IN THE CORONERS COURT
OF VICTORIA
AT MELBOURNE

Court Reference: COR 2018 5175

FINDING INTO DEATH WITHOUT INQUEST

Form 38 Rule 63(2)
*Section 67 of the **Coroners Act 2008***

Findings of:	Coroner Jacqui Hawkins
Deceased:	Annette Lee Douglass
Date of birth:	12 November 1957
Date of death:	14 October 2018
Cause of death:	I(a) Respiratory arrest in the setting of aspiration pneumonia I(b) Seizures associated with Alzheimer's disease and down syndrome
Place of death:	Barwon Health, University Hospital, Bellerine Street, Geelong, Victoria, 3220

SUMMARY

1. Annette Lee Douglass was 60 years old when she died. Ms Douglass resided at Homestead Lakes Residential Aged Care facility (RACF) in Wallington and mobilised with a four-wheeled walking frame.

2. Ms Douglass had a past medical history of Down syndrome, Alzheimer's dementia, late-onset myoclonic epilepsy in Down syndrome, bilateral pulmonary emboli, hospital admissions for aspiration pneumonia and unwitnessed falls in June and August 2018.

3. Ms Douglass died on 14 October 2018 at the University Hospital Geelong.

4. Ms Douglass' death was reported to the Coroner as it fell within the definition of a reportable death in the *Coroners Act 2008.*

THE PURPOSE OF A CORONIAL INVESTIGATION

5. The role of a coroner is to independently investigate reportable deaths to establish, if possible, identity, medical cause of death and with some exceptions, surrounding circumstances. Surrounding circumstances are limited to events which are sufficiently proximate and causally related to the death. The law is clear that coroners establish facts; they do not lay blame or determine criminal or civil liability.[1]

6. All coronial findings must be made based on proof of relevant facts on the balance of probabilities.[2] The strength of evidence necessary to prove relevant facts varies according to the nature of the facts and the circumstances in which they are sought to be proved.[3]

7. In writing this Finding, I do not purport to summarise all the evidence but refer to it only in such detail as appears warranted by its forensic significance and the interests of narrative clarity.

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1 In the coronial jurisdiction facts must be established on the balance of probabilities subject to the principles enunciated in *Briginshaw* v *Briginshaw* (1938) 60 CLR 336. The effect of this and similar authorities is that coroners should not make adverse findings against, or comments about, individuals unless the evidence provides a comfortable level of satisfaction as to those matters taking into account the consequences of such findings or comments.

2 *Re State Coroner; ex parte Minister for Health* (2009) 261 ALR 152.

3 *Qantas Airways Limited v Gama* (2008) 167 FCR 537 at [139] per Branson J (noting that His Honour was referring to the correct approach to the standard of proof in a civil proceeding in the Federal Court with reference to section 140 of the *Evidence Act 1995* (Cth); *Neat Holdings Pty Ltd v Karajan Holdings Pty Ltd* (1992) 67 ALJR 170 at 170-171 per Mason CJ, Brennan, Deane and Gaudron JJ.

IDENTITY OF THE DECEASED

8. Annette Lee Douglass was visually identified by her brother, David Douglass, on 14 October 2018. Identity was not in issue and required no further investigation.

CIRCUMSTANCES IN WHICH THE DEATH OCCURRED

9. Ms Douglass was most recently seen by her General Practitioner, Dr Janet Reid on 20 September 2018 for routine blood tests. Dr Reid documented that Ms Douglas had a cough but was looking well and that her chest was clear.

10. Ms Douglass' regular medications included the anticonvulsant phenytoin (also known as Dilantin) (150mg twice daily), which she was prescribed for her epilepsy.

11. Ms Douglass was periodically reviewed by Neurologist, Dr Peter Batchelor most recently in August 2018. Dr Batchelor documented that Ms Douglass had not had any seizures on her current medication regimen, and her behaviour was stable. He was also aware that Ms Douglass had been commenced on warfarin therapy for her pulmonary emboli the month prior.

12. On the afternoon of Wednesday 3 October 2018, a fax was sent by Gerry James at Homestead Lakes RACF to Dr Reid advising "*the pharmacy we are using say that they can no longer get Dilantin. Is there anything else to substitute this, if so, would you please write it up on med chart*." On the afternoon of 5 October 2018, Dr Reid attended Homestead Lakes RACF and noted in the records that the liquid form of phenytoin was unavailable, and so prescribed chewable phenytoin tablets instead and notified the pharmacy.

