Pharmacy
Pharmacist, Mr B

A Report by the

Deputy Health and Disability Commissioner

(Case 18HDC00536)

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Executive summary

1. This report considers the services provided to a terminally ill woman by a pharmacy and a pharmacist. The woman was taking the controlled drug fentanyl to manage the symptoms of her illness. Her husband collected the medication on her behalf.

2. The pharmacy's Standard Operating Procedures (SOPs) at the time of these events stated that no more than 10 days' supply of a controlled drug could be dispensed at any one time, with two repeats (as directed by the physician) to a maximum of 30 days' supply.

3. In October 2017, the woman was prescribed three 12.5mcg fentanyl patches with one repeat of the prescription, allowing for a total of six 12.5mcg fentanyl patches to be dispensed. Instead of dispensing as the prescription was written, the pharmacist dispensed five patches at once. This amounted to a 15-day supply being dispensed on one occasion. The sixth patch was never dispensed.

4. In January 2018, the woman was prescribed five bottles of fentanyl nasal spray and one month's supply of 12.5mcg fentanyl patches (the exact number of patches was not specified), with two repeats of the prescription. The pharmacist dispensed only three bottles of nasal spray rather than the prescribed five. He told HDC that the reason for this decision was that the prescription represented a fivefold increase in supply of the nasal spray based on previous prescriptions. He did not contact the prescribing doctor to query this increase. He also dispensed a total of 14 fentanyl patches from this prescription in one day, which amounted to a 21-day supply of the medication.

Findings

5. The pharmacist made incorrect dispensing decisions with regard to the prescriptions for fentanyl. As a result, the woman was supplied more than the accepted amount of 10 days' supply of the controlled drug, and was also deprived of a sixth patch, which amounted to three days of pain relief. The pharmacist went against accepted practice and Pharmacy Council standards by not contacting the prescribing doctor when he had doubts regarding the correct amount of fentanyl nasal spray to dispense, and the SOPs as well as Pharmacy Council standards by dispensing a 21-day supply of fentanyl patches. Accordingly, it was found that the pharmacist breached Right 4(2) of the Code of Health and Disability Services Consumers' Rights (the Code) by failing to provide services that complied with professional standards.

6. The Deputy Commissioner criticised the pharmacy's failure to review and update its SOPs in a timely manner after these events, despite the fact that the incident reports into the two events recommended this.

Recommendations

7. The Deputy Commissioner recommended that the pharmacist provide HDC with evidence of having completed the online educational refresher course "Palliative Care Best Practice Update" offered by the Pharmaceutical Society of New Zealand.

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8. The Deputy Commissioner also recommended that the Pharmacy Council of New Zealand conduct a competency review of the pharmacist, including consideration of further training on the dispensing of controlled drugs.

9. The pharmacist provided HDC with a written letter of apology to the family.

Complaint and investigation

10. The Health and Disability Commissioner (HDC) received a complaint from Mr A about the services provided to his wife, Mrs A, by a pharmacist, Mr B. The following issues were identified for investigation:

- *Whether Mr B provided Mrs A with an appropriate standard of care between 1 October 2017 and 31 January 2018.*
- *Whether the pharmacy provided Mrs A with an appropriate standard of care between 1 October 2017 and 31 January 2018.*

11. 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.

12. The parties directly involved in the investigation were:

Mr A	Complainant
Mr B	Pharmacist/provider
Pharmacy	Provider

13. Further information was received from:

Medical centre	Provider
Hospice	Provider

14. Also mentioned in this report:

Dr C	GP/provider
Dr D	GP/provider

15. Independent expert advice was obtained from Ms Sharynne Fordyce, pharmacist, and is included as Appendix A.

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Information gathered during investigation

Introduction

16. This report discusses the services provided to the late Mrs A by pharmacist Mr B. The concerns, raised by Mrs A's husband, Mr A, relate to the dispensing of a controlled drug, fentanyl,[1] on three separate occasions in October 2017 and January 2018.

17. Mrs A's condition at the time the services were provided was terminal. Mr A was his wife's caregiver and collected medicine on her behalf.

18. For the most part, Mr B worked as the sole pharmacist at the pharmacy.[2]

Dispensing of fentanyl patches — October 2017

19. On 27 October 2017, Dr C prescribed Mrs A three 12.5mcg fentanyl patches with the instruction that one patch was to be applied to her skin every three days for generalised body pain. He also prescribed one repeat of this prescription, allowing for a total of six 12.5mcg fentanyl patches to be dispensed and applied over an 18-day period (i.e., one every three days).

