumstances, clinicians may need to vary their clinical practices from what is suggested in this document. It is essential that, under such circumstances, clinicians clearly document the reasons for going outside the guidelines in the client's clinical file. Individual medical practitioners, nurse practitioners, pharmacists and other clinical staff are responsible for decisions about the safety and effectiveness of treatment for each client. The guidelines are not intended to replace professional judgement in individual cases* [emphasis added].

124. As Dr John Reilly said in evidence, the content of the Guidelines is intended to be "*reasonably strong advice but, nevertheless, it remains advice*".

125. The 2018 Guidelines were comprehensive and ran for some 148 pages. The 2012 Guidelines are equally comprehensive and ran for 188 pages.

126. At the time that Dr Pluta admitted Alex onto the QOTP in October 2014, it was the 2012 Guidelines that were current.

127. Section 3 of each of the 2012 and 2018 Guidelines discussed the assessment process for an individual to commence on the QOTP. It is materially similar as between both versions.

128. The **initial assessment** of a patient on the QOTP was said to consist of history-taking, examination, investigations, and a review of relevant collateral information. It should cover a broad range of medical and mental health conditions that frequently accompany opioid dependence. An extensive number of issues are enumerated [emphasis added].

129. Section 3 also provided for **treatment planning** for a patient on a the QOTP and is prescriptive with what the initial treatment plan should contain. Section 4 elaborated as to the ongoing treatment goals and management plan for the patient, which should be reviewed and discussed throughout the program. Section 4 also prescribed what could be contained on all patient files [emphasis added].

130. Section 4.4 addressed the **selection of QOTP medication** [emphasis added]. It provided that:

    a. *Recent data collected by the Drugs of Dependence Unit (DDU) suggests that Buprenorphine may be a preferred treatment for some clients due to flexible dosing arrangements and increased safety;*

    b. *Various matters be considered when choosing which medication to prescribe, namely: (i) the client's response to prior treatment; (ii) any previous adverse effects; (iii) the logistics of participating in treatments; (iv) the ease of withdrawal from Buprenorphine; (v) the expectations of treatment; and (vi) the capacity to transfer from Methadone;*

    c. *Buprenorphine should be strongly considered for those who have had multiple unsuccessful Methadone treatment episodes or are ambivalent about maintenance treatment;*

    d. *Buprenorphine has a longer duration of action, which allows for longer dosing intervals (e.g. every second or third day);*

    e. *Buprenorphine presents less risk of fatal overdose than Methadone; and*

    f. *It is easier to switch from Buprenorphine to Methadone than the reverse.*

131. Section 6.5.1 of the 2018 Guidelines addressed the **ongoing clinical reviews** of a patient. It provided that regular reviews by a clinician are an essential component of safe and effective QOTP, with the frequency dependent upon a patient's needs. The following topics were then recommended to be assessed at each clinical review [emphasis added]:

    a. *General health and wellbeing;*

    b. *Quantity and frequency of any substance use since the last review;*

    c. *Social circumstances;*

d. *Relevant risk factors;*

e. *Any recent investigations (including urine drug screens);*

f. *Attendance for dosing;*

g. *Adequacy of medication dose;*

h. *Side effects;*

i. *TAD's;*

j. *Frequency of reviews; and*

k. *The treatment plan, including the client's engagement with other health and social services*.

132. Section 6.5.4 of the 2018 Guidelines was directed to **urine drug screens** (UDS). It provided that UDS is an important means to: enhance the validity of a patient's self-reported use of substances; identify substances not reported by the patient that may assist diagnosis and management; and assist in assessing suitability for take-away doses. It continued to say that UDS should be performed based on clinical indications, however an "*intermittent schedule of random testing is adequate for program requirements and client safety and is likely to ensure more useful information than a system of frequent screening*" [emphasis added].

