Hillcrest Family Pharmacy Limited

Ms C, Pharmacist

Ms D, Pharmacist

Ms E, Pharmacist

Ms F, Pharmacist

Medical Centre

Dr G, General Practitioner

Creative Abilities and Associates Limited

A Report by the

Deputy Health and Disability Commissioner

(Case 16HDC00163)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. Ms A has a history of neonatal meningitis, which left her with cerebral palsy,[1] left hemiplegia,[2] hemianopia,[3] global developmental delay, and medically refractory epilepsy.[4] At the time of these events (between 2012 and 2016) she was aged 17–20 years.

2. Ms A lived in a community house under the care of a disability service provider, Creative Abilities and Associates Limited (Creative Abilities). Her mother, Mrs B, is her welfare guardian and was closely involved in the provision of her services.

3. Ms A had been a patient at her medical centre since she was a neonate, and her usual GP was Dr G.

4. On 20 September 2012, Dr G prescribed Ms A "Midazolam 15mg/3ml plastic 1 ampule for a seizure applied to skin behind ear". Between 2012 and 2016 the prescription was repeated nine times. General practitioner (GP) Dr H signed repeat prescriptions for Ms A's midazolam (to be administered behind the ear) on 30 August 2013 and 29 June 2015.

5. Between November 2012 and February 2016, a number of pharmacists at the pharmacy dispensed midazolam with the instruction to apply behind the ear.

6. On 2 February 2016, Ms A experienced a seizure. Caregiver Ms I went to get buccal midazolam but the only midazolam available was an injection. She noted that the packaging of the medication (dated 27 January 2016) stated: "Use one ampule for a seizure applied to skin behind the ear."

7. Ms I called the Creative Abilities' office to attempt to clarify the medication instructions with a registered nurse, but that was unsuccessful, so she followed the instruction on the package and administered the midazolam to Ms A behind her ear.

8. Ms A's seizures continued, so Ms I called an ambulance.

9. Mrs B arrived shortly after the ambulance and, at that stage, Ms A's seizures had settled. Mrs B said that the ambulance officer told her they were surprised that the pharmacist had instructed midazolam to be applied behind the ear.

10. On 10 February 2016, Dr G altered the prescription instructions to refer to buccal use. She agrees that there is no evidence to support the administration of midazolam behind the ear for the acute control of prolonged seizures, and that this use was outside usual accepted practice.

[1] Cerebral palsy is a group of permanent movement disorders that appear in early childhood. Signs and symptoms vary but often include poor coordination, stiff muscles, weak muscles, and tremors. There may be problems with sensation, vision, hearing, swallowing, and speaking.
[2] Paralysis that affects only one side of the body.
[3] Decreased vision or blindness in half the visual field.
[4] Seizures not controlled with seizure medications.

11. From the date of the original prescription (20 September 2012) until 2 February 2016 when the issue was discovered, there were discrepancies between the pharmacy labels (completed by the pharmacy), the medication administration chart[5] (completed by the GP), and Ms A's seizure management protocol setting out the process to follow should she have a seizure (created by Creative Abilities).

Findings

Dr G

12. It was inappropriate for Dr G to prescribe midazolam in a manner inconsistent with accepted practice. Dr G continued to prescribe midazolam to be applied behind the ear whilst recording contrary instructions on the medication administration chart, which shows a concerning lack of critical thinking.

13. It was found that Dr G failed to provide services to Ms A with reasonable care and skill, and breached Right 4(1)[6] of the Code of Health and Disability Services Consumers' Rights (the Code).

14. Dr G did not document the reasons for the change to the mode of administration of midazolam, why the particular mode was chosen, and whether there had been any discussion with Ms A's welfare guardian, Mrs B. By failing to keep appropriate clinical records, Dr G failed to provide services that complied with professional standards. Accordingly, Dr G also breached Right 4(2)[7] of the Code.

Creative Abilities and Associates Limited

15. There was contradictory information in the records with regard to the manner in which midazolam was to be administered, and this was not questioned. In addition, there was a weakness in the manner in which medication was checked, and deficiencies in the policy and procedures for safe administration of medication. There was also a lack of recorded nursing assessments. It was found that Creative Abilities failed to provide services to Ms A with reasonable care and skill, and breached Right 4(1) of the Code.

Hillcrest Family Pharmacy Ltd

16. Multiple pharmacists at the pharmacy failed to think critically, and relied on previous dispensing rather than contacting the prescriber, resulting in a pattern of behaviour by staff of non-compliance with the Standard Operating Procedures (SOPs).

17. It was found that Hillcrest Pharmacy Ltd failed to provide services to Ms A with reasonable care and skill, and breached Right 4(1) of the Code.

[5] Creative Abilities' "Safe Administration of Medication Policy and Procedures" states that once the GP issues a prescription, the GP is required to complete the client's medication administration chart with a description of the medication and a signature to confirm authorisation of the medications prescribed.
[6] Right 4(1) states: "Every consumer has the right to have services provided with reasonable care and skill."
[7] Right 4(2) states: "Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards."

Dr H

18. Adverse comment is made regarding Dr H having signed repeat prescriptions for Ms A's midazolam on 30 August 2013 and 29 June 2015.

The medical centre

19. Adverse comment is made regarding a pattern of behaviour by doctors at the medical centre not prescribing in accordance with accepted practice.

Ms D

20. Adverse comment is made about Ms D for not following the pharmacy's SOP, and having queried the instructions with a Creative Abilities' staff member rather than the prescriber.

Ms C

21. Ms C dispensed midazolam for Ms A with the instruction to apply behind the ear. Ms C noted that the instructions were unusual, and checked Ms A's history. Adverse comment is made about Ms C's failure to contact the prescriber when she recognised the unusual method of administration of the midazolam, and her actions once she was made aware of the incident on 2 February 2016.

Recommendations

22. Dr G agreed to undertake further training on safe prescribing practice and record-keeping, and to apologise in writing to Ms A and Mrs B.

23. It was recommended that Hillcrest Family Pharmacy Limited (a) undertake training of all staff involved in dispensing prescriptions with regard to the Code of Ethics, the steps to be taken if there is any uncertainly about a prescription, and the records that should be maintained; and (b) provide a written apology to Ms A and Mrs B for the repeated failure of its staff to take appropriate steps with regard to the unusual mode of administration of midazolam.

24. It was recommended that Creative Abilities and Associates Limited (a) review its Safe Administration of Medication Policy and Procedures; (b) develop a process/policy to ensure that each client's records are reviewed regularly to ensure that instructions are consistent and correct; and (c) provide a written apology to Ms A and Mrs B.

Complaint and investigation

25. The Commissioner received a complaint from Mrs B about the services provided to her daughter, Ms A, while she was in the care of Creative Abilities.

26. The following issues were identified for investigation:

- *Whether the medical centre provided an appropriate standard of care to Ms A between September 2012 and February 2016.*
- *Whether Dr G provided an appropriate standard of care to Ms A between September 2012 and February 2016.*
- *Whether Hillcrest Family Pharmacy Limited provided an appropriate standard of care to Ms A between September 2014 and February 2016.*
- *Whether Ms C provided an appropriate standard of care to Ms A between January 2016 and February 2016.*
- *Whether Ms D provided an appropriate standard of care to Ms A between September 2014 and February 2016.*
- *Whether Ms E provided an appropriate standard of care to Ms A between September 2012 and February 2016.*
- *Whether Ms F provided an appropriate standard of care to Ms A between September 2012 and September 2014.*
- *Whether Creative Abilities and Associates Limited provided an appropriate standard of care to Ms A between September 2012 and February 2016.*

27. This report is the opinion of Deputy Health and Disability Commissioner Kevin Allan, and is made in accordance with the power delegated to him by the Commissioner.

28. The parties directly involved in the investigation were:

Ms A	Consumer
Mrs B	Complainant/consumer's mother
Creative Abilities	Provider
The pharmacy	Provider
Ms C	Provider/pharmacist
Ms D	Provider/pharmacist
Ms E	Provider/pharmacist
Ms F	Provider/pharmacist
Dr G	Provider/general practitioner
The medical centre	Provider

Also mentioned in this report:

Dr H	General practitioner

Ms I	Caregiver
RN J	Registered nurse
Ms K	Pharmacist
RN L	Registered nurse
RN M	Registered nurse
RN N	Registered nurse

29. Further information was received from the Ministry of Health.

30. Independent expert advice was obtained from a general practitioner (GP), Dr David Maplesden (**Appendix A**), a pharmacist, Sharynne Fordyce (**Appendix B**), and a registered nurse (RN), Henrietta Trip (**Appendix C**).

Information gathered during investigation

Introduction

31. Ms A has a history of neonatal meningitis, which left her with cerebral palsy, left hemiplegia, hemianopia, global developmental delay, and medically refractory epilepsy. At the time of these events (between 2012 and 2016) she was aged 17–20 years.

32. Ms A lived in a community house under the care of a disability service provider, Creative Abilities. Her mother, Mrs B, is her welfare guardian and was closely involved in the provision of her services.

33. Ms A had been a patient at the medical centre since she was a neonate, and her usual GP was Dr G.

34. This opinion relates to the prescribing, dispensing, and administration of midazolam for treatment during Ms A's seizures, and the care Creative Abilities provided to her.

Prescribing of midazolam

35. Ms A had previously been prescribed rectal diazepam (Stesolid) for prolonged seizure control. Dr G stated that on 20 September 2012, Mrs B contacted her by telephone and requested a prescription for midazolam to be used by applying it to the skin behind Ms A's ear. Dr G said that she discussed with Mrs B why this method of application would not be suitable, but Mrs B persisted with her request. Dr G said that she "should have been more forceful in persuading [Mrs B] to allow the buccal[8] delivery".

36. On 20 September 2012, Dr G prescribed Ms A "Midazolam 15mg/3ml plastic 1 ampule for a seizure applied to skin behind ear".

[8] Buccal administration involves placing a drug between the gums and cheek.

37. Mrs B told HDC:

> "I can recall now how the error by the GP occurred. I believe that she was talking about a patch that can reduce salivation was available for our daughter and it just gets placed behind the ear."

38. Mrs B stated that she never requested that midazolam be applied behind the ear. She said that Dr G wrote a script for the patch to reduce salivation, but also started adding "behind the ear" for the midazolam scripts. On 10 February 2016, Mrs B emailed Dr G stating that she recalls talking with Dr G about a patch that reduces salivation that could be placed behind the ear. Mrs B added:

> "You then asked me if I would like to proceed with that and I said 'OK, sure'. My understanding … was that it was in relation to the patch to reduce salivation. You may have switched to talking about the Midazolam without my realising."

39. Dr G told HDC that the discussion about excessive salivation took place on 24 May 2013, and she prescribed a Scapoderm TTS patch at that time after checking that it was not contraindicated for a patient with epilepsy. The prescription of a Scapoderm TTS patch is noted in the medical records on that date.

40. Dr G's notes for 20 September 2012 contain only the prescription, and there is no accompanying narrative documenting the reason for the change, why the particular mode of delivery was chosen, and whether there had been any discussion with Mrs B. Dr G said that, in retrospect, she considers that her discussion with Mrs B should have been documented in the notes.

41. Between 2012 and 2016 the prescription was repeated nine times (on 16 November 2012, 30 August 2013, 30 February 2014, 5 May 2014, 7 December 2014, 7 April 2015, 29 June 2015, 26 November 2015, and 26 January 2016).

42. The medical centre stated that the doctors create prescriptions for their patients and they are either printed as a single item or entered into the "Regular drugs" file. The Regular drugs are those that are intended for repeat prescribing. In certain circumstances nurses can print items from the Regular file. The prescriptions are printed on the letterhead of the signing doctor, who takes responsibility for the accuracy and appropriateness of the prescription. The medical centre said that it is clear who the prescriber is from the scripts generated by its software "My Practice", and the clinician signing the script is responsible for ensuring that the script is clinically appropriate. It said that in this case there were only two prescribers involved in prescribing for Ms A.

43. GP Dr H was the second prescriber. He told HDC that he signed the repeat prescriptions for Ms A's midazolam (to be administered behind the ear) on 30 August 2013 and 29 June 2015. He said that he reviewed the notes and confirmed that Ms A suffered a complex neurological condition and had been reviewed regularly by Dr G and the neurology clinic. He stated that he felt that it was appropriate to continue Ms A's medication regimen

unchanged, and felt comfortable signing the prescriptions. The medical centre told HDC that Dr H acted on his own account when issuing the prescriptions and not on behalf of the medical centre.

44. On 10 February 2016, Dr G altered the prescription instructions to refer to buccal use. She told HDC that she agrees that there is no evidence to support the administration of midazolam behind the ear for the acute control of prolonged seizures, and that this use was outside usual accepted practice.

Medical centre

45. The medical centre stated that the practice is a partnership. The doctors at the practice are independent practitioners who each have a contract with the partnership for the provision of services. Dr H is a director.

46. Included in the "Practice Agreement for Cost Sharing Associateship" contract is a requirement that the doctors must comply with standards that the medical centre said are based on the RNZGP Cornerstone criteria. The medical centre stated that each doctor is financially independent, and patient payments do not pass through the practice.

47. The medical centre said that each doctor is responsible for his or her own practising standards, but the medical centre has policies "for purposes of uniformity". Doctors were able to contract with others to cover their patients, but generally patients registered with Dr G were able to see only her, as she did not have an agreement with either of the others. If Dr G was not available, her patients would usually be referred to an Accident & Emergency Department.

48. The "Practice Agreement for Cost Sharing Associateship" contract provides that the medical centre will provide the facilities, equipment, services and staff, but each doctor operates his or her own separate medical practice. The contract states that doctors cannot enter into contractual arrangements on behalf of the medical centre. The medical centre told HDC that it does not hold itself out as a collective entity on its enrolment form, and said that patients would not gain the impression that the practice assumes responsibility for the doctors working there. The medical centre noted that prospective patients must specify which doctor they are enrolling with, and they cannot enrol via the website.

49. At the time of these events, the enrolment form did not require prospective patients to specify which doctor they were enrolling with. The website referred to "Our Doctors"[9] and "Our Team", and stated: "We aim to provide the best service possible. [Our doctors] are committed to providing ongoing medical care of the highest standard for their patients." The medical centre also shared patient health information between its providers, as was done when Dr H wrote prescriptions for Dr G's patient, Ms A.

50. The "Repeat prescribing" policy in place at the time of these events provides that a patient or pharmacist may request a repeat prescription in person, by telephone, or by email. The

[9] Dr H is now the only doctor at the medical centre.

request must then be checked against the clinical guidelines, and the patient's notes must be checked to ensure that the reason the patient was last seen is relevant to the request. If the request fits within the guidelines, the prescription is printed and passed to the doctor. The doctor then signs the prescription and returns it to the staff member. The prescription is then collected or faxed to the pharmacy.

51. Following this complaint, the medical centre told HDC that it is proposing to add the following to the "Repeat prescribing" policy:

- Patients will not be able to obtain an immediate prescription, and the earliest that it will be available is the end of the day. Patients will be advised that issuing of the script will be conditional on the prescribing guidelines. If the patient will run out of medication before being seen, he or she will be given a script to cover that period only.
- Nursing staff will look at all prescription requests with a view to determining that the prescription can be issued without the patient being seen, and that any screening or recalls that are due are notified to the patient.
- The nurse will generate the script if appropriate or send a task to the doctor requesting the script. The doctor will generate or sign the prescription but only when he or she has sufficient time to do so accurately.
- Complex patients will have noted in their file the specific guideline or management plan for their repeat prescribing.

Dispensing of midazolam

52. Between November 2012 and February 2016, the pharmacy dispensed midazolam with the instruction to apply behind the ear. During that time, the pharmacy was owned by two separate companies.

Ms F

53. The dispensary staff working at the pharmacy at that time were Ms F, Ms E, and two other staff. However, Ms F has been unable to ascertain the days on which the staff worked, as staff rosters were not retained. During this time, midazolam with the instruction to apply behind the ear was dispensed for Ms A four times.

