Care Standards

The Tribunal Procedure Rules (First-tier Tribunal) (Health, Education and Social Care) Rules 2008

Mr Michael Leonard Audreson
(Mindsets Foundation)

Appellant

v

Care Quality Commission

Respondent

[2015] 2485.EA

DECISION

Before
Mr Laurence Bennett (Tribunal Judge)
Bridget Graham
Patricia McLoughlin

Heard **8 and 9 February 2016**
Pocock Street, London

Appeal

1. Mr Michael Audreson appeals under Section 32 of the Health & Social Care Act 2008 (the Act) against a notice of proposal to cancel registration as a Service Provider, Mindsets Foundation of 1 Hanway Place, London W1T 1HA in respect of regulated activity, treatment of disease, disorder or injury.

Hearing

2. The hearing took place on 8 and 9 February 2016.

3. The Appellant, Mr Audreson appeared in person. He was neither represented nor brought witnesses.

4. The CQC was represented by Mr Cyril Adjei, a Barrister instructed by CQC's Solicitors.

5. Oral evidence was given by Mr Audreson, Mrs Lea Alexander Inspection Manager CQC (C1); at the relevant times she was an Inspector with CQC, Ms Judith Edwards, CQC Inspection Manager (C77), Mr Stephen George, Inspector (C55) and Mrs Sally Allen, Pharmacist Special Inspector (C47).

6. Evidence was given on oath or affirmation.

Preliminary

7. The appeal notice is dated 17 August 2015.

8. Directions were made on occasions between 28 September and 18 December 2015 to facilitate the hearing.

9. In compliance with directions the parties submitted an agreed bundle of documents. The bundle included a Scott Schedule prepared by the Respondent specifying its understanding of the grounds of appeal. Additional documents submitted prior to the hearing included the Respondent's skeleton argument, an updated case summary and a list of witnesses.

10. References in this decision to page numbers are to the paginated bundle.

The Law

11. Section 17 of the Act provides that provides that the Commission may cancel registration in respect of a regulated activity (1)(c) on the ground that the regulated activity is being, or has at any time been carried on otherwise than in accordance with the relevant requirements.

12. The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 sets out requirements in respect of the regulated activity.

13. Section 32 of the Act provides a right of appeal against a decision of the Care Quality Commission other than a decision to give a warning notice. The Tribunal is empowered to confirm the decision or direct that it is not to have effect. The Tribunal also has power to vary or direct any discretionary condition it finds appropriate.

14. The Tribunal is required to consider the appeal on the evidence available at the time of the hearing.

Background

15. The Appellant has provided services for patients with drug addiction for around 20 years; a previous clinic known as Rivendell run by the Appellant is no longer in operation. On 13 July 2011 Mr Audreson registered Mindsets Foundation (Mindsets), initially intended to be a charity although he said there is no deed of trust, it became an operating name for him as an individual; no partners were involved.

16. On 12 February 2013 CQC carried out an inspection of the service. Subsequent inspections took place in August 2013, September 2014 and February 2015.

17. Compliance notices were issued. Some issues were addressed and are no longer the subject of a CQC requirement.

18. Following the unannounced inspection in September 2014, 4 warning notices were issued on 26 November 2014. Three compliance actions were contained in the inspection report published in December 2014. The notice of proposal to cancel the Appellant's registration followed an unannounced inspection on 5 and 6 February 2015.

19. Mr Audreson explained that as staff became aware of the CQC notice and as patients moved on, he decided to close the clinic. It has not operated since around October 2015.

20. Mr Audreson considers that the CQC has been inconsistent in its approach to inspections and resulting requirements. He disputes the accuracy of Inspectors' reports on which decisions were based and suggests that action was taken in bad faith. The documents he has provided for the appeal lack in many cases specific challenges or disagreement in respect of failures of compliance with the Regulations stated by CQC.

Evidence and submissions at this hearing

21. Mr Audreson readily accepted in his evidence that systems at Mindsets required improvement. He said that being a small team it took outsiders such as CQC to point out improvements which would then be addressed. It took time to make changes because of the lack of resources within such a small organisation but improvements were made, many satisfying regulatory requirements and others in the course of doing so. Whilst Mr Audreson took issue in respect of individual points, he suggested that had more time been given, full compliance would have resulted. He had gained the impression from meetings with CQC that further time would be allowed and the steps he was taking were broadly approved.