20. On 29 October 2017, Mr A presented this prescription to the pharmacy. The pharmacy had none of the prescribed fentanyl patches in stock.[3] Mr B told HDC that he decided to order and dispense one full pack of five fentanyl patches to Mr A, rather than three patches at a time as Dr C had prescribed. These were received by the pharmacy on 29 October 2017 and dispensed on the same day.

21. Mr B accepts that this was a 15-day supply based on the dosage set out on the prescription. He told HDC that his assessment was that the provision of five of the patches in one supply instead of dispensing three patches initially, and a further three as a repeat, would be more convenient for Mr A.

22. Mr A told HDC that he understood that the reason for the five patches being dispensed was that fentanyl patches come in packs of five, and that because fentanyl is a controlled drug, the packs could not be split.

23. Mr B stated that Mr A returned to the pharmacy the following day (30 October 2017) and queried why he had been dispensed only five patches and was therefore one patch short. Mr B told HDC that he tried to explain to Mr A that the reason he supplied only five patches was because it would save him from having to come back for just one additional patch to complete the repeat prescription. Mr B stated that the pair argued over this, and

[1] A synthetic opioid used as pain relief. It is a Class B controlled drug as defined in Schedule 1 of the Misuse of Drugs Act 1975.

[2] By late 2017/early 2018, Mr B had one locum pharmacist.

[3] Mr B told HDC that at that time, the pharmacy did not generally hold a large amount of stock of fentanyl patches because it was relatively uncommon for patients to require such strong pain medication, and because it was a Class B controlled drug that had to be logged and tracked in a secure fashion, so he did not want to carry stock unnecessarily. He also stated that Mrs A was the only patient being supplied this medication by the pharmacy at the time of these events.

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Mr B feels that their relationship declined rapidly during the exchange.[4] The final, sixth, patch was never dispensed.

24. Mr B accepts that he should have dispensed the prescription as it was written (three patches and three more as a repeat in three days' time) because it was what Mr A and Dr C were expecting would be dispensed. Mr B also stated that by dispensing the prescription as he did, he went beyond the default dispensing rule as set out in the New Zealand Pharmaceutical Schedule,[5] which prohibits more than 10 days' supply of fentanyl being dispensed at one time. He advised HDC that this was also contrary to the pharmacy's Standard Operating Procedures (SOPs) at the time of these events, which stated that no more than 10 days' supply of a controlled drug may be dispensed at any one time, with two repeats (as directed by the physician) to a maximum of 30 days' supply.

Dispensing of fentanyl nasal spray and patches — January 2018

11 January 2018

25. On 11 January 2018, Dr D from the hospice prescribed one month's supply of 12.5mcg fentanyl patches for Mrs A, with instructions to apply 1.5 patches every three days. The exact number of patches was not specified.

26. Dr D also prescribed five bottles of fentanyl nasal spray with a dosage of 2–4 sprays every 10 minutes as required and up to one bottle every two days. She prescribed two repeats of this prescription. Dr D did not specify the number of ampoules needed in each bottle, nor the volume to be in each bottle.

12 January 2018

27. On Friday 12 January 2018, Mr A presented a number of prescriptions to the pharmacy, including Dr D's 11 January 2018 prescription for fentanyl patches and bottles of nasal spray. Mr B and Mr A agreed that Mr A would pick up the medicines on Monday 15 January 2018.

28. At 6.10pm that evening, Mr B ordered 10 ampoules of fentanyl (equivalent to one bottle of fentanyl nasal spray) instead of the five bottles of fentanyl nasal spray plus two repeats that Dr D had prescribed. Mr B said that he ordered this amount based on a previous prescription for nasal spray he had dispensed to Mrs A. He told HDC that he did not have the opportunity to query the increased prescription with the Dr D, as it was too late in the day.

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[4] There are differing recollections in terms of who saw Mr A on 30 October 2017. Mr A told HDC that on this occasion, he was in fact seen by a locum pharmacist and not by Mr B. The incident reporting form that was completed on this date was filled out by Mr B, who told HDC that Mr A did see a locum pharmacist on one occasion but that this was subsequent to 30 October 2017.

[5] The New Zealand Pharmaceutical Schedule is a list of the prescription medicines and therapeutic products subsidised by the Government. Section A of the Schedule sets out restrictions and other general rules that apply to subsidies for community pharmaceuticals and the giving of hospital pharmaceuticals. In order to receive a subsidy for a community pharmaceutical, all relevant requirements of these rules must be observed in each case. Similarly, all relevant requirements must be met if a hospital pharmaceutical is to be given.