54. Mrs B told HDC that around 2014 she told "the previous pharmacist" at the pharmacy that the reference to being administered behind the ear was an error, and asked the pharmacist to update Ms A's records to ensure that the error did not occur again. Mrs B said that the pharmacist agreed to update her daughter's records. However, there is no evidence as to which of the staff working at the pharmacy in 2014 was spoken to by Mrs B.

55. Ms F stated that if the issue had been drawn to the attention of a pharmacist as stated by Mrs B, she would have expected that the prescriber would have been contacted to correct the instructions, and that this would have been recorded on the patient's file. However, there is no such documentation.

56. Ms F told HDC that due to the passage of time and her inability to check the original prescriptions and computer records, she has no recollection of any event or conversations relating to dispensing midazolam to Ms A. Ms F stated:

> "Given the number of years of experience I had had at the time, I feel that I would have thought these instructions were very unusual and I would have queried this with the doctor and/or caregiver …"

57. HDC was able to obtain the labels for the prescriptions for the period 19 November 2012 until 26 February 2014, but not the prescriptions. The labels all refer to application behind the ear. Ms F stated that she understands that the instructions were typed onto the labels in accordance with the doctors' prescription instructions.

Ms E

58. Pharmacist Ms E said that she worked part time at the pharmacy from October 2001 until the end of August 2014, and thereafter she worked there on a casual and infrequent basis. From February 2016, she worked at the pharmacy one day a month.

59. Ms E said that she has no personal recollection of dispensing midazolam, or of any conversations about the dispensing of midazolam for Ms A. Ms E stated:

> "I have no recollection of any dealings with this patient since the end of August 2014. Unfortunately due to the length of time, I am unable to supply physical evidence such as an annotated original prescription."

Ms D

60. Pharmacist Ms D told HDC that she worked at the pharmacy from September 2014 until 2016. She stated that on the two occasions on which she dispensed midazolam for Ms A, she had concerns regarding the instructions. She said she noted that Ms A had previously had midazolam with similar instructions, and recalls talking to Creative Abilities' staff about the instructions. She said that the Creative Abilities' staff did not seem concerned because midazolam had been prescribed for Ms A in the same manner previously.

61. The records show that Ms D dispensed the midazolam on three occasions, 6 January 2015, 5 May 2015, and 29 June 2015. Neither Creative Abilities nor the pharmacy has a record that Ms D contacted Creative Abilities to discuss the method of application.

Ms C

62. The pharmacy manager, Ms C, commenced working at the pharmacy ten days before she dispensed midazolam for Ms A with the instruction to apply behind the ear. Ms C stated that she noticed that the instructions for use were unusual because previously she had never seen midazolam applied topically. She said that when she checked the patient history she found that Ms A had had the same instructions on seven occasions since November 2012. Ms C stated:

> "I thought this must be a usual method of administration that works with this patient. In hindsight I should have made a note to talk to the person who collected the prescription to discuss the route of administering with them, but as those instructions have been repeated over and over since 2012, I did not."

Standard operating procedure

63. The pharmacy's standard operating procedure (SOP) "Dispensing procedure", issued 18 April 2009, states that the pharmacist must ensure that the prescription complies with legal requirements and, when dispensing the medicine, the pharmacist must "[u]sing the patient history where possible, ensure medicine is safe for the patient".

64. The SOP also requires the pharmacist to mentally review the suitability of the prescribed medicine with regard to therapeutic use, adverse effects, contraindication, dosage, and possible interactions with food and other drugs and allergies the patient may have.

65. The SOP "incident reporting", issued 10 October 2013, includes: "Dispensing errors — contact the patient and their GP if appropriate."

Creative Abilities — administration method

66. Creative Abilities' "Safe Administration of Medication Policy and Procedures" states that the Team Leader/ATS (Area Team Supervisor) must check that the medication collected corresponds to the prescription. The policy states that the administration details of PRN (as required) medication must be transferred from the label on the box or bottle onto the Non Packaged or PRN Administration signing sheet, which is signed once the medication has been administered. The PRN Administration signing sheet is on the reverse of the Medication Administration Signing Sheet.

67. From the date of the original prescription (20 September 2012) until 2 February 2016 when the issue was discovered, there were discrepancies between the pharmacy labels (completed by the pharmacy), the medication administration chart[10] (completed by the GP), and Ms A's seizure management protocol setting out the process to follow should she have a seizure (created by Creative Abilities).

68. The pharmacy labels referred to administration behind the ear.

69. The first seizure management protocol is undated, but a short-term care plan dated 8 September 2012 refers to the protocol. The undated protocol does not specify the type of seizure for which midazolam should be administered, i.e., myoclonic or tonic/clonic, but does specify that the administration method should be buccal. The seizure management protocol of 2013 refers to buccal midazolam, as do further seizure management protocols in 2014.

[10] Creative Abilities' "Safe Administration of Medication Policy and Procedures" states that once the GP issues a prescription, the GP is required to complete the client's medication administration chart with a description of the medication and a signature to confirm authorisation of the medications prescribed.

70. The medication administration chart completed by Dr G on 21 September 2012 states: "Midazolam (15mg/3ml) 1 ampule for a seizure applied to ~~skin behind ear~~ Buccal mucosa." The alteration is not initialled or dated, but Creative Abilities stated that the alteration was made by Dr G. Dr G said that she completed the chart on 21 September 2012, and made the change at the time the midazolam was charted because buccal mucosa is the correct method of administration. She said: "Regrettably, I overlooked changing this on the computer." She said that the charts are held by Creative Abilities, and that staff bring them to her to be reviewed. She stated that she "had not changed it after that date", as Creative Abilities held the chart and it was not readily accessible by her. Dr G said that a doctor reviewed the medication administration chart on 8 February 2013.

71. The medication administration chart completed by Dr G on 28 January 2015 gives the direction: "Midazolam (15mg/3ml) 1 ampule for a seizure applied to Buccal mucosa." The medication administration chart completed by Dr G on 19 June 2015 states: "Midazolam (15mg/3ml) 1 ampule per seizure applied to skin behind ear."

72. On 10 February 2016, Dr G recorded on the medication administration chart that midazolam was to be administered by way of buccal mucosa.

2 February 2016

73. On 2 February 2016, Ms A experienced a seizure. Caregiver Ms I reported in the "incident/near miss reporting form" that she recognised the onset of seizure activity and monitored Ms A's presentation to ensure her safety. She documented that she went to get buccal midazolam but the only midazolam available was an injection. She noted that the packaging of the medication (dated 27 January 2016) stated: "Use one ampule for a seizure applied to skin behind the ear."

74. Ms I recorded on the incident form that she knew that some medications can be prescribed in different forms and administered in different routes. She said that she was not taught that she should administer midazolam buccally and ignore the doctor's prescription.

75. Ms I called the Creative Abilities' office to attempt to clarify the medication instructions with a registered nurse, but that was unsuccessful, so she followed the instruction on the package and administered the midazolam to Ms A behind her ear.

76. Ms A's seizures continued, so Ms I called an ambulance.

77. Mrs B arrived shortly after the ambulance and, at that stage, Ms A's seizures had settled and her heart rate and oxygen saturations were normal. Mrs B said that the ambulance officer told her they were surprised that the pharmacist had instructed midazolam to be applied behind the ear.

78. Mrs B said that the house was hot and Ms A was overdressed, which was of concern because Ms A's seizures could be induced by overheating. The ambulance service's

"Patient report form" states that the patient's seizures increase if she gets hot and "Crew note that [temperature] inside house very warm!".

79. Subsequently, Ms I completed an incident form. The "team leader/ATS investigation" section states that Mrs B had said that the air conditioner must be turned on after 10am to prevent Ms A from having seizures. The report findings include that the GP had provided updated instructions for the administration of midazolam.

Steps following 2 February 2016

80. On 4 February 2016, Creative Abilities' RN J recorded in the nursing notes that she had spoken with the medical centre's practice nurse and was told that Dr G had stated that Mrs B had requested the midazolam to be administered behind the ear having researched it, and that Dr G changed the prescription at Mrs B's request. RN J recorded that Creative Abilities was "not informed of that discussion or change".

81. Mrs B advised Ms C that there had been a "prescription error", and Ms C apologised. Ms C told HDC that when she received the call from Mrs B she explained that the instructions were written by the doctor, and that she did check the previous dispensing history.

82. Ms C completed an incident report form dated 10 February 2016, which states: "[Ms C] dispensed as per doctor's instructions and checked history, label was the same several times."

Administration of midazolam between 2012 and 2016

83. Creative Abilities told HDC that Ms A did not require the administration of midazolam between 8 September 2012 and 8 February 2013, or between 8 September 2013 and 1 February 2016.

84. Creative Abilities stated that between 9 February 2013 and 5 September 2013, midazolam was administered to Ms A on 16 occasions, and on each occasion the seizure management protocol was followed and the midazolam was administered buccally, and never administered behind the ear. In response to the provisional opinion, Mrs B said that Creative Abilities had not informed her that Ms A had been administered midazolam 16 times during that period.

85. Creative Abilities said that the only occasion on which Ms A was administered midazolam behind the ear was on 2 February 2016.

86. Creative Abilities stated that as far as it is aware, the only time it was made aware of any query or incident involving the administration of medications for Ms A was on 2 February 2016. It said that if it had made more stringent checks when picking up prescriptions and comparing the medication with the medication charts from the GP, that would have helped it to make an earlier discovery of the discrepancy.

Further information — Creative Abilities

87. Creative Abilities said that it always tries to make sure that a registered nurse accompanies clients to neurology appointments, but that this is not always operationally viable for GP visits, and the client may be taken to the GP by a nominated staff member delegated by one of the registered nurses and/or by a parent or guardian.

88. Creative Abilities stated that on the day the 19 June 2015 prescription was issued, Ms A had been to an appointment at the orthotics department at the public hospital, and was not seen by Dr G. Creative Abilities considers it likely that Mrs B collected a dispensing of a repeat prescription on 21 June 2015 and delivered the medication to the house where Ms A resided. On 23 July 2015, Ms A was reviewed by a neurologist, Dr K. Ms A was accompanied by two Creative Abilities staff and her mother. Dr K's notes state that Ms A had stable brief seizures and that her risperidone was to be decreased by 0.5mg daily for a week and then stopped. Creative Abilities said that a reporting letter from Dr K was received and scanned into Ms A's file, notes were made in the medical section, and a short-term care plan was completed and placed in the hard copy file for use at the house.

89. Creative Abilities stated that prior to 2 February 2016 it was not aware of any query or incident regarding Ms A's medication. In contrast, in response to the provisional opinion, Mrs B said that prior to the incident in 2016 she had informed a caregiver and a team leader at the house where Ms A resided about the error on the midazolam medication label. Mrs B said that she called the nurse, RN J, and told her, and also called Dr G to inform her of the error, and Dr G responded that she would correct it right away.

90. Creative Abilities noted that previously there was a weakness in checking PRN medications, which has now been improved, and staff are now instructed to check medications against the doctor's prescribed medication chart and, if there are any discrepancies, to contact the GP or pharmacy for clarification and inform the registered nurse. The policy for safe administration of medication has been updated to include the people who should be contacted in the event of discrepancies with the administration of medication.

91. Creative Abilities said that collecting medication from the pharmacy and checking medication labels is the responsibility of each house's team leader or, if they are not available, the area team supervisor.

92. Creative Abilities said that there are nursing notes missing from Ms A's records, which it is unable to explain, but it pointed out that there are 89 entries in the communication book between 7 October 2013 and 8 March 2014, and health assessment reports were completed on 13 December 2013 and 14 January 2014.

93. Creative Abilities noted that in early 2015 it transferred all database storage to Zambion (an electronic system), and it is checking whether there were any lost documents, although it does not believe that to be the case. It stated that in order to reduce the likelihood of such an event occurring again, it has produced a template for all registered

nurse reports. In early 2014, it recruited a second registered nurse to increase the nursing cover for clients.

94. Creative Abilities stated that instructions and training for all aspects of clients' care is first introduced during each staff member's 90-day induction, and staff members always have a buddy with them the first time they do anything, in order to explain the processes and procedures.

Responses to provisional opinion

95. The responses to the provisional opinion have been included in the "information gathered" section of the report as appropriate.

96. In addition, Ms C and Ms E both stated that they had no comment to make.

97. Ms D stated that midazolam with the instruction to "apply behind the ear" had been dispensed a number of times before she took over from the previous pharmacist, and there was no evidence that it had been queried. Although Mrs B said that in 2014 the pharmacist was told to update the records as those instructions were incorrect, there was no evidence of that on the file when she (Ms D) took over.

98. Ms D also said that she mentioned the unusual instructions to the Creative Abilities' team, and they did not appear concerned because Ms A had been given that medication a number of times previously. Ms D stated: "In hindsight, I understand it would have been more appropriate to speak to the doctor about the instructions, but because [Ms A] had had those instructions repeatedly since 2012, I did not."

99. Mrs B said: "I would like to make the point that [Dr G] is a lovely person and a caring doctor. I know she would never intentionally do anything to harm any of her patients."

100. Dr H responded that he has carefully reflected on his prescribing practice and does not expect such a situation to arise again.

101. Dr G accepted that administration of midazolam behind the ear is outside usual accepted practice. She said this was the only case in which she has prescribed it in that way. She said that she has refreshed herself on the Medical Council of New Zealand guideline Good Prescribing Practice.

102. Creative Abilities responded that it accepts the recommendations. It said that its clinical advisor has reviewed and made recommendations to improve its "Safe Administration of Medication" policy and has initiated improvements to its medication reconciliation process. It is also obtaining a review by an external consultant to advise on the proposed recommendations and improvements. Creative Abilities submitted that failures by multiple parties led to this incident.

103. The pharmacy accepted the findings and stated that it is reviewing its SOPs and staff training.

104. The medical centre responded to the first and second provisional opinions. The medical centre said that it provided services to the clinicians in the form of premises and staff, and it cannot be held responsible "for the specialist decision making of individual clinicians". The medical centre said that its policies, the information given to patients, and the contracts the doctors have with the practice made it very clear that the doctors do not work as a collective or as part of the medical centre.

105. The medical centre said that it did not hold itself out as a collective entity on its enrolment forms, and patients register with a specific doctor rather than with the practice. The doctors were financially independent, and patient payments did not pass through the practice. It said that it does not hold itself out as a collective entity or that the doctors have shared practices and policies such that the medical centre should be held responsible for errors made by independent practitioners.

106. The medical centre submitted that the particular method by which clinicians organise themselves cannot be relevant to individual clinical decisions, particularly where the entity is not involved in that decision and its policies and processes are robust. It said: "We fail to see how there can be a failure to take reasonable care by [the medical centre] in these circumstances."

Relevant standards

107. The Medical Council of New Zealand publication *The maintenance and retention of patient records* (August 2008) provides as follows:

> "**01 Maintaining patient records**
>
> (a) You must keep clear and accurate patient records that report:
>
> - Relevant clinical findings
> - Decisions made
> - Information given to patients
> - Any drugs or other treatment prescribed"

108. The Medical Council of New Zealand publication *Good prescribing practice* (April 2010) provides as follows:

> "1. You should only prescribe medicines or treatment when you have adequately assessed the patient's condition, and/or have adequate knowledge of the patient's needs and are therefore satisfied that the medicines or treatment are in the patient's best interests. Alternatively you may prescribe on the instructions of a senior colleague or a practice colleague who can satisfy the above criteria, as long as you are

> confident that the medicines or treatment are safe and appropriate for that patient and the patient has given his or her informed consent. Medicines or treatment must not be prescribed for your own convenience or simply because patients demand them. To ensure that your prescribing is appropriate and responsible you should:
>
> > Be familiar with the indications, side effects, contraindications, major drug interactions, appropriate dosages, effectiveness and cost-effectiveness of the medicines that you prescribe.
> >
> > …
> >
> > Prescribe in accordance with accepted practice and any relevant best practice guidelines. Prescribing outside of accepted norms should only occur in special circumstances with the patient's informed consent. In such circumstances, it might be useful to discuss the proposed treatment with a senior colleague before completing the prescription …"

109. The Pharmacy Council of New Zealand publication *Code of Ethics* (2011) states:

> "1.10 Where you have reasonable grounds to consider that a prescription contains any error, omission, irregularity or ambiguity or is not legitimate, or that a prescribed medicine could be detrimental to a patient's health, consult with the prescriber and document the details and outcome."