133. Section 6.6 of the 2018 Guidelines then addressed "***Take-away doses***" (TAD's). It relevantly provided:

In general, treatment of opioid dependence with Methadone or Buprenorphine is based on daily supervised dosing at a pharmacy or clinic. Supervised dosing provides:

- *daily structure and routine that can be important for many clients early in treatment.*
- *greater adherence to the medication regimen, with less diversion to others and less medication misuse.*
- *less risk of overdose with pre-dosing assessment.*

Many clients find the requirements of daily supervised dosing intrusive and not compatible with community re-integration activities such as work or

study. The provision of TAD's can improve their chances of recovery by reducing the inconvenience of daily pharmacy attendance, support engagement with normal daily activities, and encourage client autonomy in the management of their medication and treatment. This is consistent with the principles of chronic of chronic disease management. An understanding of the potential harms associated with TAD's can assist with risk assessment and mitigation strategies. Potential harms include:

- *client taking a different dose to that prescribed.*
- *client using an alternative route of administration.*
- *client taking the medication while intoxicated.*
- *medication restarted by the client after several missed doses.*
- *intentional or accidental use of the opioid medication by person for whom not prescribed (with risks of intoxication, overdose, or development of dependence if regular use).*
- *reduced reputation of QOPT from misuse of TAD medication, with risk of increased stigma for clients and treatment services.*

134. Section 6.6.1 of the 2018 Guidelines provided TAD guidelines. Those Guidelines provided the need to individually tailor dosing conditions according to the benefits and risks for the patient.

135. Alex was in the maintenance phase of her QOTP when she died. The 2018 Guidelines provided that TAD's may be considered, with the number of TAD's dependent upon risk. Essentially:

    a. If the patient was a higher risk: no TAD's at all except special circumstances;

    b. If the patient was a moderate risk: zero to two TAD's per week, but with the guidance to consider whether the TAD doses should non-consecutive; and

    c. If the patient was a low risk: two to four TAD's per week.

136. Subsequent guidance provided that prescribers should tend towards conservative TAD prescribing, and that if they sought to prescribe more

TAD's than suggested, they should seek specialist advice and clearly document their decision making.

137. Section 6.6.2 provided indications for a patient being appropriate to be prescribed TAD's. Some non-exhaustive examples were then given, *viz*.:

    a. Participation in activities (study, employment, care of others, sporting, religious or recreational pursuits);

    b. Accessibility and transport (if pharmacy or transport not available 7 days per week);

    c. Associated costs of transport or supervised dosing; and

    d. Travel.

138. The Guidelines also provided that other arrangements should be considered that avoid TAD's. That included dosing at alternative pharmacies, or double/triple Buprenorphine dosing.

139. Section 6.6.3 then provided for a risk assessment for the TAD Guidelines. Introductory remarks provided that:

    a. Service providers should conduct and document regular risk assessments, which should be generally performed using clinical information routinely obtained as part of regular clinical reviews; and

    b. Risk assessments require communication and the exchange of relevant clinical information between prescribers, case managers, pharmacists, and others involved in the provision of care for the client.

140. Table 13 provided the "Risk assessment" for TAD's:

Risk factor	Lower risk	Higher risk
Stability of OTP medication	Stable dose with good attendance for dosing	Recent induction (within 1 month)
Adherence with medication, particularly current TADs and/or other medications	No significant adherence problems	Frequent missed doses or interruptions to treatment. Significant use of higher doses than authorised, alternate route of administration (e.g. injecting), diversion to others
Adherence with other treatment conditions	Good attendance with appointments, and UDS monitoring	Poor attendance with appointments and UDS monitoring
Use of alcohol or other substances	No significant use of alcohol or other substances	Frequent and heavy use of alcohol, illicit or pharmaceutical drugs, particularly sedatives
Other health or social conditions that impact upon medication adherence and/or safety of TADs	No significant medical, psychiatric, cognitive or social conditions that impair medication adherence or safety of TADs	Medical (e.g. respiratory or liver failure), psychiatric conditions (e.g. suicidality, severe anxiety and/or depression, psychosis), impaired cognition (e.g. impaired memory), homelessness, child safety concerns
After considering each of these factors, the overall risk rating for take-away dosing is identified as one of three levels: **higher risk** – presence of one or more significant risk factors **moderate risk** – presence of some risk factors, but no significant high-risk factors **lower risk** – no significant risk factors identified		

141. Section 6.6.3 went on to provide risk mitigation strategies for TAD's. Those strategies included:

a. *Clear communication, including as between agencies and with the client and relevant others (such as a carer) regarding the conditions of TAD's, their responsible storage and the use of their medication;*

b. *The use of safer opioid preparations – for example Buprenorphine is generally associated with fewer safety concerns than Methadone;*

c. *Limiting the number of consecutive TAD's;*

d. *The need for regular clinical reviews – at least every 3 months and more frequently for clients with more complex treatment needs, with regular UDS tests as part of the risk assessment process, and the assessment and documentation of key risk factors;*

e. *Addressing the use of medications other than as prescribed (such as missed doses, using additional doses, 'lost or misplaced' medication, unauthorised routes (e.g. injecting) or intoxicated presentations); and*

f. Clear documentation of the indications, risks and strategies to mitigate identified risks.