13. At approximately 7.30am on 6 October 2018, Ms Douglass was discovered with vomitus in her mouth and on her bed sheets. Homestead Lakes RACF staff applied oxygen and called an ambulance. Ms Douglass was noted to be hypoxic and tachycardic with increased work of breathing and an upper airway gurgle. She was transferred to the University Hospital, Geelong. Ms Douglass had a generalised tonic-clonic seizure in the Emergency Department (**ED**) with aspiration, followed by respiratory distress and a reduced conscious state. Treating doctors identified that Ms Douglass had missed her regular dosage of phenytoin in recent days. She was admitted to the ward and treated with an anticonvulsant as well as intravenous antibiotics for likely aspiration pneumonia evident on chest x-ray. Following discussion between medical staff and Ms Douglass' family, it was agreed that she would not be provided any escalation of care if she deteriorated.

14. Ms Douglass developed increased respiratory distress and difficulty clearing secretions on 8 October 2018. After further consultation with the family, palliative care was initiated following further respiratory complications and another decrease in Ms Douglass' conscious state two days later.

15. Ms Douglass died at 3.20am on 14 October 2018.

MEDICAL CAUSE OF DEATH

16. On 22 October 2018, Dr Michael Burke, Forensic Pathologist at the Victorian Institute of Forensic Medicine (**VIFM**) performed an autopsy on the body of Ms Douglass and reviewed the Form 83 Victoria Police Report of Death, the e-medical deposition from the University Hospital Geelong and the post mortem computed tomography (**CT**) scan.

17. The post mortem examination showed no evidence of any injury which would have contributed to or led to death.

18. The toxicological analysis showed the presence of the anti-convulsant medication levetiracetam. Phenytoin was not present.

19. Dr Burke provided an opinion that the medical cause of death was I(a) *respiratory arrest in the setting of aspiration pneumonia,* I(b) *seizures associated with Alzheimer's disease and down syndrome.* I accept and adopt this as the cause of death.

FAMILY CONCERNS

20. The family of Ms Douglass wrote to the Coroners Court with some concerns about her care and management, specifically their concern that Ms Douglass had not been administered her epilepsy medication in the two or three days prior to her death and the potential link to her death.

CORONIAL INVESTIGATION

Coroners Prevention Unit review of care and management

21. Given the circumstances of Ms Douglass' death and the concerns of the family, I referred this case to the Coroners Prevention Unit (**CPU)** for a comprehensive review and assessment of his medical care and management.

22. The role of the CPU is to assist coroners investigating deaths, particularly deaths which occur in a healthcare setting. The CPU is staffed by healthcare professionals, including practising physicians and nurses, who are independent of the health professionals and institutions under

consideration. The CPU professionals draw on their medical, nursing and research experience to evaluate the clinical management and care provided in particular cases by reviewing the medical records, the autopsy report and any particular concerns which have been raised.

23. The CPU reviewed the records of Homestead Lakes RACF, medical records of Port Lonsdale Medical Group, the University Hospital, Geelong and statements obtained from Dr Janet Reid and Kelly Sullivan, the General Manager of Homestead Lakes RACF.

Statement of Dr Janet Reid, General Practitioner

24. Ms Douglass had been a patient of Dr Reid's since August 2017, when she became a resident at Homestead Lakes RACF. Dr Reid first reviewed the fax (dated Wednesday 3 October 2018) sent to her requesting a substitute to Ms Douglass' regular medication phenytoin, the day after, on 4 October 2019, as she does not work on Wednesdays. Dr Reid confirmed that she interpreted the wording of the fax to mean that the pharmacy had a supply issue with the phenytoin suspension medication and when the current supply ran out, an alternative would need to be provided. A copy of Ms Douglass' medication chart was not attached to the faxed request. Dr Reid added that in her experience with RACFs, if the request had been urgent, she would have expected the fax to be marked "urgent" and the medication chart attached for prescribing and return by fax.

25. Dr Reid confirmed she attended Homestead Lakes RACF on 5 October 2018 and prescribed chewable phenytoin tablets to replace the phenytoin suspension order. Dr Reid did not review the medication administration record on the medication chart at the time, stating that she had no reason to believe the medication had not been given as per the existing order. During Dr Reid's visit, nursing staff did not mention that any doses of phenytoin had been missed. Additionally, Dr Reid explained that she was unable to easily review the medication administration as this is recorded electronically at Homestead Lakes RACF, with assistance from the nursing staff required.

26. Dr Reid stated that in her experience, RACF nursing staff alert doctors promptly when any regular prescribed medication has been missed (for whatever reason). Had she been notified that phenytoin doses had been missed, Dr Reid advised that she would have provided a phone order for both the regular tablets as well as a loading dose on 4 October 2018.