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29. Mr B also stated that as he had only four of the prescribed fentanyl patches in stock, he ordered a further 10 to be delivered on Monday 15 January 2018. Later that evening, Mr B dispensed some of the prescriptions for Mrs A but not prescriptions for the fentanyl patches or fentanyl nasal spray.

15 January 2018

30. On Monday 15 January 2018, Mr A arrived at the pharmacy before the ordered fentanyl patches had arrived. Mr B dispensed the four fentanyl patches he had in stock, as well as the one 20ml bottle (10 ampoules) of nasal spray (which he had ordered on 12 January 2018). Mr B told HDC that he explained to Mr A that the fentanyl patches had not yet arrived, and that he could also provide more nasal spray at a later time.

31. The fentanyl patches arrived later that morning. Mr B dispensed all of the 10 patches that had been ordered as a single dispensing. Thus, a total of 14 patches (21 days' supply according to the prescription dosage)[6] and one bottle (of 10 ampoules) of nasal spray were dispensed on this day.

32. Mr B told HDC: "[I]t was my fault that I didn't ensure that I had enough stock [of fentanyl patches]". He said that the fentanyl patches should have been dispensed as six patches at a time,[7] plus two repeats, which would have amounted to one month's supply of the patches.[8]

17 January 2018

33. Mr A returned to the pharmacy on 17 January 2018. Mr B told HDC that Mr A wanted to know why he was not given five bottles of nasal spray.

34. Mr B told HDC that Mr A insisted that he be supplied with more fentanyl nasal spray. Mr B said that at that point, the relationship between the two men broke down completely, and Mr B called security to have Mr A removed from the premises.

35. Mr A told HDC that prior to this interaction, there had been no ill will between himself and Mr B. Mr A said that as Mrs A's caregiver, he felt frustrated that he was unable to retrieve the additional medication that he understood would provide the level of comfort she required, and he felt humiliated at having been removed from the premises during what was a particularly vulnerable time of his life.

36. Mr B told HDC that he contacted Dr D and arranged for a replacement prescription to be generated so that Mr A could present it at another pharmacy. Mr B also stated that he "made provision for [Mr A] to have a further repeat of 20 ampoules (40ml) [i.e., two

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[6] Taking into account that one half of a patch is discarded to give the correct dose of 1.5 patches every 3 days.

[7] Six patches would amount to approximately a 10-day supply of patches.

[8] As stated above, taking into account that one half of a patch is discarded to give the correct dose of 1.5 patches every 3 days.

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bottles] to ensure that [Mrs A] ha[d] sufficient supply until the next prescription was filled".[9]

18 January 2018

37. Mr A returned to the pharmacy on 18 January 2018 and collected a further two bottles (20 ampoules) of nasal spray. Thus, between 15 January 2018 and 18 January 2018, Mr A was dispensed a total of three of the five bottles of nasal spray that were prescribed by the 11 January 2018 prescription.

Further information from Mr B

October 2017 dispensing

38. Mr B told HDC that before making his dispensing decision for the October 2017 prescription, he considered the following factors:

- The default dispensing rule for pharmacists (as set out in the New Zealand Pharmaceutical Schedule) that up to a 10-day supply of Class B controlled drugs such as fentanyl may be dispensed at any time.

- The Misuse of Drugs Regulations 1977, which state that no more than one month's supply of Class B controlled drugs can be dispensed at any given time.

- The fact that the prescription was for just under 10 days, and that if dispensed according to what Dr C had written, it would require the patient to come back to the pharmacy approximately 8–9 days later for another three patches.

- The fact that "Safety Medicines", of which fentanyl is one,[10] may be prescribed to be dispensed more frequently than the 10-day rule,[11] meaning there is no hard and fast rule about how many fentanyl patches can be supplied in a 10-day period.

- He had no reason to believe that Mrs A was abusing the medication or dealing with it otherwise than in accordance with the dosage instructions.

39. Mr B told HDC that he accepts that his communication to Mr A regarding the dispensing of the prescription on 29 October 2017 may have been confusing, and may have caused Mr A stress and frustration.

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[9] There are differing versions of events with regard to who arranged for the repeat prescription. Mr A told HDC that he personally arranged for the replacement prescription, not Mr B. A sticker added to this prescription by staff at the pharmacy at the time reads: "Doctor contacted, all further repeats cancelled."

[10] Part 10, Section A of the New Zealand Pharmaceutical Schedule defines "Safety Medicine" as a Community Pharmaceutical identified in the Schedule as a safety medicine. Section B of the Schedule states that fentanyl is a safety medicine.