22. Mr Audreson referred to his lack of experience in such matters, particularly informally challenging CQC notices and the need to present evidence at the hearing. Although he appeared to have extensive documentation, he did not present specific documents or the audio evidence to which he referred in respect of certain issues. Mr Audreson has made formal complaints against individuals at CQC. He was made aware that such complaints are not the purpose or subject of the appeal procedure.

Specific issues and Tribunal's conclusions

23. Although Mr Adjei attempted to identify in his skeleton argument, Scott Schedule and case statement, unsatisfied requirements of CQC that have not been challenged, we find in the light of the oral evidence that it is necessary to consider the position in respect of each. We have first addressed those he identified as unchallenged.

Lack of clinical governance structure Regulation 10-1(C115) – Paragraph B10

24. Mr Adjei has not identified a challenge to this non-compliance. It relates to a failure to have operating systems based on appropriate professional and expert guidance. Mrs Alexander stated that the prescribing doctor at the clinic, Dr Dalla Valle suggested to her it would take at least 6 months to produce a clinical governance structure whereas Mr Audreson had said he could produce some of the policies "by tomorrow."

25. Mr Audreson acknowledged the clinic had operated its own procedures which had not been documented. He spoke of the difficulty and pressure in producing schemes as quickly as required. He regretted very much his comment about writing policies but he had not intended to be flippant. He said it was proposed the clinic would employ a person who was experienced in these matters to complete the task but this was overtaken by the notice of proposal to cancel.

Tribunal's conclusions

26. We note Mr Audreson acknowledged that improvements were required to the Provider's management systems. From the evidence that this was not in hand prior to CQC involvement we consider there was a failure to systematically and appropriately monitor the quality of the services provided. Whilst we can understand how this might have been neglected in a small team it is of major importance. We find there were insufficient records and procedures for all relevant persons to be able to rely on the Provider's governance structures. We conclude there was a lack of compliance up to the date of the notice of cancellation and continuing through to the cessation of the service.

Updating of patient files (Service User files)

27. There is some confusion as these were referred to as both personal files and personnel files. (C115 / B11). Mr Audreson accepted this is a requirement and said some 50% of files had been brought up to date. This was work in progress. He was particularly concerned that CQC had not taken into account assessments held on the doctor's computer which were available to staff who could, when the doctor's office was empty, access his computer. The computer password was simple and known.

28. CQC consider as this was the subject of a warning notice, the issue should have been fully addressed.

Tribunal's conclusions

29. Taking into account Mr Audreson's evidence that this was work in progress, we find this lack of compliance is established.

Quarterly staff assessment tool (C117 / B18)

30. Following issues raised during inspection, Mr Audreson stated he had created a staff appraisal system. It was noted on inspection on 5 & 6 February 2015 that 2 staff had been appraised but on examination the assessment tool was considered unsatisfactory by CQC. It largely provided for feedback by staff on the service and did not appraise them.

31. Mr Audreson did not provide contradictory evidence nor challenge the comments made about the nature of the tool.

Tribunal's conclusions

32. Taking into account Mr Audreson's evidence that this was yet to be developed, we find that this lack of compliance is established.

Prescribing protocols (C117 / B19)

33. Mrs Allen referred to production of prescribing protocols dated 2009 found during the February 2015 inspection. These were obviously out of date and had not been reviewed.

34. Mr Audreson said at the hearing that he subsequently provided 2012 protocols but these were not produced to the Tribunal. Mr Audreson gave the impression that they were found by him during the inspection. Mrs Allen commented that there was no evidence that any 2012 protocols were kept up to date.

Tribunal's conclusions

35. We note that the regulatory requirement relates to unsafe use and management of medicines. Whilst we find from Mr Audreson's evidence that it is likely 2012 protocols were available, the nature of their production and application leaves doubt whether they were known to staff and followed nor were they subject to systematic consultation and update. We conclude from that evidence that the Provider failed to comply with the regulatory requirements.

Records of Service Users

36. During the 5 and 6 February 2015 inspection, Mrs Alexander and Mr George were given to understand that all records of Service Users were to be entered into a patient ledger. It was apparent from an interview with a nurse on duty that she was not aware of this.