27. Dr Reid stated that arrangements already exist regarding communication between her clinic and the four RACFs she visits for both urgent and non-urgent issues. When a matter requires

urgent attention, a fax from the RACF is sent to the GP clinic marked "urgent" and this is followed up with a phone call to the clinic reception, where the issue is brought to the attention of the primary GP (or if unavailable, to the duty GP). It is not uncommon for a consultation to be interrupted so the GP can promptly discuss the matter with the RACF nursing staff.

Statement of Kelly Sullivan, Homestead Lakes RACF

28. A statement was obtained from Kelly Sullivan, General Manager of TLC Homestead Lakes.

29. Ms Sullivan advised that Homestead Lakes RACF staff utilise Best Health Solutions "BESTdose" electronic medication ordering system to order resident medications from Soul Pattison Pharmacy in Geelong.

30. In relation to the re-supply of phenytoin suspension from the pharmacy prior to it running out, Ms Sullivan reported that a new bottle of phenytoin had been ordered by Homestead Lakes RACF staff on 23 September 2018. However, upon review of the BESTdose ordering history, a 500ml bottle of phenytoin was ordered on this date and appears to have been supplied to Homestead Lakes RACF the following day. As Ms Douglass was prescribed 150mg twice a day, it is noted that each 500ml bottle of phenytoin suspension (30mg per 5ml) would be used every ten days (25ml per dose, twice a day).

31. It appears the subsequent bottle of phenytoin was ordered on 1 October 2018 at 7.26pm, and the following morning a message was sent from the pharmacy to Homestead Lakes RACF via the BESTdose medication ordering system advising that phenytoin suspension was out of stock from the supplier. At 5.21pm on 2 October 2018, Margaret Wheat, Registered Nurse (**RN**) from Homestead Lakes RACF replied to a further message from Mel Archer at the pharmacy regarding a query whether Ms Douglass could take capsules instead. Ms Wheat then placed another order for phenytoin suspension, noting in the order "*please contact RN if problem, we will finish a bottle in a day*".

32. On 2 October 2018, the Homestead Lakes RACF staff member administering the phenytoin to Ms Douglass that evening notified the RN in charge of the recent messages from the pharmacy as well as advising that the phenytoin bottle was almost empty.

33. Further messages via BESTdose from the pharmacy to Homestead Lakes RACF between 3 and 5 October 2018 reiterated that there was a supply issue with phenytoin suspension and

advised they were checking with the drug company whether the tablets could be crushed for administration to Ms Douglass, while also trying to source a bottle of phenytoin suspension, that was unable to be supplied until 8 October 2018.

34. Ms Douglass was administered her last dose of phenytoin suspension at 8am on 4 October 2018. That night, the Homestead Lakes RACF staff member administering medications to Ms Douglass documented that the RN in charge had been notified of the non-availability of phenytoin, and also noted that Dr Reid had been faxed regarding the issue the previous day. Ms Douglass missed her twice daily doses of phenytoin on the evening of 4 October and the following morning, before being administered phenytoin chewable tablets on the evening on 5 October 2018. Dr Reid's documentation of her attendance at Homestead Lakes RACF to prescribe chewable phenytoin tablets was time-stamped 5.22pm on 5 October 2018.

35. Ms Sullivan confirmed that the Homestead Lakes RACF staff followed the TLC Aged Care Medication Management policy and procedure. After review of the document, the CPU confirmed that policy and procedure was adhered to, however, they noted a potential prevention opportunity in that the policy does not appear to cover the two key issues relevant to this incident; ie: the non-supply of prescribed medication from the pharmacy and b) communicating with the GP/prescribing doctor in relation to missed doses of essential medication.

36. Ms Sullivan advised that the issue of medication non-availability at the pharmacy was reviewed at a quarterly Medication Advisory Committee meeting at Homestead Lakes RACF on 21 November 2018. The committee noted that the pharmacy is not notified by the wholesaler of non-availability of stock until an order is placed. The committee identified that the pharmacy sending a message to Homestead Lakes RACF via BESTdose medication ordering system was not sufficient when a medication was unable to be supplied. It was agreed that the pharmacy should send an email to the Homestead Lakes RACF General Manager, team leaders and other staff.

37. Ms Sullivan noted "*there have been no further incidents where medication stock has not been available"*. It is unclear whether this means the amended communication process has proven effective or whether there haven't been any further incidents of non-availability of medication.

Conclusions

38. The Australian Product Information – Dilantin (phenytoin) brochure explains that "*phenytoin should not be abruptly discontinued because of the possibility of increased seizure frequency*".