[11] Paragraph 5.4.1, Part 5, Section A, of the New Zealand Pharmaceutical Schedule provides that a Community Pharmaceutical identified in the Schedule as a Safety Medicine may be dispensed more frequently than the default frequency specified under rule 4 (e.g., 10 days), provided both of the following conditions are met: A) the patient is not a resident in a Prison, or one of the residential placements or facilities referenced under rule 5.2, and B) the Prescriber has determined the patient requires increased frequency of dispensing, and specified the maximum quantity or period of supply to be dispensed for each Safety Medicine at each dispensing.

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January 2018 dispensing

40. With respect to the January 2018 dispensing, Mr B told HDC that Dr D's prescription represented a fivefold increase in supply of the nasal spray based on previous prescriptions. He noted that Mrs A's past prescriptions for the fentanyl nasal spray required only 10 ampoules to be dispensed at a time, equating to 20ml of fentanyl to be dispensed in one bottle. He stated that this is why he conservatively dispensed one bottle of 10 ampoules, rather than five bottles of 10 ampoules each, and decided to watch Mrs A's usage and increase the amount of the repeats if required.

41. Mr B told HDC that he is familiar with the district health board's (DHB's) guidelines that relate to fentanyl, which he is required to follow. [12] He explained:

> "[T]hey involve the preparation of a 50mcg/ml, 20ml intranasal spray using ten ampoules of fentanyl 100mcg/2ml. This provides 200 x 0.1ml doses of 5mcg fentanyl. The dosage is 5–10 sprays and repeat after 15 minutes if inadequate response."

42. Mr B stated that Dr D's prescription was a supply of one thousand doses in terms of the DHB's guidelines, which was a significant amount.

43. Mr B accepts that he should have called Dr D in January 2018 to query the significant increase in supply for the prescription for fentanyl nasal spray. Mr B told HDC that this is his usual practice. He also stated that his usual approach was "to monitor the usage of the medicine and supply more of it in accordance with that usage".

44. Mr B told HDC that he accepts that prescriptions should always be dispensed according to regulations, as written by the prescribing doctor. He also stated that any variances due to stock supply issues should be explained compassionately and clearly to the customer.

45. Mr B told HDC that the relationship between Mr A and himself broke down, and that he felt pressure from Mr A, which he considers may have affected his dispensing decisions. Mr B said that he dispensed more than a 10-day supply of fentanyl patches (21 days' supply in total) in order to diffuse the situation.

46. Mr B stated that he deeply regrets any confusion and/or stress that he may have caused Mr and Mrs A as a result of his dispensing decisions. He recognises that this was a difficult time for their family, and told HDC that he is "determined to learn from his mistakes" and has taken steps to ensure that he does.

47. Mr B told HDC that since the time of these events, he has refreshed his knowledge of the rules and regulations relating to the dispensing of controlled drugs, and has also consulted with a senior pharmacist to discuss the October 2017 and January 2018 dispensings.

Incident Reports

48. On 30 October 2017, Mr B completed an incident report relating to the dispensing of the fentanyl patches on 29 October 2017. The report recommended that the pharmacy review

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[12] Each community pharmacy provider in New Zealand has entered into a contract with their local District Health Board for the provision of pharmacy services.

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its dispensing policy and ensure that pharmacy staff provide an explanation before dispensing medication.

49. On 18 January 2018, Mr B completed another incident report into the events surrounding the 11 January 2018 prescription. The report again recommended that the pharmacy's dispensing policy be reviewed, and emphasised the need for pharmacy staff to "ensure dialog with [the] customer at [the] onset".

SOPs as at October 2017

50. The pharmacy's SOP at the time of these events stated the following with respect to avoiding errors in dispensing:

> "PRESCRIPTION AND DISPENSING SERVICES — [THE] PHARMACY
>
> 6.1 Dispensing
> …
>
> Avoiding errors in dispensing
> …
>
> — highlight and check with the prescriber any unusual doses, particularly high doses, and annotate the prescription to indicate the verification."

51. The SOP at the time of these events stated the following with respect to the dispensing of controlled drugs:

> "6.1a CONTROLLED DRUGS
>
> … All dispensing of controlled drugs must comply with the Misuse of Drugs Act & regulations.
>
> No more than 10 days supply may be dispensed at any one time, with 2 repeats (as directed by the Physician) to a maximum of 30 days supply."

SOPs as at May 2018

52. The SOPs were updated in May 2018. Mr B stated that the SOPs now include a section titled "Time Frames for Repeat Dispensing of Controlled Drugs" to ensure that the patient is seen by the prescriber regularly; sections regarding the communication of prescription rules to patients and the communication of any changes in prescription quantities; and sections regarding the dispensing of controlled drugs where there is insufficient stock at the first dispensing.