Opinion: Dr G — breach

Prescribing

110. On 20 September 2012, Dr G prescribed Ms A "Midazolam 15mg/3ml plastic 1 ampoule for a seizure applied to skin behind ear". Dr G said that she did so because Mrs B had requested a prescription for her daughter for midazolam to be used behind Ms A's ear. Mrs B said that the error occurred because of confusion as to whether they were discussing a patch for excessive salivation or the use of midazolam. However, Dr G said that this is not correct, as the discussion about excessive salivation took place on 24 May 2013.

111. My expert advisor, GP Dr David Maplesden, stated that there is no reference to administration of midazolam behind the ear for any medical condition, including seizure control. He also noted that seizure control is not listed on the MedSafe datasheet as an approved indication for the use of midazolam, although he noted that commonly it is used for this, especially in the paediatric population.

112. Dr Maplesden advised that the prescription of midazolam for Ms A to be used behind the ear for acute control of a prolonged seizure was not in accordance with accepted practice.

He stated that it was clinically unsafe and, if Mrs B had requested administration of midazolam behind the ear for her daughter, Dr G should have declined the request while discussing the very valid clinical reasons for declining. I agree and note that the Medical Council of New Zealand guideline *Good prescribing practice* states that medicines or treatment must not be prescribed because patients demand them, and that doctors should prescribe in accordance with accepted practice and any relevant best practice guidelines.

113. I am unable to make a finding as to the conversation that took place between Mrs B and Dr G; however, I do not consider the matter to be relevant. In my view, it was inappropriate for Dr G to prescribe midazolam in a manner inconsistent with accepted practice. I note that Dr Maplesden advised that he is at least moderately critical of Dr G's action.

114. As part of the prescribing process, Dr G was required to complete the medication administration chart held at Creative Abilities. However, she did so inconsistently. On 21 September 2012, the chart states: "Midazolam (15mg/3ml) 1 ampule for a seizure applied to ~~skin behind ear~~ Buccal mucosa." The alteration is not initialled or dated, but Dr G said that she made the alteration because that is the correct form of administration. However, the medication administration chart completed by Dr G on 28 January 2015 states, "Midazolam (15mg/3ml) 1 ampule for a seizure applied to Buccal mucosa", and the medication administration chart completed on 19 June 2015 states, "Midazolam (15mg/3ml) 1 ampule per seizure applied to skin behind ear". I am critical that Dr G continued to prescribe midazolam to be applied behind the ear whilst recording contrary instructions on the medication administration chart. This shows a concerning lack of critical thinking.

115. I find that for the above reasons Dr G failed to provide services to Ms A with reasonable care and skill and, accordingly, breached Right 4(1) of the Code.

Record-keeping

116. In addition, I am critical that Dr G did not document the reasons for the change to the mode of administration of midazolam, why the particular mode was chosen, and whether there had been any discussion with Ms A's welfare guardian, Mrs B.

117. I note that Dr Maplesden advised that he is moderately critical of the lack of clinical documentation accompanying the introduction of midazolam to Ms A's treatment.

118. By failing to keep appropriate clinical records, Dr G failed to provide services that complied with professional standards. Accordingly, I find that Dr G also breached Right 4(2) of the Code.

Opinion: Creative Abilities and Associates Limited — breach

119. Between 2012 and 2016, Ms A resided in a community house operated by Creative Abilities. I have a number of concerns about the services provided to Ms A, as follows.

Documentation

120. I am concerned about the inconsistencies in the documentation with regard to the administration of midazolam to Ms A. In my view, Creative Abilities had a responsibility to ensure that the instructions given to its staff were checked and were not contradictory.

121. Creative Abilities' medication administration chart for PRN midazolam on 19 June 2015 states, "To be applied to skin behind ear", while the seizure management protocol refers to the administration of buccal midazolam. Throughout the period in question, the pharmacy labels referred to application behind the ear. It is concerning that these discrepancies were not detected and questioned.

122. In addition, the protocol has no date to indicate when the forms were completed, and there is no legible signature authorising the protocol.

123. My expert nursing advisor, Henrietta Trip, advised me that the information regarding the administration of PRN midazolam for Ms A was confusing for staff, as it provided differing routes for administration. Ms Trip stated that this is not an acceptable standard of care, and would be a moderate departure from accepted practice.

124. I am critical that no Creative Abilities staff questioned that the administration instructions on the label of Ms A's midazolam differed from the protocol or the altered instruction on the doctors' medication administration chart on 19 June 2015. Furthermore, none of the registered nurses questioned the method of administration of midazolam. In my view, that demonstrated either a lack of critical thinking on the part of the registered nurses, or a failure to review the documentation.

Policy

125. Creative Abilities has agreed that if more stringent checks had been performed when picking up prescriptions and comparing them to the medication administration chart completed by the GP, it would have helped to make an earlier discovery of the discrepancy with regard to the mode of administration of midazolam. Ms Trip advised that the Safe Administration of Medication Policy and Procedures document was not sufficiently clear about the roles and responsibilities of staff members and the steps required in the processes for collection and storage of medications. She noted that the policy largely relates to blister packs.

126. Ms Trip also advised that the Safe Administration of Medication Policy and Procedures document should specify the circumstances in which two staff must be involved in medication administration. In addition, she stated that the policy should state who should be contacted for clarification with regard to questions about medication administration.

127. The Safe Administration of Medication Policy and Procedures document requires staff to transfer information from the label on the box or bottle onto the medication signing sheets. Ms Trip stated that the transcription of any prescribed medication that is to be administered to a client is a severe departure from the standard of care because of the risk of errors being made during transcription and the potential for staff to rely on secondary sources rather than the original medication order form, resulting in incorrect medication administration.

128. In my view, the Safe Administration of Medication Policy and Procedures document is unclear with regard to non-blister-packed PRN medications, and requires review.

129. Creative Abilities said that its staff are now instructed to check medications against the doctor's prescribed medication chart, and, if there are any discrepancies, to contact the GP or pharmacy for clarification and inform the registered nurse. The policy for safe administration of medication has been updated to include who should be contacted in the event of discrepancies with the administration of medication. In the circumstances, I find these changes to be appropriate.

Nursing notes

130. There are two gaps of several months in the clinical records, with no registered nurse entries. It is unclear whether this was caused by a limitation of, or transfer to, the Zambion system, or reflected the documentation practice of the registered nurses. Creative Abilities agreed that there are nursing notes missing from Ms A's records, but it pointed out that there are 89 entries in the communication book between 7 October 2013 and 8 March 2014, and health assessment reports were completed on 13 December 2013 and 14 January 2014.

131. Creative Abilities has been unable to explain the missing nursing notes, but considers it unlikely that it is related to the electronic database storage. Creative Abilities said that it transferred all records to database storage in early 2015, and it does not believe there were any lost documents.

132. Ms Trip advised that if the gap in the nursing notes was due to a failure by the registered nurses to review and document Ms A's health care, it would be a severe departure from the expected standard of care.

133. I am unable to make a finding as to why the nursing notes are missing from Ms A's records. However, I am critical that either the records are incomplete, or the registered nurses did not review Ms A for extended periods.

2 February 2016

134. With regard to the incident on 2 February 2016, Ms Trip advised that there was a reasonable and timely escalation of the error by Ms I and, subsequently, by the registered nurse, and the follow-up of the incident with the respective parties was of an acceptable standard. I accept this advice.

Conclusions

135. Overall, I consider that the care provided to Ms A by Creative Abilities was not of an appropriate standard. In particular, I am concerned that there was contradictory information with regard to the manner in which midazolam was to be administered, and that this was not questioned. In addition, there was a weakness in the manner in which medication was checked, and deficiencies in the policy and procedures for safe administration of medication. There was also a lack of recorded nursing assessments. Accordingly, I find that Creative Abilities failed to provide services to Ms A with reasonable care and skill, and breached Right 4(1) of the Code.

Opinion: Dr H — adverse comment

136. Dr H signed repeat prescriptions for Ms A's midazolam on 30 August 2013 and 29 June 2015. He said that he reviewed the notes and confirmed that Ms A suffered from a complex neurological condition and had been reviewed regularly by Dr G and the neurology clinic with no apparent change in, or comment on, her management for some time. Consequently, Dr H considered it reasonable to continue with the prescription unchanged.

137. Dr Maplesden advised that many GPs in Dr H's position would have signed Ms A's prescription having checked that the medication and dose were appropriate and had been prescribed previously, and would have assumed that the mode of administration was appropriate because the prescription had been generated on several previous occasions without apparent concerns.

138. Dr Maplesden advised that this is not best practice, as the prescriber should be comfortable that all aspects of the prescription are clinically appropriate. However, he noted that it is common practice to do so. Dr Maplesden stated that Dr H's actions did not depart significantly from common practice.

139. While I accept this advice, Dr H should take note of Dr Maplesden's comment below, and reflect on his practice:

> "This incident illustrates the importance when providing repeat prescriptions for a colleague of checking all aspects of the prescription being signed (onerous though this may be) rather than assuming one's colleagues have done so previously."

Opinion: Medical centre — adverse comment

140. The medical centre is a partnership. The doctors at the practice each had a contract with the partnership for the provision of services. Included in the contract is a requirement that the doctors must comply with certain standards, which the medical centre said are based on the RNZGP Cornerstone criteria.

141. The medical centre submitted that it does not hold itself out as a collective entity in its website or its enrolment form. It said it provides services to the clinicians in the form of premises and staff and it cannot be held responsible "for the specialist decision making of individual clinicians".

142. The medical centre said that its policies, the information given to patients, and the contracts the doctors had with the practice make it very clear that the doctors did not work as a collective or as part of the medical centre. It said that it did not hold itself out as a collective entity on its enrolment form, and patients registered with a specific doctor rather than with the practice. It said that the doctors were financially independent, and patient payments did not pass through the practice.

143. The medical centre submitted that the particular method by which clinicians organise themselves cannot be relevant to individual clinical decisions, particularly where the entity is not involved in that decision and its policies and processes are robust.

144. It is my view that at the time of these events the medical centre was a collective entity providing health care services to patients. It was apparent on its website and its enrolment form that it held itself out as a collective entity that provided health and disability services. The wording of the form leads me to believe that the medical centre operated as a collective entity. It referred to "Our Doctors" and "Our Team" and stated: "We aim to provide the best service possible. [Our doctors] are committed to providing ongoing medical care of the highest standard for their patients."

145. Furthermore, I do not consider that there is anything in the enrolment form that made it clear that the medical centre was not a collective entity. I note that patients were not required to specify on the enrolment form which doctor they were enrolling with.

146. The medical centre also shared patient health information between providers at the medical centre, as was done when Dr H wrote prescriptions for Dr G's patient, Ms A. This is consistent with a consumer giving permission to an entity regarding the collection, access, and sharing of their personal health information, as opposed to permission to an individual doctor only.

147. The doctors in the practice also developed shared practices and policies. In addition, they worked together, for example by issuing repeat prescriptions for one another's patients. I consider that the medical centre is a healthcare provider and, as a healthcare provider, that the medical centre is responsible for providing services in accordance with the Code.

148. The practice at the medical centre was that the doctors created the prescriptions for their patients and they were either printed as a single item or entered into the "Regular drugs" file. The Regular drugs were intended for repeat prescribing. In certain circumstances nurses could print items from the Regular list. They were printed on the letterhead of the signing doctor, who took responsibility for the accuracy and appropriateness of the prescription.

149. The medical centre said that it is clear who the prescriber is from the scripts generated by its software "My Practice", and the clinician signing the script is responsible for ensuring that the script is clinically appropriate. Dr Maplesden advised me that the amended repeat prescribing policy appears robust and consistent with similar policies. He noted that if the amended policy is followed correctly, it should reduce the risk of repeat prescribing errors.

150. The Medical Council of New Zealand includes in its statement on good prescribing practice:[11]

> "(i) Prescribe in accordance with accepted practice and any relevant best practice guidelines. Prescribing outside of accepted norms should only occur in special circumstances with the patient's informed consent. In such circumstances, it might be useful to discuss the proposed treatment with a senior colleague before completing the prescription.
>
> …
>
> (iv) If you are the doctor signing and issuing the prescription you bear responsibility for that treatment; it is therefore important that, as the prescriber, you understand the patient's condition as well as the treatment prescribed and can recognise any adverse side effects of the medicine should they occur."

151. In addition to Dr G's prescribing, Dr H signed repeat prescriptions for Ms A's midazolam to be applied behind the ear on 30 August 2013 and 29 June 2015. In this case, I am critical that there was a pattern of behaviour by doctors at the medical centre not prescribing in accordance with accepted practice.

Opinion: Ms D — adverse comment

152. Ms D worked as a pharmacist at the pharmacy from 2014 until 2016. The records show that she dispensed midazolam on three occasions.

153. Ms D had concerns regarding the administration instructions when she dispensed midazolam, but noted that previously Ms A had had midazolam dispensed with similar

[11] https://www.mcnz.org.nz/assets/News-and-Publications/Statements/Good-prescribing-practice.pdf Accessed 16 March 2016

instructions. She said that she talked to staff from Creative Abilities about the instructions, and they did not seem concerned because Ms A had had midazolam dispensed in the same manner previously.

154. My expert pharmacy advisor, Sharynne Fordyce, advised me that given the nature of the drug and the purpose for which it was being used, it would have been appropriate for Ms D to have telephoned the prescriber to clarify or confirm the instructions. Ms Fordyce said that caregivers change frequently, and the person who picks up the medication may not be the one who administers it. She noted that the pharmacy SOP specifies that all prescriptions are to be assessed for validity, safety, and appropriateness, and that Ms D did not follow the SOP completely, which was a departure from an accepted standard of care.

155. I accept this advice, but recognise that Ms D was falsely reassured by the mode of administration having been prescribed on a number of previous occasions. However, I note that the Pharmacy Council of New Zealand *Code of Ethics* (2011) requires a pharmacist to consult with the prescriber and document the details and outcome. I am very critical that Ms D queried the instructions with a Creative Abilities staff member rather than the prescriber.

Opinion: Ms C — adverse comment

156. Ms C commenced working at the pharmacy a few days before she dispensed midazolam for Ms A with the instruction to apply behind the ear. Ms C noted that the instructions were unusual, and checked Ms A's history, finding that she had had the same instructions on seven occasions since November 2012.

157. Ms Fordyce advised me that it is not surprising that Ms C was reassured by the previous dispensing with the same label, given that cerebral palsy and refractory epilepsy can be difficult to treat, and often patients have different individual treatment regimens. Despite this, Ms Fordyce considers that as it was the first time Ms C had dispensed midazolam with these instructions, it would have been an appropriate standard of care for her to contact the prescriber to confirm the instructions. Ms Fordyce does not think it was appropriate for Ms C to speak to the person who collected the prescription. I note that the Pharmacy Council of New Zealand *Code of Ethics* (2011) requires a pharmacist to consult with the prescriber and document the details and outcome.

158. While Ms C should have contacted the prescriber to clarify the instructions, I have taken into account that Ms C was influenced by the previous dispensing history.

159. Following the incident on 2 February 2016, Mrs B contacted Ms C, who apologised and told Mrs B that the instructions had been written by the doctor and she had checked the previous dispensing history. Ms C completed an incident report on 10 February 2016.

160. Ms Fordyce stated that it is of concern that Ms C did not make a follow-up telephone call the following day to ascertain whether Ms A had suffered any ill effects. Ms Fordyce stated that the lack of follow-up was not in accord with the pharmacy's SOP on incident reporting, and was not an appropriate standard of care.

161. Ms Fordyce also noted that it is not good practice for there to have been eight days between the notification of the error and preparation of the incident report. She stated that Ms C's actions were lax and lacking attention to detail. However, Ms Fordyce noted that Ms C had been working at the pharmacy for only 10 days when Ms A's script was dispensed, which would have made her more reliant than usual on previous script history for unusual scripts.