142. Section 6.6.8 provided for the collection of TAD's by an agent. It was in the following terms:

*On **rare occasions** an agent can be authorised to collect TAD's on behalf of a client. This can be considered where other options for OTP dosing are not available (such as home dispensing by pharmacist), and where significant acute medical issues preclude pharmacy attendance. Authorisation is for a brief, specific period, and is contingent upon* [emphasis added]:

- *OTP prescriber verifying the medical condition with the client's treating physician;*
- *clarification of current medications prescribed to client;*
- *assessment of continued safe treatment with OTP medication based on current; and*
- *medical issues.*

The OTP service provider is to advise the pharmacist of the client details, the name of the nominated agent (e.g. family member), and the period they are authorised to collect the TAD's. The authorised agent is to provide photo identification when they attend pharmacy to collect the OTP medication (see Sections 5.7.3, 9.4.6).

143. Section 6.6.13 provided guidance as to when a prescriber should stop providing TAD's. The relevant section commenced by stating that there is often considerable pressure on clinicians to overlook a patient's instability and continue to authorise TAD's. That was said to not be good clinical practice. Enumerated issues listed in the 2018 Guidelines as to when TAD's should be stopped included:

a. Self-reporting or clinical evidence of relapse to opioid or other dependent substance use;

b. Evidence of diversion;

c. Recent injection marks; and

d. Deterioration in psychological, physical or social well-being.

144. Re-introduction of TAD's was then recommended to occur gradually based on an assessment of risk, with at least 12 weeks of evident stability.

Annexure B

1. The 2018 Guidelines provided guidance to pharmacists dispensing Methadone to a patient on the QOTP. The guidance was primarily contained in Section 9, although section 6.6.14 recommended that each TAD dose of Methadone is diluted to 200mL with purified water.

2. Subsection 9.1.2 prescribed the role of the dispensing pharmacist. It included:

    a. Checking the written instruction form satisfies the legal requirements[23];

    b. Ensuring positive identification of the patient before administration of any dose;

    c. Explaining side-effects of medication where appropriate;

    d. Assessing the patient for intoxication;

    e. Supervising the consumption of each administered dose;

    f. Supplying any TAD's in accordance with the prescription; and

    g. Providing any relevant information about the patient's progress (missed doses, restarts, dose diversion, intoxication and any other issues of concern) to the prescriber.

3. Subsection 9.4 addressed the provision of TAD's by pharmacists. It provided, amongst other things:

    TADs may only be provided to the client for whom they are prescribed and can only be dispensed in accordance with prescriber instructions on a valid Written Instruction…

    TAD(s) must be given directly to the client on the day(s) before the scheduled day(s) of absence from the pharmacy. TADs must not be provided to a third party on behalf of any client without written approval by the OTP service provider …

    The client is to be informed that methadone … [is] *only for oral and sublingual consumption respectively. Further, advice should be given about the dangers of misuse, the hazards of using methadone … in*

[23] 9.1.3, 10.9, 11.3 and 11.4.

combination with other drugs, and the toxic potential if taken [by] *a child or a person not tolerant to opioids.*

…

Diluting TADs of methadone lowers the concentration of a methadone dose in a given volume. This reduces the chance of an entire dose being accidentally swallowed by an opioid naïve person (e.g. a child), discourages injection, and reduces the value of diverted methadone.

It is recommended each TAD of Methadone or Biodone is made up to 200ml with purified water.

…

On rare occasions, an agent can be authorised to collect TAD's on behalf of a client (see section 6.6.8 and 9.4.6). *An example of this is where significant medical issues preclude pharmacy attendance, and an agent (e.g. family member) has been authorised to collect their OTP medication. The OTP service provider is to advise the pharmacist of the client details, the name of the nominated agent, and the period they are authorised to collect the TAD's. The OTP medication is only to be supplied upon production of photo identification by the nominated agent.*