Response to provisional decision

53. Mr A was provided with an opportunity to respond to the "information gathered" section of the provisional decision. Where appropriate, his comments have been incorporated above.

54. Mr B was provided with an opportunity to respond to the provisional decision. He stated that he "continues to regret any distress and inconvenience that his actions may have

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caused to the family". He advised that he will soon complete the online educational refresher course entitled "Palliative Care Best Practice Update", run by the Pharmaceutical Society of New Zealand.

55. The pharmacy was provided with an opportunity to respond to the provisional decision, and it had no further comments to make.

Relevant standards

Misuse of Drugs Regulations 1977

> "31 Restrictions on supply on prescription
>
> (1) A person may not supply a controlled drug on a prescription —
>
> …
>
> (d) in a quantity that, having regard to the dose and frequency of dose or the directions given by the controlled drug prescriber, is greater than a quantity sufficient for use for a period of 1 month."

Pharmacy Council of New Zealand Competence Standards for the Pharmacy Profession (2015)

> "Domain M1: Professionalism in Pharmacy
>
> Comply with ethical and legal requirements. Follows legal, ethical, professional and organisational policies/procedures and codes of ethics.
>
> …
>
> Domain 03: Supply and administration of medicines
>
> O3.1.1 Validates prescriptions ensuring they are authentic, meet all legal and professional requirements and are correctly interpreted.
>
> …
>
> O3.1.4 Initiates action, in consultation with patient/carer and/or prescriber to address identified issues.
>
> …
>
> O3.4.2 Follows relevant policies, procedures and documentation requirements for the administration of medicines."

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Opinion: Mr B — breach

Dispensing of fentanyl patches — October 2017

56. On 27 October 2017, Mrs A was prescribed three fentanyl patches (one patch every three days) for her generalised body pain, with one repeat prescription for a further three patches. On 29 October 2017, instead of dispensing three patches, Mr B dispensed five. The sixth prescribed patch was never dispensed.

57. My expert pharmacy advisor, Ms Sharynne Fordyce, advised that this dispensing was a moderate departure from accepted standards. She stated:

> "The accepted practice in this case would have been to dispense 3 patches and a repeat of 3 patches in ten days time, as was originally annotated on the October prescription.
>
> …
>
> 5 patches, at the dose stipulated on the prescription, exceeds the 10 day period of supply laid down in the regulations governing the dispensing of Controlled Drugs, and also present in [Mr B's] SOP for dispensing of controlled drugs."

58. Ms Fordyce further stated that by dispensing only five fentanyl patches in total, Mr B deprived Mrs A of one patch, which amounted to three days of pain relief. Ms Fordyce said that Mr B had "no authority or good reason for doing so".

59. Mr B told HDC that he accepts that he should have dispensed the 27 October 2017 prescription as it was written — in two lots, one lot of three patches initially, with a repeat of three more at a later date. He also accepts that by dispensing the prescription as he did, he acted contrary to the pharmacy's SOPs at the time, which stated that no more than 10 days' supply of a controlled drug, of which fentanyl is one, may be dispensed at any one time.

60. The Pharmacy Council of New Zealand Competence Standards for the Pharmacy Profession (the Pharmacy Council Standards) require that prescriptions are validated, ensuring that they are authentic, meet all legal requirements, and are interpreted correctly. Further, the Pharmacy Council Standards require that pharmacists follow relevant policies, procedures, and documentation requirements for the administration of medicines. Mr B did not comply with these standards when he failed to dispense all six fentanyl patches in accordance with the 27 October 2017 prescription, and supplied more than 10 days' worth of patches at one time, contrary to the pharmacy's SOP at the time of these events.

61. I accept the advice provided to me by Ms Fordyce. I am critical that Mr B failed to dispense the fentanyl patches in accordance with the October 2017 prescription. By dispensing five fentanyl patches at once and in total, Mr B supplied more than the accepted amount of patches allowed in one dispensing, and deprived Mrs A of the sixth patch, which would have constituted three days' pain relief. I am also critical that Mr B failed to follow the pharmacy's SOPs and the Pharmacy Council Standards as stated above.

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Dispensing of fentanyl nasal spray bottles — January 2018

62. On 11 January 2018, Mrs A was prescribed five bottles of fentanyl nasal spray with a dosage of 2–4 sprays every 10 minutes as required, and up to one bottle every two days (a 10-day supply). She was prescribed two repeats of this prescription. Dr D did not specify the number of ampoules needed in each bottle, nor the volume to be in each bottle.