162. I am very critical of Ms C's failure to contact the prescriber when she recognised the unusual method of administration of the midazolam, and her actions once she was made aware of the incident on 2 February 2016.

Opinion: Hillcrest Family Pharmacy Limited — breach

163. The pharmacy had an SOP "Dispensing procedure", issued 18 April 2009, and an SOP "Incident reporting", issued 10 October 2013.

164. Ms Fordyce advised me that the SOPs are generic Green Cross Health SOPs and cover all legal requirements. However, she noted that the tone to be taken when dealing with customer complaints is not as positively focused as would be expected.

165. Ms Fordyce stated that the dispensing staff involved in this matter, particularly the pharmacists, did not provide an adequate standard of care.

166. I accept that this was not a "pharmacy error" as such, as the prescriber had deliberately instructed that the midazolam was to be applied behind the ear. Despite this, it is concerning that multiple pharmacists at the pharmacy failed to think critically and relied on previous dispensing rather than contacting the prescriber, resulting in a pattern of behaviour by staff of non-compliance with the SOPs at the pharmacy.

167. In my view, SOPs are of value only if the expectation is that all staff follow them. A number of the pharmacy staff clearly did not follow the SOPs. Accordingly, I find that Hillcrest Pharmacy Ltd failed to provide services to Ms A with reasonable care and skill, and breached Right 4(1) of the Code.

Opinion: Ms E — no breach

168. Between November 2012 and February 2014, midazolam was dispensed for Ms A with the instruction that it was to be applied behind the ear.

169. Ms E said that she worked part time at the pharmacy from October 2001 until the end of August 2014. She said that she has no recollection of dispensing midazolam, or having any conversations about dispensing midazolam for Ms A.

170. The annotated original prescriptions are not available. Consequently, I am unable to determine whether Ms E dispensed midazolam to Ms A with the instruction that it was to be applied behind the ear.

171. Mrs B stated that in 2014 she told a pharmacist at the pharmacy that the instruction to administer midazolam behind the ear was an error, and asked that Ms A's records be updated to ensure that the error did not happen again. Mrs B does not recall which pharmacist she spoke with, and there is no record of such a conversation in the pharmacy diary.

172. While Ms E did work at the pharmacy at the time, I am unable to determine whether she was the pharmacist spoken to by Ms A. However, I would be critical if she had been alerted to concerns and failed to contact the GP. I note that Ms Fordyce advised that she would consider it to be a moderate to severe departure from accepted practice if a pharmacist had been alerted to a potential error by Mrs B and had taken no action.

Opinion: Ms F — no breach

173. Ms F owned the pharmacy until it changed hands in 2014. Midazolam with the instruction that it was to be administered behind the ear was dispensed on four occasions. Ms F said that she was unable to check the original prescriptions, and does not recollect any event or conversations relating to dispensing midazolam to Ms A. However, she said that if she had dispensed the midazolam she would have thought the instructions were very unusual and would have queried them with the doctor and/or caregiver.

174. Mrs B stated that in 2014 she told a pharmacist at the pharmacy that the instruction to administer midazolam behind the ear was an error, and asked that Ms A's records be updated to ensure that the error did not happen again. Mrs B does not recall which pharmacist she spoke with, and there is no record of such a conversation in the pharmacy diary.

175. I am unable to make any finding as to whether Ms F was the pharmacist spoken to by Ms A. However, I would be critical if she had been alerted to concerns and failed to contact the GP. I note that Ms Fordyce advised that she would consider it to be a moderate to

severe departure from accepted practice if a pharmacist had been alerted to a potential error by Mrs B and had taken no action.

Recommendations

176. In response to my recommendations in the provisional report, Dr G agreed to:

a) Undertake further training on safe prescribing practice and record-keeping, within three months of the date of this report, and report to HDC with evidence of having attended the training, and the content of the training.

b) Apologise in writing to Ms A and Mrs B. Dr G's apology for her breaches of the Code is to be provided to HDC within three weeks of the date of this report, and will be forwarded to Ms A and Mrs B.

177. I recommend that within three months of the date of this report, Hillcrest Family Pharmacy Limited undertake training of all staff involved in dispensing prescriptions with regard to the Code of Ethics, the steps to be taken if there is any uncertainly about a prescription, and the records that should be maintained. The pharmacy is to report back to HDC on the content of the training and the staff who attended.

178. I also recommend that Hillcrest Family Pharmacy Limited provide a written apology to Ms A and Mrs B for the repeated failure of its staff to take appropriate steps with regard to the unusual mode of administration of midazolam. The apology is to be provided to HDC within three weeks of the date of this report, and will be forwarded to Ms A and Mrs B.

179. I recommend that Creative Abilities and Associates Limited:

a) Review the Safe Administration of Medication Policy and Procedures in light of the criticisms in this opinion, and provide the updated policy to HDC within three months of the date of this report.

b) Develop a process/policy to ensure that each client's records are reviewed regularly to ensure that instructions are consistent and correct, and provide the policy to HDC within three months of the date of this report.

c) Provide a written apology to Ms A and Mrs B for its breach of the Code. The apology is to be provided to HDC within three weeks of the date of this report, and will be forwarded to Ms A and Mrs B.

Follow-up actions

180. A copy of this report with details identifying the parties removed, except the experts who advised on this case, Hillcrest Family Pharmacy Limited, and Creative Abilities and Associates Limited, will be sent to the Pharmacy Council of New Zealand. The Pharmacy Council of New Zealand will be advised of the names of Ms C, Ms D, Ms E, and Ms F, in covering correspondence.

181. A copy of this report with details identifying the parties removed, except the experts who advised on this case, Hillcrest Family Pharmacy Limited, and Creative Abilities and Associates Limited, will be sent to the Medical Council of New Zealand and Waitematā DHB. The Medical Council of New Zealand and Waitematā DHB will be advised of Dr G's name in accompanying correspondence.

182. A copy of this report with details identifying the parties removed, except the experts who advised on this case, Hillcrest Family Pharmacy Limited, and Creative Abilities and Associates Limited, will be sent to HealthCERT, MedSafe, and the Health Quality & Safety Commission, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Independent GP advice to the Commissioner

The following expert advice was obtained from GP Dr David Maplesden:

"1. Thank you for providing this file for advice. To the best of my knowledge I have no conflict of interest in providing this advice. I have reviewed the available information: complaint from [Mrs B] — mother of [Ms A] ([date of birth]); response from [Dr G]; GP notes ([the medical centre]); copies of e-mail correspondence between [Mrs B] and [Dr G]; response from pharmacist [Ms C] with prescription records and standard operating procedures (SOPs); e-mails between [Mrs B] and Creative Abilities.

2. [Ms A] was being cared for in a residence run by Creative Abilities. She had a history of neonatal meningitis leaving her with cerebral palsy (left hemiplegia, hemianopsia, global developmental delay) and medically refractory epilepsy. [Mrs B] is concerned that in September 2012 [Dr G] prescribed Midazolam to be administered to the skin behind [Ms A's] ear when required for non-resolving tonic-clonic seizure. She feels this was an error which was not subsequently detected by the pharmacist even though she brought it to the pharmacist's attention, or by [Dr G], and the prescription was repeated on several occasions with the same instructions. [Mrs B] states she became aware of the ongoing error when her daughter suffered a prolonged seizure in early February 2016 and the prescription was subsequently changed to buccal administration of Midazolam. [Mrs B] states she recalls discussing with [Dr G] use of a behind the ear medication (Scopoderm) for [Ms A's] hyper-salivation issues around the time the Midazolam was first prescribed and is of the opinion that [Dr G] confused the two drugs.

3. [Dr G] responds that [Ms A] was previously using rectal diazepam (Stesolid) for prolonged seizure control. On 20 September 2012 she states [Mrs B] contacted her by phone and requested a prescription for Midazolam to be used behind [Ms A's] ear. She states she discussed with [Mrs B] why this method of application would not be suitable but [Mrs B] persisted with her request, which was granted. [Dr G] states: *From when the Midazolam was first charted behind the ear on 20/9/12 neither [Mrs B], Creative Abilities, nor the pharmacist approached me to discuss changing this until after [Ms A] had the prolonged seizure on 2/2/16.* [Dr G] also refers to [Mrs B's] comment in an e-mail that Scopoderm (prescribed on 24 May 2013 for *excessive* dribbling) was contraindicated for [Ms A]. I have reviewed the New Zealand Formulary[1] and concur with [Dr G] that there was no contraindication to prescribing of that drug.

4. [Dr G's] notes dated 20 September 2012 appear to contain only a prescription for: *Midazolam 15mg/3ml plastic ampoule 1 ampoule for a seizure applied to skin*

[1] http://www.nzf.org.nz Accessed 16 March 2016

behind ear. There is no accompanying narrative documenting the reason for this new prescription, why the particular mode of delivery was chosen and whether there had been any discussion with the patient's representative. The same prescription was repeated on 16 November 2012 (together with prescription for rectal diazepam — provider [initials], 30 August 2013 (provider [initials], 13 February 2014 [initials], 5 May 2014 [initials], 17 December 2014 [initials], 7 April 2015 [initials], 29 June 2015 [initials], 26 November 2015 [initials] and 26 January 2016 [initials]. On 10 February 2016 the prescription instructions were altered to buccal use ([Dr G]).

5. On reviewing the medical literature I can find no evidence that supports the administration of Midazolam behind the ear for any medical condition including seizure control. There is no reference to this method of administration in the manufacturer data sheet[2] although a variety of administration methods are discussed (IV, IM, SC, oral, buccal and nasal). Seizure control is not listed on the Medsafe data sheet as an approved indication for use of Midazolam. However, there is ample evidence that supports such use including administration by the intra-nasal route, predominantly in the pediatric population[3].

6. The Medical Council of New Zealand includes the following point in its statement on good prescribing practice[4]:

   (i) Prescribe in accordance with accepted practice and any relevant best practice guidelines. Prescribing outside of accepted norms should only occur in special circumstances with the patient's informed consent. In such circumstances, it might be useful to discuss the proposed treatment with a senior colleague before completing the prescription.

   (ii) Keep a clear and accurate patient record containing all relevant clinical findings; decisions made; information given to the patient and the medicines and any other treatment prescribed.

   (iii) Where a patient's care is shared between clinicians, the doctor with the responsibility for continuing management of the patient has a duty to keep him or herself informed about the medicines that are prescribed.

   (iv) If you are the doctor signing and issuing the prescription you bear responsibility for that treatment; it is therefore important that, as the prescriber, you understand the patient's condition as well as the treatment prescribed and can recognise any adverse side effects of the medicine should they occur.

[2] http://www.medsafe.govt.nz/profs/datasheet/m/MidazolaminjPfizer.pdf Accessed 16 March2016
[3] Humphries L et Eiland L. Treatment of Acute Seizures: Is Intranasal Midazolam a Viable Option? J Pediatr Pharmacol Ther. 2013 Apr–Jun; 18(2): 79–87.
[4] https://www.mcnz.org.nz/assets/News-and-Publications/Statements/Good-prescribing-practice.pdf Accessed 16 March 2016

7. I do not believe [Dr G's] prescribing to [Ms A] of Midazolam to be used behind the ear for acute control of a prolonged seizure was in accordance with accepted practice. I also believe it was clinically unsafe as there is no evidence regarding the efficacy of such administration in what could be a potentially life-threatening situation. If [Mrs B] had requested administration of Midazolam behind the ear for her daughter, I believe [Dr G] should have declined this request while discussing the very valid clinical reasons for declining. While it is possible there was some misperception on the part of [Mrs B] and [Dr G] regarding whether the discussion related to Scopoderm or Midazolam, the fact remains that [Dr G] consciously prescribed Midazolam in a manner inconsistent with accepted practice and with the potential to cause harm and I am at least moderately critical of this action. I am also moderately critical of the lack of clinical documentation accompanying the introduction of Midazolam to [Ms A's] regime, including absence of a record of the discussion that [Dr G] states she had with [Mrs B] regarding the prescribing.

8. I am mildly critical that it appears five separate providers at [the medical centre] were involved with writing repeat prescriptions for the Midazolam between 2012 and 2016, and it seems none of these providers questioned the prescribing instructions for Midazolam which they were endorsing by signing the script. However, I can see that when multiple providers are involved in writing repeat prescriptions as in this case, it is easy to assume the previous prescriber has 'checked' the prescription, leading to perpetuation of prescribing errors. I recommend the medical centre review its repeat prescribing policy to ensure it follows the principles outlined in the cited Medical Council of New Zealand statement.

9. It is disappointing that none of the Creative Abilities' staff apparently questioned the unorthodox administration instructions attached to [Ms A's] Midazolam prescriptions. I am unable to determine on how many occasions the Midazolam was required and whether it appeared efficacious when used. However, I note when it was used on 2 February 2016 it failed to terminate the seizure after 18 minutes and an ambulance was called.

10. The responding pharmacist notes she commenced working at the pharmacy concerned in [2016] when the previous owner [left]. She states on receiving the Midazolam prescription dated 26 January 2016 she found the administration instructions unusual so checked against dispensing records over the previous three years. She was reassured to find the same instructions on each of the seven prescriptions dispensed over that period and assumed *this must be an unusual method of administration that works with this patient.* The pharmacy SOP refers to the requirement for checking all prescriptions for *appropriate dosage, form and route of administration* prior to dispensing and to *investigate and confirm any changes or differences with the patient and/or prescriber as appropriate.* This was not a dispensing error per se as the prescription label accurately represented the

prescriber's instructions. However, I am mildly critical that the pharmacist did not act further on her observation that the administration instructions were unorthodox. I would be more critical if this was the first prescription received with those instructions (and therefore would be more critical of the pharmacist dispensing the medication in 2012), but I feel it was reasonable to some extent to assume the SOPs had been followed when the prescription was first received or at any time subsequently with regard to confirming with the prescriber the accuracy of the medication administration instructions."

Further clinical advice

"1. Advice requested

I would be grateful if you could review [Dr G], [Dr H] and [the medical centre's] responses to your advice report and provide further expert advice. In particular please comment on the:

i. Appropriateness of the services [Dr G] provided to [Ms A].

ii. Appropriateness of the services Dr H provided to [Ms A].

iii. Appropriateness of the services [the medical centre] provided to [Ms A].

Please include specific comment regarding:

(a) the practice of nurses generating prescriptions.

(b) the adequacy and appropriateness of [the medical centre's] repeat prescribing policy.

iv. Any other matter you consider relevant to comment on.

2. Documents reviewed:

i. [Dr G's] response and clinical notes dated 7 March 2016
ii. [Dr G's] response dated 8 November 2016
iii. [The medical centre's] response dated 29 September 2016
iv [The medical centre's] response (including [Dr H's] statement) dated 12 October 2016
v. Creative Abilities (CA) response dated 6 October 2016 including seizure management protocols for [Ms A], statements from staff regarding management of [Ms A's] seizures, and selected medication administration charts.