39. The multi-day delay to Ms Douglass receiving her regular anti-convulsant medication appears to have been due to miscommunication between Homestead Lakes RACF and her GP, Dr Reid. It is unclear whether communication between the pharmacy supplying the phenytoin and the Homestead Lakes RACF also contributed to the medication delay.

40. The CPU agrees with Dr Reid that the 3 October 2018 fax communication regarding the phenytoin supply issue made no reference to any urgency relating to the request, nor did it advise that Ms Douglass had missed any of the twice daily doses of her regular medication. Additionally, when Dr Reid attended Homestead Lakes RACF two days later, staff did not communicate that Ms Douglass had not received her phenytoin for multiple days.

41. While it remains unclear whether Ms Douglass sustained a seizure prior to being found in respiratory distress due to suspected aspiration of vomitus by Homestead Lakes RACF staff on the morning of 6 October 2018, she did sustain a seizure with a recurrence of respiratory distress in the ED later that morning. Based on a review of the medical records available, the CPU has concluded that the sudden cessation of Ms Douglass' regular anticonvulsant medication phenytoin increased her risk of seizure activity, which in turn, increased her risk of aspiration pneumonia which led to her death.

42. From the review of the Medication Advisory Committee meeting minutes, it appears the BESTdose electronic medication ordering system had only been implemented at Homestead Lakes RACF in July 2018. Therefore, the CPU considered it was reasonable that some unanticipated issues regarding medication management may arise in the subsequent months, as they did in this case.

43. Having considered the evidence I am satisfied that no further investigation is required.

COMMENTS

44. Pursuant to section 67(3) of the Coroners Act, I make the following comments connected with the death.

45. I acknowledge that the Homestead Lakes RACF staff members repeatedly recognised and notified the RN in charge of the low stock/non-availability of the phenytoin, from the

afternoon of 2 October 2018 until the evening of 5 October 2018. It appears, however, that nursing staff may not have appreciated the importance of Ms Douglass receiving her phenytoin medication regularly, and as prescribed, for example:

a) the fax sent to Dr Reid on 3 October 2018 requesting a prescription change conveyed no sense of urgency;

b) when the phenytoin ran out, the RNs in charge could have potentially taken a more proactive approach; and

c) when Dr Reid visited Homestead Lakes RACF on 5 October 2018, the RN in charge should have communicated that Ms Douglass had not received her previous two doses of phenytoin.

46. This investigation has identified that nursing staff should have a clear understanding of the importance of residents at Homestead Lakes RACF receiving their medication regularly and as prescribed and know what to do when essential medications run out or unavailable. I have made two recommendations consistent with.

47. This investigation had also identified a potential prevention opportunity in that there is no instruction for staff in the TLC Aged Care Medication Management policy and procedure regarding:

a) How to manage non-supply/non-availability of medications from the pharmacy; and

b) The importance of communication with the GP/prescribing doctor about missed doses of essential medications.

For this reason, I have made a recommendation consistent with this.

FINDINGS

48. Pursuant to section 67(1) of the *Coroners Act 2008*, I make the following findings connected with the death:

(a) the identity of the deceased was Annette Lee Douglass, born on 12 November 1957;
(b) Ms Douglass died on 14 October 2018 from I(a) *respiratory arrest in the setting of aspiration pneumonia I(b) seizures associated with Alzheimer's disease and down syndrome*; and
(c) in the circumstances described above.

49. I wish to express my sincere condolences to Ms Douglass' family. I acknowledge the grief and devastation that you have endured as a result of your loss.

RECOMMENDATIONS

50. Pursuant to section 72(2) of the Coroners Act, I make the following recommendations connected with the death.

Recommendation One

I recommend that the General Manager of TLC Homestead Lakes, arrange for the TLC Aged Care Medication management policy and procedure to be amended to include instruction for staff on urgent management of the following issues:

a) Non-supply/non-availability of medications from a pharmacy; and

b) Communication with the GP/prescribing doctor about missed doses of essential medications.

Recommendation Two

I recommend that Homestead Lakes RACF provide internal education to all staff responsible for dispensing and supervision of medication administration to residents regarding recommendation one.

Recommendation Three

I recommend that Homestead Lakes RACF review the need for internal pharmacology education of essential medications for all staff responsible for dispensing and supervision of medication administration to residents.

51. Pursuant to section 73(1) of the Coroners Act, I order that this finding be published on the internet.

52. I direct that a copy of this finding be provided to the following**:**

The family of Ms Douglass;

Dr Janet Reid, Point Lonsdale Medical Group;

Ms Kelly Sullivan, General Manager, TLC Homestead Lakes Residential Aged Care Facility;

Information recipients.

Signature:

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JACQUI HAWKINS
Coroner
Date: 3 June 2020