63. The prescription was partially dispensed on 15 January 2018, that is, one bottle of 10 ampoules was dispensed to Mr A. Mr B stated that on 17 January 2018, he "made provision for Mr A to have a further repeat of 20 ampoules (40ml) [i.e., two bottles]". On 18 January 2018, the two bottles of 10 ampoules were dispensed, resulting in a total of three of the five prescribed bottles being dispensed to Mr A.

64. Mr B told HDC that because the new prescription of spray represented a five-fold increase based on previous prescriptions, on 15 January 2018 he conservatively dispensed one bottle of 10 ampoules, rather than five bottles of 10 ampoules each, and decided to watch Mrs A's usage and increase the amount of the repeats if required. He dispensed one 20ml bottle of nasal spray, and intended to double this for the repeat.

65. Ms Fordyce advised that accepted practice was to follow the instructions written on the prescription, which were specific for dose, usage, and number of bottles. Ms Fordyce acknowledged that the prescription did not designate the number of ampoules needed in each bottle, or the volume to be in each bottle. She stated that if Mr B was "at all unclear" about the prescription details, he needed to contact the prescriber to verify the prescription.

66. Ms Fordyce noted that doses of medication are frequently higher with patients who are terminally ill. She stated that Mr B's failure to consult with the prescriber was a moderate to severe departure. I accept Ms Fordyce's advice.

67. The Pharmacy Council standards require a pharmacist to consult with the prescriber "to address identified issues", and that organisational policies must be followed. I note that the pharmacy's SOP also stated that a pharmacist is "to highlight and check with the prescriber any unusual doses, particularly high doses, and annotate the prescription to indicate the verification".

68. Mr B told HDC that he accepts that he should have contacted the prescriber to query the significant increase in supply of fentanyl nasal spray bottles in the 11 January 2018 prescription.

69. I am critical that Mr B failed to dispense the fentanyl bottles in accordance with accepted practice and contrary to the pharmacy's SOP and the Pharmacy Council standards. If Mr B was unsure about the prescription details, it was incumbent upon him to make contact with the prescribing doctor before dispensing the fentanyl bottles.

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Dispensing of fentanyl patches — January 2018

70. On 11 January 2018, Dr D from the hospice prescribed one month's supply of 12.5mcg fentanyl patches to Mrs A, with instructions to apply 1.5 patches every three days. The exact number of patches was not specified.

71. Mr B dispensed 14 patches of fentanyl overall on 15 January 2018. Based on the instructions that were provided by the prescribing doctor, this amounted to a 21-day supply of patches. Mr B told HDC that he dispensed a greater number than 10 days' worth of patches to Mr A in an effort to "diffuse the situation".

72. Ms Fordyce advised HDC that accepted practice is to dispense no more than 10 days' supply of a controlled drug, of which fentanyl is one, at any one time unless otherwise stated on the prescription. She advised that doing so represented a moderate to severe departure from the accepted standard of care.

73. The pharmacy's SOP also stated that no more than 10 days' supply could be dispensed at any one time, with two repeats (as directed by the physician) to a maximum of 30 days' supply. I also note that the Pharmacy Council standards state that pharmacists must follow "legal, ethical, professional and organisational policies/procedures".

74. I am critical that Mr B dispensed 14 fentanyl patches in one day to Mr A, which amounted to a 21-day supply of the medication. By doing so, Mr B failed to dispense the fentanyl patches in accordance with accepted practice and contrary to the pharmacy's SOP and the Pharmacy Council standards.

Conclusion

75. I am critical that Mr B made the following errors with regard to the dispensing of Mrs A's medications:

- In October 2017, Mr B dispensed five fentanyl patches instead of the prescribed six. This resulted in Mrs A being supplied more than the accepted amount of 10 days' supply, but also deprived Mrs A of the sixth patch, which would have constituted a further three days' pain relief.

- In January 2018, Mr B dispensed only three bottles of fentanyl nasal spray rather than the prescribed five. Accepted practice would have been to contact the prescribing doctor if he had any doubt as to the correct amount to dispense.

- In January 2018, Mr B dispensed 14 fentanyl patches in one day, which amounted to a 21-day supply of the medication. This is contrary to accepted practice and the pharmacy's SOP at the time of these events, which stated that no more than 10 days' supply could be dispensed at any one time.

76. I acknowledge that there was a breakdown in the relationship between Mr B and Mr A, and that Mr B believes that this affected his dispensing decisions. I also note that Mr B thought that by dispensing as he did, he was creating the most convenient solution for Mr

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and Mrs A. However, these two aspects do not outweigh the need to comply with his professional and legal obligations.

77. I consider that Mr B failed to provide Mrs A with services that complied with professional standards, and, accordingly, that he breached Right 4(2) of the Code.[13]

Opinion: the pharmacy — adverse comment

78. As the registered company under which the pharmacy was operating at the time the services were provided, the pharmacy was responsible for providing services in accordance with the Code.