3. This advice should be read in conjunction with my initial advice dated 16 March 2016.

4. The CA documentation clarifies the following points:

i. [Ms A's] seizure management protocols appear to have been reviewed and rewritten on occasions between 2011 and 2016. All of the protocols reviewed refer to buccal administration of Midazolam. The protocol rewritten in July 2014 was co-signed by [Dr G] with reference to a change in duration of seizure prior to

administration of Midazolam (from 30 seconds to five minutes). The mode of administration of Midazolam (buccal) is recorded just below this section.

ii. Some medication administration charts have been supplied:

a. 18 September 2012 — Midazolam is charted as: *Midazolam (15mg/3ml) 1 ampoule for a seizure applied to ~~skin behind ear~~ buccal mucosa*. The alteration is not initialled or dated but the CA response indicates this was done by [Dr G]. [Dr G] has signed that the chart was reviewed by her on 8 February 2013.

b. 28 January 2015 — *Midazolam (15mg/3ml) 1 ampoule for a seizure applied to buccal mucosa*

c. 19 June 2015 — *Midazolam (15mg/3ml) 1 ampoule for a seizure applied to skin behind ear*. The CA response states this was the only medication chart entry referring to this mode of administration

d. 10 February 2016 — *Midazolam (15mg/3ml) buccal mucosa. To be administered 30 seconds after onset of tonic/clonic seizure*

iii. It is stated in the CA response that [Ms A] did not require administration of Midazolam from 8 September 2012 to 8 February 2013, nor between 8 September 2013 to 1 February 2016. Between 9 February 2013 and 5 September 2013 Midazolam was administered on 16 occasions. While not apparently specifically recorded in the patient the medication was administered buccally and never behind the ear. It was only on 2 February 2016 when a new staff member followed the instructions on the medication label (administer behind the ear) rather than the seizure protocol that the administration issue was detected.

iv. There is no clarification of precisely what verbal or written advice was received from [Dr G] when the mode of administration of Midazolam was to be changed from buccal to behind the ear in September 2012.

v. The response acknowledges that the discrepancy between the medication chart, medication label and seizure management protocol should have been detected earlier than it was and remedial measure have been put in place to minimize the risk of a similar incident occurring in the future. I think the delay in recognizing and clarifying the discrepancies represents a significant departure from expected standards of nursing care and peer (nursing) advice might be required to quantify this departure and the adequacy of the remedial measures.

5. [Dr G] reiterates in her response her understanding that [Ms A's] mother requested the 'behind the ear' mode of administration of Midazolam for [Ms A] despite advice from [Dr G] regarding likely lack of efficacy and lack of evidence of such administration. [Mrs B] disputes this version of events and I am unable to prefer one version over the other. However, no new information has been provided to change my view that it was clinically inappropriate, and potentially harmful to the patient, for Midazolam to be prescribed by [Dr G] in the manner it was between September 2012 and February 2016. The reasons for this opinion have been outlined in my original

advice. I have no concerns at [Dr G's] management of [Ms A] apart from this issue, and her care otherwise appears to have been conscientious and compassionate. However, I am concerned at the apparent failure by [Dr G] to effectively communicate the intended change in management regarding administration of [Ms A's] Midazolam from September 2012 with respect to the medication charting and review of [Ms A's] seizure management protocols (see section 4). This resulted in discrepancies between medication chart, medication label and the seizure protocol although I note there was only one occasion (the event precipitating the complaint in February 2016) on which the seizure protocol (buccal administration of Midazolam) was not followed. I have already noted the absence of any documentation outlining the rationale for the change in [the medical centre] notes (see previous advice). Taking all of these factors into account, I remain of the view that the management of [Ms A] by [Dr G], with respect to prescribing of Midazolam between September 2012 and February 2016 and documentation/communication associated with the change in management, represents at least a moderate departure from expected standards of care.

6. [Dr H] states in his response that he signed repeat prescriptions for [Ms A's] Midazolam (to be administered behind the ear) on 30 August 2013 and 29 June 2015. He states he reviewed the notes and confirmed [Ms A] suffered a complex neurological condition and had been regularly reviewed by [Dr G] and the neurology clinic with no apparent change in, or comment on, her management for some time. He felt under the circumstances it seemed appropriate to continue her medication regime unchanged and felt comfortable signing the prescriptions. Since this incident, he takes a more critical approach to signing repeat prescriptions for colleagues. I believe many GPs in [Dr H's] position would have signed [Ms A's] prescription on checking that the medication and dose was appropriate and had been previously prescribed, assuming that the mode of administration was appropriate as the prescription had been generated on several occasions previously without apparent concerns. While this is not best practice in that the prescriber should be comfortable that all aspects of the prescription being signed are clinically appropriate, I think it is common practice related to attempts to provide an efficient repeat prescribing service often under significant time constraints. Under the circumstances, I have revised my original opinion that [Dr H's] actions represented a mild departure from expected standards of care and feel that his prescribing practice on the occasions in question, while not best practice, did not depart significantly from common practice. However, I think it is appropriate that [Dr H] has reflected on his prescribing on the occasions in question and that the practice has reviewed its repeat prescribing process. This incident illustrates the importance, when providing repeat prescriptions for a colleague, of checking all aspects of the prescription being signed (onerous though this may be) rather than assuming one's colleagues have done so previously.

7. [The medical centre] has clarified its repeat prescribing process and provided the relevant policy document which I have reviewed. While the process of having practice nurses generate repeat prescriptions is not universal, it is not uncommon. I am not familiar with the software being used at [the medical centre] but note that the records

do not indicate who has actually signed the prescription when it has been generated by a practice nurse and this might be of some concern (presumably a software issue). The repeat prescribing policy appears otherwise robust and is consistent with similar policies I have reviewed from other practices. If correctly followed, the risk of repeat prescribing errors should be reduced but the clinician actually signing the script must still take ultimate responsibility for ensuring the script is clinically appropriate. There will always be a tension between providing an efficient repeat prescribing service (as demanded by the patient) and optimizing safety of that service. I do not believe that any specific systems deficiency in [the medical centre's] repeat prescribing processes contributed to the incident in question but it is appropriate they have taken the opportunity to review this process. The issue of accurate identification in the clinical notes of the clinician signing the prescription should be addressed."

Appendix B: Independent pharmacist advice to the Commissioner

The following advice was received from Sharynne Fordyce on 2 February 2017:

"**Health and Disability Commission Report**

Reference: C16HDC00163

I, Sharynne Fordyce, have been asked to provide an opinion to the Commissioner on Case number C16HDC00163. I have read and agreed to follow the Commissioner's Guidelines for Independent Advisers. My qualifications include a Diploma of Pharmacy, and a Masters of Clinical Pharmacy. I have worked in Retail Pharmacy for over 30 years, both in New Zealand and in England, and also locum for the Wairarapa DHB.

Expert advice requested

Please review the enclosed documentation and advise whether you consider the care provided to [Ms A] by pharmacy staff at [the pharmacy] was reasonable in the circumstances, and why.

In particular, please comment on:

1. The adequacy and appropriateness of [pharmacy] services provided by [Ms C] in January and February 2016. Please include comment on:
   a. The steps taken when dispensing midazolam on 27 January 2016.
   b. The steps taken following notification of the prescription error on 2 February 2016 including but not limited to the preparation of the incident report dated 10 February 2016.
   c. Any other matter you consider relevant.
2. To the extent you are able, the adequacy and appropriateness of [the pharmacy] services provided by other dispensing staff between 2012 and 2015.
3. The adequacy and appropriateness of [the pharmacy's] standard operating procedures.
4. Any other matters in this case that you consider warrant comment.

For each question, please advise:

a. What is the standard of care/accepted practice?
b. If there has been a departure from the standard of care or accepted practice, how significant a departure do you consider this to be? (i.e. mild, moderate, severe)
c. How would it be viewed by your peers?
d. Recommendations for improvement that may help to prevent a similar occurrence.

If you note that there are different versions of events in the information provided, please provide your advice in the alternative. For example, whether the care was appropriate based on scenario (a), and whether it was appropriate based on scenario (b).

Documents provided

1. Copy of complaint.
2. [Ms C's] letter dated 7 March 2016 and attachments.
3. [Ms C's] letter received 13 October 2016 and attachments.

Background

[Ms A] has a history of neonatal meningitis which left her with cerebral palsy[1] (left hemiplegia,[2] hemianopsia,[3] global development delay[4]) and medically refractory epilepsy.[5] At the time of these events (2012–2016), she was aged 17–20 years and lived in a community house under the care of disability service provider Creative Abilities. [Ms A] had been a patient at [the medical centre] since she was a neonate and her general practitioner (GP) was [Dr G].

On 20 September 2012, [Dr G] recorded that she prescribed 'Midazolam 15mg/3ml plastic ampoule 1 ampoule for a seizure applied to skin behind ear'. Between 2012 and 2016 this prescription was repeated nine times by staff at [the medical centre]. On 2 February 2016, [Ms A's] mother [Mrs B] stated:

> 'Today my daughter went into status epilepticus and the caregiver caring for her at the time squirted Midazolam behind her ear, as per the pharmacist's written instructions on the box. When she continued to seizure for a further 5 minutes after application, the care giver called an ambulance.
>
> The paramedics reported that she had recovered from her 18 minute seizure without treatment. They were surprised to hear that the pharmacist had put instructions to advise to administer the Midazolam behind the ear. I called the pharmacist on duty, [Ms C], who quickly blamed our daughter's GP for writing these instructions on the script.'

[Pharmacy Manager Ms C] has provided a response to this complaint. [Ms C] told HDC that she dispensed the prescription for Midazolam on 27 January 2016. With respect to the instruction to apply the medication 'behind the ear' [Ms C] states:

[1] A condition marked by impaired muscle coordination (spastic paralysis) and/or other disabilities, typically caused by damage to the brain before or at birth.
[2] Paralysis on one vertical half of the body. In [Ms A's] case the left half.
[3] Decreased vision of blindness in half the visual field, usually on one side of the vertical midline.
[4] A general term used to describe a condition that occurs during the developmental period of a child between birth and 18 years. It is usually defined by the child being diagnosed with having a lower intellectual functioning than what is perceived as 'normal'.
[5] A condition where seizures are unable to be controlled by seizure medication.

> 'I noticed the instructions for use were unusual as I have never seen Midazolam applied topically before, only via injection, rectal, intranasal or buccal routes. On checking against the patient history, I found that this patient has had the exact same instructions on seven occasions since November 2012. I thought this must be an unusual method of administration that works for this patient. In hindsight I should have made a note to talk to the person who collected the prescription to discuss the route of administering with them, but as those instructions have been repeated over and over since 2012. I did not.'

[Ms C] also stated that the diary notes documented in [the pharmacy's] computer system under [Ms A's] patient file did not contain any instructions related to Midazolam.

On 10 February 2016, [Ms C] recorded her 27 January dispensing in an incident reporting form and stated that there were 'incorrect directions on label … dispensed as per doctor instructions and checked history label was the same several times'. Also on 10 February 2016, [Dr G] prescribed [Ms A] Midazolam 15mg/3ml with the instruction to 'administer 15mg into the buccal mucosa after 30 seconds of a tonic/clonic seizure' which [Ms C] dispensed.

[Ms C] confirmed that [the pharmacy's] computer file for [Ms A] had the following label/date entries (note this list excludes the 27 January and 10 February 2016 dispensings):

19 Nov 2012, 9 July 2013, 30 August 2013, 26 February 2014, 5 May 2014 (was held), 6 January 2015, 5 May 2015, 29 June 2015, 26 November 2015 (was held).[6]

[The pharmacy] is currently in the process of obtaining further information regarding these dispensings.

1. *Standard of care*

    a. 27 January 2016 midazolam dispensing by [Ms C]. As stated in her letter [Ms C] recognised that the application of the midazolam seemed very unusual, so she checked on the computer records to confirm a medical history (Competence Standard 03.1.2). The fact that it had been dispensed by [the pharmacy] numerous times in the past few years (before [Ms C] worked there) with the same label led [Ms C] to believe the directions to be appropriate to this particular patient. This is not a surprising decision given that cerebral palsy and refractory epilepsy can be difficult to treat, and patients can often have very individual treatment regimes. However as this was the first time she herself had dispensed this item with these instructions it would have been an appropriate standard of care for [Ms C] to phone [the medical centre] to confirm the instructions (Competence Standards 01.3.3,

[6] Ms C has clarified that 'was held' means that these prescriptions were held by the pharmacy but not dispensed.

03.1.3, 03.1.4). Unfortunately, nowhere in her letter does [Ms C] suggest phoning [the medical centre], only talking to the person collecting the prescription. Given that [Ms A] is in a care facility, and the person picking up the prescription may not be administering [Ms A's] medication this action would not be an appropriate standard of care.

[Ms C] has clarified that 'was held' means that these prescriptions were held by [the pharmacy] but not dispensed.

b. This departure from the standard of care would be considered moderate to severe.

c. This departure would be regarded by the profession as a serious deviation from acceptable standard of care. This route of administration of midazolam is very unusual, and given the rotation of staff frequently present at care facilities, relying on a discussion to confirm dose instructions, at pick up, is not appropriate.

d. [The pharmacy's] SOP for Prescription assessment and clinical check would appear to have been amended in March 2016, to insist on a clinical check by the pharmacist prior to dispensing. This should also include the need to confirm any unusual instructions with the doctor or medical centre concerned.

1b. Notification of prescription error on 2 February 2016 and preparation of the incident report dated 10 February 2016.

a. [Ms C] was notified of the prescription error by [Mrs B], at which point she apologised. However no mention is made of [Ms C] offering to phone the doctor concerned to clarify the dosage instructions, and no mention is made of a follow up phone call the next day to ascertain that [Ms A] had not suffered any ill effects from the error. Although maybe not intentional, this lack of concern or follow up deviates both from [the pharmacy's] SOP on Incident Reporting and an appropriate standard of care.

The 8 days between the notification of the error and the preparation of the incident report is not consistent with good practice or [the pharmacy's] SOPs. Details need to be recorded as soon as possible to ensure accuracy.

b. Both of the courses of action discussed above would represent a moderate to severe departure from accepted practice (I have included severe here because the initial response to the customer after an error has been reported can greatly influence following actions).

c. Given the emphasis on customer satisfaction and keeping accurate records, the profession would regard the above actions as lax and lacking attention to detail.

d. An in-house refresher course on both dealing with prescription errors, and recording them would be helpful, with direct reference to their own SOPs.

2. Pharmacy services provided by other dispensing staff between 2012 and 2015:

    a. Recorded in one of [Mrs B's] emails is a reference to telling the pharmacist at the time, approximately two years prior, that the label for the midazolam was incorrect and could she get it corrected. Unfortunately this did not happen and over the ensuing years no-one has thought to query the label. Thus all dispensing staff, particularly any pharmacists involved, have not provided an adequate standard of care. That no incident has occurred or been reported is not due to [the pharmacy] services provided at this time.

    b. I would consider this a moderate to severe departure from accepted practice given that a pharmacist had been alerted to this potential error by [Mrs B], and no action had been taken, or note recorded in the computer.

3. [The pharmacy's] standard operating procedures (SOPs) are generic forms produced by Green Cross for all their pharmacies, and as such comply with requirements. However all the SOPs supplied for this complaint have issue dates that post date the date of the error, and none of them have a date for review. This calls into question what SOPs were actually present in [the pharmacy's] system at the time of the error, and what processes are in place to ensure that these SOPs are kept current and up to date. If indeed there were no current SOPs at the time of the error, and nothing in place to update the present SOPs this would indicate an unacceptable departure from accepted practice and require immediate action.

4. Given that the prescription for the midazolam topical application was recorded by [Dr G] in 2012, and from this date until 2016, the instructions were printed out on prescriptions and signed nine times, one could query whether a phone call from [the pharmacy] would have been effective.

Reference

Competence Standards for the Pharmacy Profession
www.pharmacycouncil.org.nz"

The following further expert advice was obtained from pharmacist Sharynne Fordyce:

"I, Sharynne Fordyce, have been asked to provide an opinion to the Commissioner on Case number C16HDC00163. I have read and agreed to follow the Commissioner's Guidelines for Independent Advisers.

My qualifications include a Diploma of Pharmacy, and a Masters of Clinical Pharmacy. I have worked in Retail Pharmacy for over 30 years, both in New Zealand and in England, and also locum for the Wairarapa DHB.

Advice requested

The adequacy and appropriateness of the services provided to [Ms A] by the following pharmacists:

[Ms C], [Ms D], [Ms E], [Ms F], [Ms K]

When answering this question please also include references to relevant SOPs in force at the time of these events (attached). Where relevant, please include comment on the appropriateness of the steps taken upon notification of the dispensing error.

The adequacy and appropriateness of the services Hillcrest Family Pharmacy Limited provided to [Ms A]. Please comment on:

a) Whether you consider any system issues contributed to the care provided.
b) The standard operating procedures in force at the time of these events.
c) The appropriateness of the changes Hillcrest Family Pharmacy Limited has made to its practice.
d) Any other matter you consider clinically relevant to comment on.