79. On 30 October 2017, Mr B completed an incident report relating to the dispensing of the fentanyl patches on 29 October 2017. The report recommended that the pharmacy review its dispensing policy and ensure that pharmacy staff provide an explanation before dispensing medication.

80. On 18 January 2018, Mr B completed another incident report into the events surrounding the 11 January 2018 prescription. The report again recommended that the pharmacy's dispensing policy be reviewed, and emphasised the need for pharmacy staff to "ensure dialog with [the] customer at [the] onset".

81. I note that despite the fact that two separate incident reports were completed in October 2017 and January 2018, and both recommended that the pharmacy's SOPs be reviewed and updated, this was not done until May 2018. It is important to ensure that SOPs are kept up to date, and I am critical that this did not occur in a more timely manner.

Recommendations

82. I note that since these events, Mr B has reviewed the rules and regulations relating to the dispensing of controlled drugs, discussed his dispensings with a senior pharmacist colleague, and written a letter of apology to Mr A and his family.

83. I note that Mr B intends to complete the online educational refresher course "Palliative Care Best Practice Update" offered by the Pharmaceutical Society of New Zealand. I welcome that initiative. I recommend that Mr B provide HDC with evidence of having completed this course within four months of the date of this report.

[13] "Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards."

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84. I recommend that after considering the information and concerns raised in this report, the Pharmacy Council conduct a competency review of Mr B, including consideration of further training on the dispensing of controlled drugs.

85. I note that the pharmacy is no longer trading. I therefore make no recommendations to this entity.

Follow-up actions

86. A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Pharmacy Council of New Zealand, and it will be advised of Mr B's name.

87. A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the New Zealand Pharmacovigilance Centre and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

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Appendix A: Independent advice to the Commissioner

The following expert advice was obtained from Ms Sharynne Fordyce:

"Background

[Mr A] complains that [Mr B] at [the pharmacy] failed to dispense Fentanyl patches and nasal spray, for his terminally ill wife, according to the prescription presented on two separate occasions.

Expert advice requested

In particular, please comment on:

1. The appropriateness of [Mr B's] actions on 29 October 2017, in only dispensing 5 Fentanyl patches.

a) The accepted practice in this case would have been to dispense 3 patches and a repeat of 3 patches in ten days time, as was originally annotated on the October prescription. [Mr B] claimed he was allowed by [the DHB] to dispense in an original pack (5 patches) 'for slow moving or expensive items'. The 2018 Pharmac wholesale price for 5 x Fentanyl patches 12.5mcg is $2.95 excl gst, and the 12.5mcg strength a common starting dose. 5 patches, at the dose stipulated on the prescription, exceeds the 10 day period of supply laid down in the regulations governing the dispensing of Controlled drugs, and also present in [Mr B's] SOP for dispensing of controlled drugs.

b) The departure from the standard of care or accepted practice is moderate to significant. In supplying only 5 Fentanyl patches for [Mrs A], [Mr B] has deprived her of 1 patch, 3 days pain relief, and has no authority or good reason for doing so. His explanation to [Mr A] was not accurate or clear.

c) Given the nature of the medication, and the nature of [Mrs A's] illness, my peers would view this action as unhelpful, lacking in empathy and not strictly legal.

d) Recommendations for improvement that may help to prevent a similar occurrence in future would be to dispense the prescription according to regulations, as written by the doctor. If there was any variance due to stock supply issues, to explain compassionately and clearly to the customer, and ensure enough stock was ordered to supply the repeat.

2. The appropriateness of [Mr B's] actions on 15 January 2018, in reasoning how to dispense the Fentanyl spray bottles.

a) The accepted standard of care/accepted practice is to follow the instructions written on the prescription which were specific for dose, usage and number of bottles. However the prescription did not designate the number of ampoules needed in each bottle, nor the volume to be in each bottle. On [the DHB's] website, however there is a description of this product made by the hospital, with volumes and ampoules used per bottle, and acceptable dose ranges. If [Mr B] was at all unclear about any of these issues, he needed to have contacted the prescriber and

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verified the facts he was unsure of, a procedure that is listed in his own dispensing SOPs. [Mr B's] decision to 'watch [Mrs A's] usage and increase the amounts of repeats if required' is an unacceptable practice and standard of care.

b) This is a significant departure from the standard of care and accepted practice.

c) This would be viewed by my peers as being unhelpful and unethical and potentially lacking in knowledge regarding acceptable dose ranges for this product.

d) Recommendations for improvement that may help to prevent a similar occurrence in the future would be to check with the prescriber if at all unsure about instructions, doses or volumes, especially when dealing with a terminally ill patient and controlled drugs. Doses are frequently higher than regularly seen with these patients. To stay within one's scope of practice, watching [Mrs A's] usage was not [Mr B's] primary responsibility in this case. The doctor had already ascertained her usage in the Hospice setting.