Adequacy and Appropriateness of the Services Provided.

a) [Ms C] had been working in [the pharmacy] for 10 days when [Ms A's] script was dispensed. Being new to the business and its customers would have made her more reliant than usual on previous script history for unusual scripts. The SOP in place specifies that all prescriptions are to be assessed for validity, safety and appropriateness. Given [Ms C's] brief tenure it is likely that she had yet to physically read this SOP, however its purpose is accepted standard practice, and, as mentioned in my previous report, contacting the prescriber would have been the appropriate step. This is a moderate to severe departure from an accepted standard of care.

   The SOP in place at the time for Customer Complaints is very comprehensive but does require that the customer is kept fully informed of resolution steps, and any changes of practice to prevent a similar incident happening again. This does not appear to have happened and would be considered a moderate to severe departure from an accepted standard of care. (I do hope that [Ms C] was very apologetic, not apathetic, as she mentions in her letter!)

b) [Ms D] dispensed two of the previous prescriptions for [Ms A], with the same unusual directions. [Ms D] did query the instructions with the caregiver, who was picking up the medication, and was reassured that they were the regular instructions. However, given the nature of the drug, and for what it was being used, it would have been appropriate for [Ms D] to have phoned the doctor to clarify or confirm these instructions. Caregivers change frequently, and the person picking up the medication may not be the one administering it. Assuming the dispensing SOPs were the same ones that were in place for [Ms C], these were not

followed completely, resulting in the continuation of the error. This is a moderate to severe departure from an accepted standard of care.

c) [Ms E] worked part-time as a pharmacist at [the pharmacy] from [2001] until [2014], then infrequently until [2016], when she started working [one day a] month. She cannot recall any dealings with [Ms A] since [mid] 2014. In my last report I commented on the collective responsibility all the pharmacists working at [the pharmacy] had for checking unusual instructions. In [Ms E's] letter dated 26/01/17 she lists four changes in her practice that she is implementing to reduce the likelihood of such an event recurring.

d) Ms F owned [the pharmacy] [until 2014]. During this time there were 4 dispensings of Midazolam for [Ms A] between November 2012 and February 2014. In her letter of complaint [Mrs B] mentions telling a pharmacist about the incorrect instructions and requesting a correction, mentioning a date of sometime in 2014 (two years prior to the complaint). Due to the vagueness of this date culpability for this oversight could fall on any of the three pharmacists working at [the pharmacy] at the time. The dispensing SOPs in place adequately cover appropriate dispensing practices, but were not followed in this instance. [Ms F] has no personal 'recollection of any event or conversations relating to the dispensing of Midazolam to [Ms A]' (letter dated 31/01/17), so had not contacted the doctor regarding the instructions.

e) [Ms K] was working as a pharmacist at [the pharmacy] on the 19 November 2012, the date of the initial dispensing of this prescription from [the pharmacy]. If [Ms K] was sole charge on that day it must be assumed that she was responsible for the initial dispensing of this prescription to [Ms A] with these instructions. In [Ms K's] letter dated 01/08/17 she states 'When dispensing medicines with unusual instructions, alarm bells go off, and it is usual to look further into whether all is correct. However, when the medicine has been dispensed with these unusual instructions previously, it is customary for the pharmacist to include in the notes, details of the conversation with the prescribing doctor'. This statement contrasts markedly with the facts that the 19 of November was the first dispensing of this prescription in this pharmacy, and that there were no entries in the computer to indicate a conversation with a prescribing doctor. If [Ms K] did dispense this prescription as written she did not provide adequate and appropriate services to [Ms A], or follow the dispensing SOPs in place at the time. This is a severe departure from an accepted standard of care. However there is no visual proof of who dispensed this first prescription, which resulted in a computer record that four other pharmacists did not adequately check.

Services Hillcrest Family Pharmacy Limited provided to [Ms A]

I consider it would have been appropriate for [Ms D] to have been more involved with the complaint process, given [Ms C's] newness to the job. This would have helped confirm that she was aware of the expectations of the company in situations such as this, and also aware of the company's SOPs. As owner of [the pharmacy], a letter of

apology from [Ms D] would have been appropriate and very helpful for [Mrs B]. Given that [Ms D] had also dispensed scripts with the same instructions, for the same person, I would have expected [Ms D] to take a much closer interest and involvement in the situation. It would seem to appear that she was trying to distance herself from the situation, which did not contribute positively to the care provided to [Ms A] and would be considered a moderate departure from an accepted standard of care.

a) The SOPs in place at the time are generic Green Cross Health SOPs and as such cover all legal requirements. Although the tone to be taken when dealing with customer complaints is not as positively focused as would be expected from such a large organisation.

b) In May 2016, [the pharmacy] was routinely audited by the Ministry of Health and all SOPs were reviewed and updated. Copies were then given to all pharmacists working in [the pharmacy], and their signatures obtained to confirm they had read them. [Ms C] also states in her letter of 23/01/17 that for any unusual instructions or dose, the prescriber will be contacted for clarification. Both of these changes are very appropriate.

In a letter dated 12/05/17 [Ms D] also lists appropriate changes in practice. However with the notification of errors I think 24 hours would be a more appropriate time frame than 2 business days. She mentions keeping in monthly contact with [Ms C] which would seem rather infrequent to provide any support during a rather stressful time such as this and is a moderate departure from an accepted standard of care. A brief weekly meeting would be more in line with normal business practice, and so would brief minutes of such meetings. These also provide a good record of events. Having only one dispensary staff member does not exonerate [Ms D] from providing staff training. There are many external courses available if she does not feel able to provide training herself.

As this prescription had been presented at other pharmacies before this one, presumably with the same instructions, it would be interesting to know what action, if any, was taken. I also noted the note in the computer dated 24/01/14 which emphasised (stressed) 'the use of signing sheets as [Ms A] is not always getting her meds' which indicates a concern from [the pharmacy] staff re the care [Ms A] was receiving."

Appendix C: Independent nursing advice to the Commissioner

The following expert advice was obtained from registered nurse Henrietta Trip:

"I have been asked to provide an opinion to the Commissioner on Case 16/00163, and have read and agreed to the follow the Commissioner's Guidelines for Independent Advisors.

I am a Registered Nurse (DipNS, BN, PGDipHealSc(Nursing), MHealSc(Nursing), PhD) with over 20 years clinical experience in working with individuals, family/whānau as well as health and disability service providers in the field of intellectual disability. Over this time I have held clinical, educational and auditing roles hence, I have an understanding of the standards required for Disability Support Services. Currently I work as a lecturer and researcher in a tertiary nursing education setting with a particular focus on health and long term conditions of populations considered vulnerable. I continue to be involved in the local disability provider's network and nationally with nurses working in the intellectual disability sector.

Referral Instructions from the Commissioner:
Please review the enclosed documentation and advise whether you consider the care provided to [Ms A] by Creative Abilities and its staff between September 2012 and February 2016 was reasonable in the circumstances, and why. Please note separate expert advice regarding the GP and pharmacy services is being sought.

In particular, please comment on:

The adequacy of the nursing care provided to [Ms A] including but not limited to:

a. Whether the discrepancy between the Midazolam administration instructions detailed on [the pharmacy] label, seizure management protocols, and the medication administration charts should have been identified prior to 2 February 2016. If so, please outline the steps that should have been taken.

b. The standard of clinical record keeping with respect to the administration of medications to [Ms A].

c. The adequacy and appropriateness of the nursing staff's involvement to ensure the seizure management protocols and drug administration charts were regularly reviewed and updated by relevant clinicians.

d. Any other matter related to nursing care you consider relevant.

Where possible please include specific comment on the nursing services provided by [RN L], [RN J] and [RN M].

1. With reference to relevant policies and procedures please comment on the adequacy and appropriateness of the services provided by the disability caregiver [Ms I] to [Ms A] on 2 February 2016, including but not limited to:

a. The steps taken during, and immediately following, [Ms A's] seizure; and
b. The escalation of the error and subsequent incident reporting.

2. Whether and to what extent any systems issues contributed to the standard of nursing and disability services [Ms A] received.
3. The adequacy and appropriateness of Creative Abilities policies and procedures including but not limited to the 'Safe Administration of Medication Policy and Procedures' current at the time of these events.
4. The adequacy and appropriateness of the steps Creative Abilities have taken following notification of the medication error on 2 February 2016 including but not limited to, any changes to practice.
5. Any other matters you consider relevant to comment on.

For each question, please advise:

a. What is the standard of care/accepted practice?
b. If there has been a departure from the standard of care or accepted practice, how significant a departure do you consider this to be?
c. How would it be reviewed by your peers?
d. Recommendations for improvement that may help to prevent a similar occurrence in future.

Sources of Information for Opinion:

I received the following information:

1. Copy of complaint
2. Creative Abilities' letter dated 6 October 2016 and enclosures
3. Email from Creative Abilities' [general manager] dated 18 January 2017 and attachments.
4. Email from [general manager] dated 25 January 2017 and attachments.
5. Email from [general manager] dated 27 January 2017 and attachments including nursing notes and nursing reports.
6. Email from [general manager] dated 27 January 2017 and attached general notes
7. Seizure Record Forms 2012–2016
8. Position Description — Registered Nurse
9. Personal Care Plan for [Ms A]
10. Health and Safety Risks for [Ms A]
11. Specific Care Needs for [Ms A]

I sourced the following additional information

1. NZS 8134.0:2008 New Zealand Standard Health and Disability Services (General) Standard

2. SNZ HB 8134.3:2004 Health and Disability Sector Standards (Intellectual Disability) Audit Workbook.
3. Health and Disability Commissioner (1994). Code of Health and Disability Services Consumers' Rights.
4. McVilly, K. & Newell, C. (Eds) (2007). Australasian Code of Ethics for Direct Support Professionals.
5. Ministry of Health (2013). Medicines Management Guide for Community Residential and Facility-Based Respite Services — Disability, Mental Health and Addiction. Wellington: MOH
6. Nursing Council of New Zealand (NCNZ) (2012). Code of conduct. Wellington: NCNZ.
7. New Zealand Nurses Organisation. (2012). Guidelines for nurses on the administration of medicines. Wellington: New Zealand Nurses Organisation.

Summary of Facts from HDC

[Ms A] has a history of neonatal meningitis which left her with cerebral palsy (left hemiplegia, hemianopia, global developmental delay) with medically refractory epilepsy. At the time of these events (2012–2016), she was aged 17–20 years and lived in a community house under the care of disability service provider Creative Abilities (CA). [Ms A] had been a patient at the [medical centre] since she was a neonate and her GP was [Dr G].

On 20 September 2012, [Dr G] recorded that she prescribed 'Midazolam 1mg/3ml plastic ampoule 1 ampoule for a seizure applied to skin behind ear'. Between 2012 and 2016, this prescription was repeated nine times. On 2 February 2016, [Ms A] experienced a seizure and caregiver [Ms I] applied Midazolam behind the ear as prescribed. [Ms I] then called an ambulance. Paramedic staff queried with [Mrs B] the method of administration of Midazolam.

Following [Ms A's] seizure, [Mrs B] made contact with CA regarding a different method of administering Midazolam. Between 2 February and 10 February 2016 multiple correspondence between [Mrs B], CA and [Dr G] occurred. On 10 February 2016, after she was able to make contact with [Mrs B], [Dr G] altered the Midazolam instructions to buccal use.

Date	Source	Comment
? 2012	Seizure Management Protocols	CA have provided the first seizure management protocol which is undated. They have also supplied a Short Term Care Plan dated 8 September 2012 which makes reference to this protocol. The Protocol does not specify which seizures Midazolam should be administered for e.g. myoclonic or tonic/clinic but does specify that the

		administration method should be buccal.
21 Sep 2012	CA Doctor's Medication Administration Chart	[Dr G] *'(Midazolam 15mg/3ml) 1 ampoule for a seizure applied to buccal mucosa'.* The alteration was not initialled or dated but the CA response indicates this was done by [Dr G]. [Dr G] has signed that the chart was reviewed by her on 8 February 2013.
2013	Seizure Management Protocols	?Author. Title *'Administration of BUCCAL MIDAZOLAM'* Myoclonic seizures — *'if their seizure does not settle 15 minutes after the administration of Buccal Midazolam'* Tonic Clonic seizures — *'please get Buccal Midazolam ready to use. I will stop breathing'.*
2014	Seizure Management Protocols	Signed by [Dr G] and [Neurology registrar] on 10 July 2014.[1]* Title *'Administration of Buccal Midazolam …'* Myoclonic seizures — *'if their seizure does not settle 15 minutes after the administration of Buccal Midazolam …'* Tonic Clonic seizures — *'please get Buccal Midazolam ready to use. I will stop breathing'.*
28 Jan 2015	CA Doctor's Medication Administration Chart	[Dr G]: *'Midazolam (15mg/3ml) 1 ampoule for a seizure applied to buccal mucosa.'*
19 June 2015	CA Doctor's Medication Administration Chart	[Dr G]: *'Midazolam (15mg/3ml) 1 ampoule for a seizure applied to skin behind ear.'*
4 Feb 2016	Nursing notes	[RN J]: *I have just spoken with [practice nurse] at [Ms A's] GP … [Dr G] stated [Mrs B] had requested the Midazolam to be administered behind the ear upon researching it. [Dr G] change the prescription at [Mrs B's] request.* ***We were not informed of this discussion or change*** *[emphasis added].'*
10 Feb	CA Doctor's	[Dr G] recorded *'Midazolam (15mg/3ml) buccal mucosa.*

2016	Medication Administration Chart	*To be administered 30 seconds after onset of tonic/clonic seizure.'*

[1] Accompanying this protocol, [neurology registrar] wrote on a CA 'health assessment form' also dated 7 July 2014 'note changes to meds. Letter to follow'. Under the changes to medications section [neurology registrar] recorded that Epilim was added and Dilantin was reduced. No mention is made to changes to Midazolam.

The pertinent standards that apply to this case include:

Health and Disability Commissioner (1994). Code of health and disability services consumers' rights.

Right 4: Right to Services of an Appropriate Standard

1) Every consumer has the right to have services provided with reasonable care and skill.

2) Every consumer has the right to have services provided that comply with legal, professional, ethical and other relevant standards.

3) Every consumer has the right to have services provided in a manner consistent with her or her needs.

4) Every consumer has the right to have services provided in a manner that minimises the potential harm to and optimises the quality of life of that consumer.

5) Every consumer has the right to co-operation among providers to ensure quality and continuity of services.

Health and Disability Commissioner (1994). Code of health and disability services consumers' rights.

Right 6: Right to be Fully Informed

1) Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including —

   (a) an explanation of his or her condition, and
   (b) an explanation of the options available, including as assessment of the expected risks, side effects, benefits, and costs of each option; and
   (e) any other information required by legal, professional, ethical, and other relevant standards

2) Before making a choice or giving consent, every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, needs to make an informed choice or give informed consent.

3) Every consumer has the right to honest and accurate answers to questions relating to services, including questions about —

   (a) the identity and qualifications of the provider; and
   (b) the recommendation of the provider

4) Every consumer has the right to receive, on request, a written summary of information provided.

Health and Disability Services (Core) Standards

NZS 8134.1.3.12: Continuum of Service Delivery — Medicine Management

3.12.1 A medicines management system is implemented to manage the safe and appropriate prescribing, dispensing, administration, review, storage, disposal, and medicine reconciliation in order to comply with legislation, protocols and guidelines.

3.12.2 Policies and procedures clearly document the service provider's responsibilities in relation to each stage of medicine management.

3.12.3 Service providers responsible for medicine management are competent to perform the function for each stage they manage.

3.12.4 A process is implemented to identify, record and communicate a consumer's medicine-related allergies or sensitivities and respond appropriately to adverse reactions or errors.

3.12.6 Medicine management information is recorded to a level of detail, and communicated to consumers at a frequency and detail to comply with legislation and guidelines.

3.12.7 Continuity or treatment and support is promoted by ensuring the views of the consumer, their family/whānau of choice where appropriate and other relevant service providers, for example, GPs, are considered and documented prior to the administration or new medicines and any other medical interventions.

Opinion based on Referral Instructions from the Commissioner:

1. The adequacy of the nursing care provided to [Ms A] including but not limited to:

   a. Whether the discrepancy between the Midazolam administration instructions detailed on [the pharmacy] label, seizure management protocols, and the medication administration charts should have been identified prior to 2 February 2016. If so, please outline the steps that should have been taken.

The information provided included a *Table of Midazolam Administration* which documents that between 09.02.2013–08.09.2013 there were 16 instances recorded in which Buccal Midazolam was administered and one further entry in which *[Ms A] refused medication.* The next entry in the list was 02.02.2016 in which it was given topically.

On review of the *Seizure Record Forms* from 05.10.2012–20.09.2016, Midazolam was listed as having also been administered on 06.02.2014. From the information available, the route of administration is unknown (and would not be expected on this form). Based on the timeframe in the *Summary of Facts*, in my opinion, it would be fair to assume that this was Buccal administration.

Based on the information provided, the last prescription by [Dr G] for Midazolam was 19.06.2015. On CA Doctor's Administration Medication Chart under PRN Medications (As Required Medications) it was stated 'Midazolam (15mg/3ml) 1 ampoule for a seizure applied to skin behind ear.' It is noted that the HDC summary indicates that: 'Between 2012 and 2016, this prescription was repeated nine times.' This alludes to 'Midazolam … applied to skin behind ear.' The prescription prior to 19.06.2015 (28.01.2015) by [Dr G] was for 'Midazolam (15mg/3ml) 1 ampoule for a seizure applied to buccal mucosa.'

From the information available, there is no record in either the *RN Notes* or *RN Reports* (monthly) that [Ms A] was seen by [Dr G] on 19.06.2015 (or 28.01.2015). It is not known who arranged the appointment, for what purpose, nor who supported [Ms A] to attend this appointment, or whether other person(s) attended on [Ms A's] behalf. As the prescription for Midazolam was on CA *Doctor's Administration Medication Chart* it would be reasonable to assume that a staff member from CA attended.

- In light of the previous point, it is not clear as to whether a script was subsequently written at this time and filled by the identified supplier. If this were the case, the *Transport/Collection* and *Storage/Disposal* sections of the CA *Safe Administration of Medication Policy and Procedures* would have been part of this process (See Number 4).
- The available seizure management forms provided from this period provide information on the *Administration of BUCCAL MIDAZOLAM* for [Ms A] for both myoclonic and tonic/clonic seizures. There is no date on these forms nor signature of authorisation for the prescribed practice.

In the monthly *RN Reports* it is documented that on:

23.07.2015: '6 monthly Neurology review' [Ms A] was supported by '[name], [RN J] and [Ms A's] mother attended'. The Comments (Health Professional) states '[Dr K]: Stable brief seizures. Decrease risperidone 0.5mg daily 1/52 then stop'. The outcome of this was 'To be seen again in 6 months, STCP in place to stop Risperidone. Neurologist to do referral to Dual Disability Services'.

- The decrease in Risperidone was charted by [Dr K] on CA's *Doctor's Administration Medication Chart* both on the day of the Neurology appointment 23.07.2015 and is further signed and dated by [Dr K] when discontinued one week later (30.07.2015).

- The aforementioned *Doctor's Administration Medication Chart* appears to be that which was also updated by [Dr G] on 19.06.2015.
- In the available *RN Notes*, there appears to be no corresponding record of the reported 23.07.2015 neurology appointment. The following was documented in the *RN Notes* for this timeframe:

  20.07.2015:

  Entry by [RN J], regarding the week 6–12 July included *'For Neurology review in August'.*

  06.08.2015: [Ms I] noted 'Risperidone finished on the 30th July.'

What is the standard of care/accepted practice?

If [Ms A] was supported by CA to attend the GP practice on 19.06.2015, the expected standard of care would require that staff to document the visit including what was discussed and the outcome. As the information available indicates, there was a change made in the prescription on this date as to how Midazolam was to be administered *'applied to skin behind the ear'.* The person(s) from CA who attended would be expected to communicate with the RNs any changes or outcomes and/or:

If a RN had attended the appointments in question (28.01.2015/19.06.2015/ 23.07.2016), they would be expected to: check and clarify the prescribed regular and PRN medications, any proposed changes with the prescribing professional, ensure the seizure management protocol for [Ms A] was updated accordingly and clearly communicate this to [Mrs B], CA management as well as staff and document the consultation and outcome in the *RN Notes.*

Further, all documentation that provides information about, and requires a specific health intervention must be dated and signed by the health professional responsible for its development and implementation. In regard to a seizure management protocol therefore, (which is informed by the *Doctor's Prescribed Administration Chart)* the responsibility for this standard of care is clearly stated in the *RN Job Description* (who should complete this in consultation with the prescribing health professional) as outlined below:

Client Clinical Support:

Accountability and responsibility is shown for providing accurate information to clients and team members about prescribed interventions or treatments to ensure that they are being understood and the Healthcare Professionals directions are being followed.

All health related documentation is completed accurately and within specified timeframes and all requirements of internal and external correspondence are actioned as required.

Client Care Plan Support:

Liaison with client and family/whānau regarding GP and other health professional appointments. Ensure any changes to client medical requirements are clearly and promptly communicated to house and day service staff.

- In my opinion, when attending a GP or neurology appointment about [Ms A's] seizure management, it would be expected that all medications pertaining to her seizure history and management would be discussed and documented — including regular and PRN medications.
- In my opinion, the discrepancy between [the pharmacy] label, seizure management protocols, and the medication administration could have been identified prior to 02 February 2016.

If there has been a departure from the standard of care or accepted practice, how significant a departure do you consider this to be?

In my opinion, CA documentation and communication was a severe departure from the expected standard of care or accepted practice.

How would it be reviewed by your peers?

This would be deemed by my peers as a severe departure of care or accepted practice.

Recommendations for improvement that may help to prevent a similar occurrence in future.

- A RN should attend all health appointments pertaining to the prescription, review and management of a person who is suspected of or who experiences seizure activity.
- The RN should ensure that all the relevant documentation (including but not limited to the *Doctor's Prescribed Medication Chart*, STCP template, seizure or other specific health management protocols) accompanies the person to their appointment: The regular and PRN medications, required observations, interventions and/or management strategies/protocols should also be reviewed with the respective health professional concerned (e.g. GP/Neurologist/Epilepsy Nurse) and signed and dated accordingly.
- Ensure consistency of documentation between planned and completed health appointments across the *RN Notes* and *RN Reports*.
- RNs to review and summarise the seizure activity of a person at regular intervals (e.g. three or six monthly depending on frequency): This should include the use of PRN medications and administration route: This would further inform the second point above.

Also see below (Number 4) regarding reference to the *Safe Administration of Medication Policy and Procedures* that was in place at this time.

b. The standard of clinical record keeping with respect to the administration of medications to [Ms A].

As noted in 1(a) there was an incongruity between the *Doctor's Prescribed Medication Form* for PRN Midazolam (19.06.2015) *'to be applied to skin behind ear'* and the available seizure management protocol from this period regarding the *Administration of BUCCAL MIDAZOLAM* for [Ms A] for both myoclonic and tonic/clonic seizures. Regarding the latter, there was no date to indicate when these forms were completed nor was there a legible signature authorising the prescribed protocol.

- In my opinion, the information available to staff regarding the administration required for PRN Midazolam for [Ms A], was confusing for staff as it provided differing routes. This is not considered an acceptable standard of care and is a moderate departure in practice.
- See opinion for 1(a) regarding the accepted standard of care and 1(a) — second bullet point for recommendations.
- The protocol itself for the *Administration of BUCCAL MIDAZOLAM* clearly provided identified indications for use, the steps required for both Buccal administration and monitoring.

In regard to the administration of medications, the CA *Safe Administration of Medication Policy and Procedures* states that *'it is best practice to have at least 2 colleagues present, one to administer, record and sign and one to confirm correct procedures, operational constraints or shift patterns permitting'.* The Needs Assessment document (whilst dated 27.04.2016) identified that [Ms A] has '*1:1 support during the day, 1:1 awake support*' which, from the information provided reflects was in place at the time — namely, there was one staff person on at the time of the incident.

- In my opinion, whilst having two staff available for the administration of medications is ideal in the residential context, it would important for CA to identify examples in which there may be a requirement for two staff to be involved in this process.
- I would expect the aforementioned policy to clearly state: who can (or should) be contacted, at which times of the day and on which telephone number should clarification be required for medication administration. This information should be readily available to staff either in this policy and/or on the *Medication Signing Sheet.*

In the *Safe Administration of Medication Policy and Procedures, Appendix 4, Medication Signing Sheets* provides information for *Tube/Feed Medication Signing* and for *Non-packaged or PRN Administration.* Regarding the latter, *this is when clients have been prescribed a short course of medications such as Antibiotics, Panadol or even creams/lotions/ointments, and the administration details are transferred from*

the label on the box or bottle, onto this form. This means that staff 'transcribe' or 'copy' prescribed information.

- In my opinion, the transcription of any prescribed medication which is to be administered to a client is a severe departure of care and accepted practice. This is based on the following:

  The New Zealand Nurses Organisation (NZNO, 2012, p.31) *does not recommend this practice due to:*

  — The risk of errors being made during transcription including duplication and/or omission; and

  — The potential for staff to reply on secondary sources rather than the original medication order form, resulting in incorrect medication administration.

- To reduce the likely risk of significant harm to clients, the recommendation is that the *Non Packaged or PRN Administration Signing Sheet* should be taken with the *Doctor's Prescribing Medication Chart* to all health appointments in which there is a prescribing professional and that staff request that the prescribing professional complete both forms.

c. The adequacy and appropriateness of the nursing staff's involvement to ensure the seizure management protocols and drug administration charts were regularly reviewed and updated by relevant clinicians.

In reviewing the RN Notes 12.10.2012–26.09.2016, following a review with either Neurology and GP (which occurred at least six monthly) or other prescribing health professional, the RN (or other) completed a STCP (Short Term Care Plan) and/or TFM (Tube/Feed Medication) to indicate changes in protocol and/or administration. Usually, nursing staff were either directly involved in appointments or they followed up with the relevant CA staff and then took responsibility to ensure the relevant protocols and charts were updated.

Whilst the majority of the RN Reports correlated with the nursing notes provided (*for example 6-month Neurology Review 15.01.2015 [RN J]*, there was an instance in which this was not the case. From the information available, the following excerpt from the *RN Report September 2015* is not in the *RN Notes* and it appears that no further reference or follow up was made about this appointment:

15.09.2015 Dual Disability Meeting with Psychiatrist

— Attended by [initials], [RN J], [initials], [Mrs B] & partner

— Comments: [two doctors] Review of current concerns re epilepsy, behaviour and anxiety. Med changes. [Dr] to check with neurology re starting Keppra (levetiracetam). As required clonazepam 3–5drops for days when [Ms A] is very distressed. As required Brufen for period pain.

— Evaluation: Waiting for clinic letter before any medication changes are made.

On occasions prior to the case in question, RNs in CA have checked and clarified information regarding prescribed medication. For example:

> *15.01.2016 4:19.51pm [Ms I]*
> *[CA Staff] gave me the original script for Epilim 200mg/5ml to be given 15mls BD, dated 18th Dec from a [Dr K], Specialist. This is different from what [Ms A] has been having since Nov 26 last year which is 200mg/5ml to be given 15ml mane and 11.25ml nocte. I phoned the Pharmacy and the Practice to reconcile. I was informed by both the Pharmacist and Receptionist at the GP practice that [Ms A's] epilim dose has not changed since Nov as per their respective files. I rang [Mrs B] to clarify this but she's not picking up the phone. I also requested for a Practice Nurse to call me for discussion. Still waiting for the call.*
>
> *15.01.2016 4:24.54pm [Ms I]*
> *I received a call from [Practice Nurse], to discuss about [Ms A's] Epilim. We agreed that she will inform [Dr G] on Monday. The plan is to enquire if [Dr G] is aware of this or if she received any correspondence from the specialist. I gave the reg. number of [Dr K] to track him easily. [Practice Nurse] will call me on Monday. To be followed up. I rang the Pharmacy to inform about my discussion with [Practice Nurse]. We agreed not to prepare the medication until everything is clear.*
>
> *19.01.2016 2:29.28pm [Ms I]*
> *Received a call from [Practice Nurse] and was informed that she is following it up with [Dr K] as [Dr G] (GP) doesn't know anything about increasing [Ms A's] Epilim dose. I phoned [Mrs B] and asked her to email me her knowledge about the appointment with the Neurologist plus contact number/email. To be followed up.*
>
> *19.01.2016 3:24.52pm [Ms I] RN*
> *I phoned [Practice Nurse] and was informed that [Dr G] is fine with the adjustment of [Ms A's] Epilim dose. Pharmacy, [initials] and [Mrs B] were informed. STCP is in place.*

There were two gaps of several months in the Zambion programme in which there appears to have been no nursing note entries. For the purposes of the review HDC requested the information be transferred from Zambion into Word. The following statement was inserted for each gap:

> *No data entries in Zambion between dates below and above. Please see RN reports to supplement the gap.*

The last and subsequent entry which indicate the timeframes in which this occurred were: [1] 07.10.2013–11.04.2014; [2] 23.06.2014–13.01.2015.

It is not clear as to whether this was a limitation of the system or reflected the practice of documentation undertaken by the nurses. If it was the latter, this is a

significant gap in the health record for [Ms A]. During each timeframe there are two RN Reports [1] January 2014; April 2014 and [2] July 2014; August 2014.

What is the standard of care/accepted practice?

- In my opinion, the provision of *RN Reports* (2012–2016) which provide a monthly summary record of identified health issues, appointments with health professionals as well as actions taken/needed — is in keeping with best practice. These are usually informed by nursing or progress notes which cover clinical decision-making and the context of the Report.
- According to the Position Description for the RN in CA, responsibilities are outlined in regard to:

  Client Clinical Support:

  — Accountability and responsibility is shown for providing accurate information to clients and team members about prescribed interventions or treatments to ensure that they are being understood and the Healthcare Professionals directions are being followed.

  — All health related documentation is completed accurately and within specified timeframes and all requirements of internal and external correspondence are actioned as required.

  Client Care Plan Support:

  Liaison with client and family/whānau regarding GP and other health professional appointments. Ensure any changes to client medical requirements are clearly and promptly communicated to house and day service staff.

  - Per the Nursing Council of New Zealand (2012) Code of Conduct:

    Principle 4: Maintain health consumer trust by providing safe and competent care

    4.8 Keep clear and accurate records. (See Guidance Documentation)

    Guidance Documentation:

    — Keep clear and accurate records of the discussions you have, the assessments you make, the care and medicines you give, and how effective these have been.

    — Complete records as soon as possible after an event has occurred,

    — Do not tamper with original records in any way.

    — Ensure any entries you make in health consumers' records are clearly and legibly signed, dated and timed.

If there has been a departure from the standard of care or accepted practice, how significant a departure do you consider this to be?

- In my opinion, where information contained in the monthly RN Reports was not clearly evidenced in the nursing notes, this constitutes a moderate departure of the expected standard of care.
- If the gap in nursing notes in the Zambion programme was due to a failure by the RNs to review and document [Ms A's] health care, for a person with her history, then it would be considered a severe departure of the expected standard of care. If observations and interventions were undertaken in this timeframe but not documented or were captured elsewhere, my view is that it would be a moderate departure.

How would it be reviewed by your peers?

Whilst there was no reported concerns until the case in question, the inconsistent attention to detail in documenting practice would be seen by my peers as placing both the RN and the consumer at risk of harm and would be a moderate departure of care.

Recommendations for improvement that may help to prevent a similar occurrence in future.

- Ensure that what is documented in the *RN Notes* and the *RN Report* (monthly) provide a clear and corroborative record of the presenting health issue(s), assessments undertaken, clinical decision-making, recommendations and/or actions taken.
- The use of a template for *RN Notes* for assessing and documenting a person's health (for example when doing *Rounds*) would support the consistent recording of an individual's presentation, and the care provided over time. Furthermore, it would enable the collation of pertinent information in regard to specific health presentations and responses over time.

d. Any other matter related to nursing care you consider relevant.