3. Should [Mr B] have made contact with the prescribing GP on 15 January 2018 to clarify their intention for the dosage to be prescribed before dispensing the medication?

a) If [Mr B] was unsure about the intention of the GP for the dosage to be prescribed accepted practice would have been to contact the GP to clarify matters. In fact [Mr B] himself mentions he has 'a professional and ethical responsibility to not dispense excessive quantities', the same responsibility that requires him to check with the GP.

b) This is a significant departure from accepted practice, particularly given the nature of the drugs [Mr B] was dispensing, the patient he was dispensing to, and the dosages involved.

c) This would be viewed by my peers as unwise and irresponsible.

d) See above 2 (d).

4. Any other matters.

Given the emotional pressure [Mr A] would have been [under] during this time, it is difficult to accurately assess the level of provocation and intimidation mentioned by both men. It does highlight the need for compassion and clear communication when dealing with terminally ill patients and their carers/families."

The following further advice was obtained from Ms Fordyce on 4 June 2019:

"Further advice re: file C18HDC00536

In the comments below I refer to the report I, Sharynne Fordyce, made in reference to the above case.

Referring to 1(b) [of my initial report] the departure from the standard of care or accepted practice in providing [Mr A] with one less Fentanyl patch than the doctor had prescribed for his wife could be viewed as moderate.

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Referring to 2(b) and 3(b) I would still consider that [Mr B's] actions constitute a significant departure from accepted practice and standard of care. If [Mr B] had any professional concerns about the prescription for the Fentanyl nasal spray, a controlled drug, contacting the prescriber is the accepted practice before dispensing the prescription. As admitted by [Mr B], to not do so went against his own SOP and knowledge of preferred dispensing practice for Controlled Drugs.

[Mr B's] actions and evident remorse after the complaint are thorough and sincere. My view is that [Mr B] provided services that departed from the accepted standard of care at an overall moderate level of seriousness, but am aware, as in any profession, my view may differ from others in my profession. Ethically, however, I feel, there is a particular responsibility to palliative patients and their carers that was not met in this case."

The following further advice was obtained from Ms Fordyce on 29 August 2019:

"Advice from Sharynne Fordyce M.P.S.

18HDC00536

1) Did [Mr B] comply with accepted standards of care when he arranged for a duplicate of this prescription to be generated after speaking with [Mrs A's] GP at the Hospice? Please explain why/why not.

2) Was it acceptable practice for [Mr B] to dispense the amounts of fentanyl (both patches and nasal spray) that he did on 15 January and 18 January 2018, as annotated on the prescription? Please explain why/why not.

If you consider there have been departures from accepted standards of pharmaceutical care in relation to the above questions, please advise the level of departure for each (mild, moderate or severe).

1) After the breakdown in the relationship between [Mr B] and [Mr A] this would be considered acceptable practice by [Mr B], in that he has arranged for a duplicate prescription to be generated to provide a continuation of care to the customer. That the relationship between [Mr A] and [Mr B] had deteriorated to such an extent as to require this step would definitely not be regarded as optimal practice, but [Mr B] was ensuring [Mrs A] still had a supply of medication available, even if it meant finding a new pharmacy to dispense the medication.

2) On the 15/16 January 2018 [Mr B] dispensed 14 patches of Fentanyl. From the instructions given on the prescription this amounted to 21 days supply of patches, accepted practice is to dispense 10 days supply of controlled drugs at a time, unless otherwise annotated on the prescription. By his own admission [Mr B] dispensed this greater number of patches to [Mr A] in an effort 'to diffuse the situation'. This is a moderate to severe departure from accepted practice as controlled drugs such as Fentanyl are subject to many dispensing constraints because of safety concerns for the patients.

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On the 15 and 18th of January 2018 [Mr B] dispensed 3 bottles of Fentanyl nasal spray. From the instructions given on the prescription this amounted to only 6 days supply of the nasal spray. [Mr B] stated that he did not dispense the requested amount due to concerns re the dosage and usage of this medication. This would be regarded as a moderate to severe departure from accepted practice because [Mr B] did not act on these concerns by contacting the prescriber to confirm dosage, and his action of restricting the amount of nasal spray available further inflamed the relationship between himself and [Mr A].

Sharynne Fordyce 29/08/2019"

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