Where possible please include specific comment on the nursing services provided by [RN L], [RN J] and [RN M].

During the timeframe in question, the RNs consistently ensured that [Mrs B] was kept informed about all aspects of [Ms A's] care and was consulted about these and/or kept up to date with decisions, outcomes and progress. They also responded to requests and suggestions from [Mrs B] about her daughter in a timely and respectful manner.

The manner in which the RNs worked with [Ms A's] family/whānau is in keeping with the Nursing Council of New Zealand (2012) Code of Conduct:

Principle 3:

Work in partnership with health consumers to promote and protect their well-being.

3.2: Respect health consumers' rights to participate in decisions about their care and involve them and their families/whānau where appropriate in planning care. The concerns, priorities and needs of the health consumer and family/whānau must be elicited and respected in care planning.

27.02.2013: [RN M]

I went to visit [Ms A] to check on here bruises reported by staff. I viewed and noted a bruise (yellowish, almost healed) below her right breast, 5–6 days old. There was no evident pain. No treatment required as it was almost healed. I filled up the RN section on the I/E Reporting Form and submitted to the Quality Manager.

From the information available, it is not known as to (a) when the injury was sustained, (b) who reported it and (c) to whom it was reported. In my opinion, whilst it appears that it had been reported by staff, an incident of this nature would usually warrant follow up earlier than 5–6 days later. See above regarding comments pertaining to documentation as it applies in this situation.

2. With reference to relevant policies and procedures please comment on the adequacy and appropriateness of the services provided by the disability caregiver [Ms I] to [Ms A] on 2 February 2016, including but not limited to:

   a. The steps taken during, and immediately following, [Ms A's] seizure; and

According to the Incident/Near Miss Reporting Form Chippendale 401 [Ms I] recognised the onset of seizure activity and monitored [Ms A's] presentation to ensure her safety: 'I stopped giving her food and, monitoring her, talking to her to direct her attention. In the meanwhile, I moved the table to ensure she did not get hurt from hard objects around her.'

[Ms I] documented that she went 'to get Buccal Midazolam but Midazolam we had were Midazolam Injection'. This suggests that [Ms I] was aware that usually [Ms A] receives Midazolam via the buccal route 'as we were trained to administer buccal Midazolam between lower cheek and teeth'. However, the packaging of the medication dated 27 Jan 16 stated 'Use one ampoule for a seizure applied to skin behind the ear.'

As a caregiver [Ms I] knew that 'some medications can be prescribed in different forms which would be administered in different routes. I was not taught that as long as "Midazolam" is contained in the medication names, I should administer them as how I should administer Buccal Midazolam and ignore doctor's prescription.'

[Ms I] called the office in an attempt to clarify the medication with a RN. As this was unsuccessful she 'followed the instruction in Midazolam Injection's package to

administer the Midazolam. Because I would not put a prescription medicine into a client's mouth when the medication's name and routes are different as directed in the package.' Hence she administered the Midazolam behind the ear and, 'As [Ms A's] seizures were still going on I called the ambulance after a couple of minutes to ensure her safety.'

- In my opinion, [Ms I] is a caregiver and not a registered health professional, and responded based on the information that was in front of her. It would be fair for her to assume up to that point the required checks and balances had taken place according to Creative Abilities' *Safe Administration of Medication Policy and Procedures (Issued 13.02.2012).*
- Regarding *Prescriptions/Ordering*, the above policy states:

  Following a consultation/visit to the clients GP a prescription will be obtained for their medication, the GP will complete the clients medication chart with a comprehensive, legible description of the medication and a signature in the appropriate section to confirm authorisation of the medicines prescribed, this is a directive from the MOH as well as Creative Abilities policy.

- When unable to discuss the medication discrepancy with anyone, [Ms I] acted on the most salient documentation available, i.e. [the pharmacy] packaging. Whilst this is not in keeping with the above policy statement, should she have checked the *Doctor's Prescribed Medication Chart* for [Ms A] she would have found a signed entry under *PRN Medications* dated 19.06.2015:

  Midazolam 15mg/3ml Applied to skin behind ear. 1 ampoule per seizure

- [Ms I] attempted to seek assistance and identified a gap in her knowledge base which is in keeping with:

  McVilly, K. & Newell, C. (Eds) (2007). Australasian Code of Ethics for Direct Support Professional in regard to Professional Competence:

  — Recognise that on-going training and education are necessary to ensure that knowledge and skills are current and relevant to the needs and priorities of clients and services (p.8)

  — When they doubt their own level of competency they ask for assistance.

b. The escalation of the error and subsequent incident reporting.

The timeframe indicated on the *Incident/Near Miss Reporting Form Chippendale 401* was 1355–1430 for the initial events. According to the RN notes completed by [RN J] on Zambion, the following escalation of the error is documented as occurring:

02.02.2016

2.10pm: [Name] came up the stairs and informed us that [Ms I] phoned an ambulance for [Ms A], apparently [Ms A] has had many seizures today and was given medication to stop the seizures which did not work and therefore [name] phoned an ambulance.

2.12pm: I phoned [Ms I] who said the ambulance just arrived and that she did not have time to talk. I texted [Ms I] my direct dial number and asked her to phone me when she can so we can inform [Mrs B]. [Client Services Manager] informed of the above information — he will contact [Mrs B].

2:30pm: Just spoke with the [ambulance driver], [Mrs B] turned up at the house during our conversation and I suggested to him to speak with her about what she would like to do for [Ms A] at this stage. According to [the ambulance driver] [Ms A's] seizures have settled now and her HR is 76 and O_2 is 96% which are both normal.

Spoke with [Ms I], [Mrs B] is still speaking with the ambulance office … When I spoke with the ambulance driver he said it was written to give the Midazolam behind the ears which he has not heard of before, I asked [Ms I] about this and she stated that the Midazolam box said to give it behind the ears and the protocol said to give it via the mouth. [Ms I] stated she was confused and tried to phone the office to speak to someone and couldn't get hold of anyone so she gave it behind the ears, I asked [Ms I] to complete an accident incident form and to phone me when they have decided what they are doing with [Ms A].

3.04pm: I spoke to [Ms I] who stated [Mrs B] will stay with [Ms A] from now until bedtime … The ambulance is still there and [Client Services Manager] is on his way to the house. [Ms I] states she is unable to complete an incident form as she can't find one. I asked [Ms I] to come to the Centre after her shift as per [Client Services Manager] and [RN] instructions. [Ms I] will bring the box that stated to give the Midazolam behind the ears and complete and incident form here. [Area Team Supervisor] and management informed.

It is unclear as to whether the incident report was completed 02.02.2016 or 03.02.2016 — it reads as the latter. It was reviewed by [name] 04.02.2014.

03.02.2016: [Name] phoned this morning at 10.40am to clarify [Ms A's] seizure protocol. I went to the house around 11am and went over the care plans with [name]. STCP made to inform staff or changes made to specific care needs to include seizure management and seizure prevention … Specific Care Needs and health and safety risks fact sheets have been updated and given to the house. Waiting to hear back from the GP around route of administration for Midazolam. Will follow up later today, already left a message for the practice nurse.

03.02.2016: Spoke to practice nurse [at medical centre] at 1.40pm. She was unable to give insight as to why the Midazolam changed from buccal mucosa (Jan 2015) to

behind the ears (June 2015) — as per the drug charts. I also enquired about the use of nasal Midazolam as per [Mrs B's] request. She is going to speak about the above to [Dr G] today and get back to me this afternoon.

Further to the above, and as summarised in the HDC Summary of Facts, there were a number of communications between [Mrs B], Creative Abilities, [Dr G] and [the] DHB. This reportedly followed a query from [Mrs B] as to whether the Midazolam could be administered nasally. This was undertaken between parties between 02.02.2016 and 10.02.2016 the outcome of which was the *Prescription was dispensed (with buccal administration).*

After checking with the Pharmacy [Dr G] advised [Mrs B] 09.02.2016:

I have now been asked to chart nasal Midazolam and the pharmacist stated they will make it up from the 15mg/3ml ampoules, But the nasal spray is used for agitation in terminally ill patients and this is not appropriate for [Ms A]. She would need 30 sprays to receive the correct dose for a seizure. I believe I should be charting Midazolam 1 ampoule (15mg/3mls) to be administered buccally after 30 seconds of a seizure commencing … Please let me know if you are happy with this, as I would like to chart ASAP.

Text message

10.19pm [Ms A] — Hi [Dr G]. That's fine to chart the Midazolam buccally after 30 secs.

What is the standard of care/accepted practice?

- In my opinion, there was a reasonable and timely escalation of the error by [Ms I] and subsequently by [RN J]. The response and follow up to the incident by CA with the respective parties does not constitute a level of departure from expected practice.

3. Whether and to what extent any systems issues contributed to the standard of nursing and disability services [Ms A] received.

As identified above, [Ms I's] reference to not having been taught about thinking about medication in terms of whether the same medication may be given by an alternate route, suggests that there may have been some limitations in the training provided about medication management. However, in my opinion the staff member is a non-registered health professional and she should not be expected to make such decisions and she was correct in not making any assumption.

CA has a system in place to provide staff with a *Medication Support Assessment*. In this process, they were taught the following: the five rights of medication administration, need to identify routes of administration, describe an understanding of key statements, provide examples of medication errors and appropriate actions, recording, and *Six Steps to Administer Buccal Midazolam.* In addition, there is a practical component in which staff need to demonstrate correct handwashing, the

process of medication checks and administration as well as *'What to do if an error is made'.*

Regarding the *Safe Administration of Medication Policy and Procedures:* Whilst it appears that the seizure management protocol at the time was for the *Administration of BUCCAL MEDICATION,* according to the policy the decision of what to administer, and how, would be based on checks between the information provided by the prescriber and supplier — which was for the Midazolam to be *'applied behind the ear'.* (See Number 4 regarding the policy as an issue with the system).

What is the standard of care/accepted practice?
It is standard care and accepted practice (MOH, 2008; 2013), that all staff within disability services are required to be provided education and training on the management of medications within the service.

If there has been a departure from the standard of care or accepted practice, how significant a departure do you consider this to be?
Based on the *Safe Administration of Medication Policy and Procedures* at the time, it was for all new employees and those already in the service. A re-sit test was required following a reported error or mistake. This is a mild departure from accepted practice as it would be expected that staff undertake a refresher at regular intervals.

How would it be viewed by your peers?
This would be viewed as a moderate departure of the expected standard of care.

Recommendations for improvement that may help to prevent a similar occurrence in future.

- At the time of this opinion, the proposed recommendation for regular refreshers for staff in the administration of medications has been implemented by CA '*The CTDO (Clinical Training and Development Officer) immediately made amendments to the Administration of Medication Practical Assessment to include Buccal Administration, every staff member is re-assessed every 12 months.'*
- When undertaking the Medication Support Assessment, if available, consider including an example of a person's *Administration of Buccal Medication* seizure management protocol at the same time. Demonstrate with staff the link between the *Doctor's Prescribed Medication Form*, the *Safe Administration of Medication Policy and Procedures* to the *Medication Support Assessment.*

4. The adequacy and appropriateness of Creative Abilities policies and procedures including but not limited to the 'Safe Administration of Medication Policy and Procedures' current at the time of these events.

At the time of these events, it is my opinion that the aforementioned policy was not clear enough about the roles and responsibilities of staff members in the processes around the *Transport/Collection* and the *Storage/Disposal* of medications.

Transport / Collection:
All medicines will be collected from the authorised supplier. The amount and description shall be confirmed as recorded on the medical chart for each specified client … Client's medicines will be collected by each house's Team Leader, where the TL is unavailable then the responsible Cluster Coordinator will make alternative arrangements.

Storage / Disposal:
All collected medicines shall be returned to each respective client's house and stored in a safe and secure location … The TL will record on the RL Medication Check Record the details of the date the medication was picked up and who picked them up, and what client they are for … Pharmacies have been known to make mistakes in the preparation of the blister packs, it is Creative Abilities responsibility to confirm the contents prior to administration of the medication to its clients.

- The steps listed above relate primarily to *'blister packs'*; there is no mention of PRN or other medications.
- In my opinion, based on the above, and as identified by [the] General Manager in correspondence to the HDC (06.10.2016) a key factor is identified which may have reduced the likelihood of the events leading up to and including 02.02.2016:

  Creative Abilities agree that if we had made more stringent checks when picking up prescriptions and PRN notes from the GP (as specified under our Safe Administration Policy — App 6), it would have helped make an earlier discovery of the discrepancy.

  The error was reported as soon as it was discovered. However, the policy at the time was not clear about the steps required in this process:

  All errors or mistakes must be reported as soon as they are discovered, using the appropriate documentation …

What is the standard of care/accepted practice?

The MOH (2013, p.15) Medicines Guide stipulates that *'There must be a clear hand-over process to a designated person when medication is received.'*

The MOH (2013, p.7) states that:

Organisational policies and procedures should clearly state what actions staff should take when there is a medication error. They should cover how to report and document medication errors, such as by completing an incident form. They should also state that staff should inform the person taking the medication and other relevant people of the error and of subsequent action to address the error.

The procedures should also identify who to seek advice from, appropriate to the type of error involved. For example, appropriate contacts might be the organisation's own

staff, clinical on-call staff, [the pharmacy], general practitioner (GP) or after-hours service, emergency services (dial 111) or the National Poisons Centre.

The National Poisons Centre runs a 24-hour, 7-day, toll-free emergency telephone service: 0800 POISONS or 0800 764 766. See also its website, www.poisons.co.nz

If there has been a departure from the standard of care or accepted practice, how significant a departure do you consider this to be?

In my opinion, the points raised above are a moderate departure from the standard of care.

How would it be viewed by your peers?

I would expect that the identified issues have the potential to place the health professional and ultimately the client, at risk of harm.

Recommendations for improvement that may help to prevent a similar occurrence in future.

- Further review of the *Safe Administration of Medication Policy and Procedures* is needed in regard to the management of a medication error and the policy as a whole to ensure that is in keeping with the:

  Ministry of Health (2013). Medicines Management Guide for Community Residential and Facility-Based Respite Services — Disability, Mental Health and Addiction.

- Regarding the collection and transportation of medicines, the checks should apply to all medications, including PRN.

- The reconciliation of the medications collected from the supplier need to be undertaken not only with the medication chart, but with the relevant protocols to which they apply, for example, seizure management for which a regular and/or PRN is prescribed. This may (or may not) be covered from the change noted in 5(ii) and 5 (iii) below.

5. The adequacy and appropriateness of the steps Creative Abilities have taken following notification of the medication error on 2 February 2016 including but not limited to, any changes to practice.

It is noted that since February 2016 the documentation contained in the *RN Notes* now includes specific information as to what has been documented in the STCP. This provides greater transparency about both content, rationale, process and the expectations for implementation by staff.

Correspondence from [the] General Manager, CA dated 06.10.2016 informs what has been implemented since becoming aware of the discrepancy 02.02.2016.

i. As indicated above, the Introduction of the Clinical Training and Development Officer (CTDO) whose role is to ensure that each staff member has direct training in the administration methods required by the clients they are supporting … CA has mandated that staff undertake refreshers every 12months.

ii. Staff are now required to reconcile instructions *on packs* (from Pharmacy) *with the medical chart.*

iii. CA has two RNs who monitor the medications and also conduct regular audits, part of their routine is to carry out checks on paperwork health in each of the client's personal folder and match it against the medication records.

- As previously stated, as there are a number of areas which may be frequently covered by RNs in monitoring the health of clients in CA, the use of a template would strengthen this practice further.
- In my opinion, CA have implemented a number of actions that seek to reduce the likelihood of a recurrence of the same or a similar incident.
- In my opinion, the wording in the *Safe Administration of Medication Policy and Procedures* between the 14.03.2012 document and that updated on 04.10.2016, requires further revision to more clearly demonstrate the changes already identified by CA as there is similarity in the existing wording.
- There are a number of additional recommendations provided in this opinion which may further strengthen the process of medication management in CA.

6. Any other matters you consider relevant to comment on.

Limitations: Opinion based on the information provided."