37. Neither party further addressed the issue at the hearing.

Tribunal's conclusions

38. We find that even if a patient ledger was in existence, non systematic use and lack of awareness by staff is consistent with the general lack of rigour and informality of the approach at the clinic. We conclude that there was a failure to comply with requirements.

Patient assessments

39. A sample of Service User records checked by Mrs Alexander during the February 2015 inspection was not considered satisfactory as it contained limited information. Mrs Alexander noted that in 3 records identified, no risk assessment information regarding mental health and safeguarding are mentioned. Further, the initial assessments did not comprehensively identify needs. She noted the introduction of a new format but because of the lack of information within it, concluded that the provider could not be sure that Service Users physical and mental welfare could be addressed.

40. Mr Audreson considers that his initial assessment together with the doctor's assessment stored on the doctor's computer were sufficient. He does not believe CQC took into account the doctor's assessments.

41. CQC identified a lack of ECG's for Service Users prescribed daily doses of Methadone in excess of 100mg which potentially gave rise to cardiac risk.

42. Mr Audreson's view is that it might inevitably be necessary to prescribe Methadone in excess of 100mg. Once the ECG issue had been highlighted he wrote to patient's GPs. At the time of the latest inspection one GP response had been received out of 31. Mr Adjei commented on the lack of follow up or procedure in respect of non replies.

43. Mr Audreson said that over the years his service has requested ECG's when considered appropriate. He did not dispute that systematic steps had been taken only after the CQC inspection requirement.

Tribunal's conclusions

44. At best Mr Audreson's view is that initial documents completed by the clinic and the assessment on the doctor's computer are sufficient records to ensure patient welfare. He does not consider patients were at risk because the small team would have access to any necessary information. Whilst these ad hoc arrangements might have worked so far and we were told that individual patient difficulties had not arisen, we consider this was unacceptable. We find an absence of suitable central consistent and comprehensive systems so that patients' records or requirements could be known to any member of staff as the need arose. It is clearly unsatisfactory that even if Mr Audreson's description is accurate, information would have to be checked in 2 places for a complete picture; this would also depend on whether the doctor was using his office. We conclude that Mr Audreson's evidence emphasises the absence rather than availability of proper records even if individual assessment tasks were undertaken. Moreover, this continued despite the warning notice issued following inspection in September 2014. We conclude this was a failure to comply with requirements.

Safety of the children of Service Users

45. In 2014 it was found that the service did not have a system of risk assessment for children of Service Users. The February 2015 inspection revealed ongoing breaches and inconsistent information available about Service Users and their children. This was a failure to apply the Orange Book (Drug misuse and dependence: UK Guidelines on Clinical Management).

46. Mr Audreson pointed out that information about children relies on self reporting by Service Users. He did not challenge or contradict the lack of systematic records save making the point that information would have to be supplied by the Service User.

Tribunal's conclusions

47. We find that there was neither sufficient appreciation of the importance of this requirement nor rigour in application. It is a clear guideline for obvious reasons, to protect children and vulnerable adults. We conclude this was a failure to comply with Regulations.

Ampoule Return

48. Following a requirement by CQC Mr Audreson developed a policy relating to ampoule return involving verbal and written warnings. On inspection in February 2015 Mrs Alexander found that the system was neither robust nor consistent and there was no follow up to a failure to respond to verbal and written warnings.

49. Mr Audreson commented upon the need for prescriptions to continue and that on the 3rd occasion a Service User might be referred to the doctor however it appears there was disagreement between Mr Audreson and the doctor about what should happen. Mr Audreson did not think it was necessary for such a prescriptive policy to be in place and considers the actuality has been cast in the worst light. He does not believe this a material failure not least because of his opinion of the risk to patients of sudden withdrawal.

Tribunal's conclusions

50. Mr Audreson stated his pragmatic view on how a policy beyond warnings could be enforced. CQC witnesses drew attention to the risks of illicit drug use and duplicate prescriptions. We accept in that light this issue is important. Whilst a policy was developed by Mr Audreson we are not satisfied it was sufficiently applied and agreed by staff nor was it complete. We conclude this remains a regulatory non-compliance.

Staff recruitment

51. From the February 2015 inspection CQC were not satisfied that the staff recruitment policy and procedure was sufficient, in particular the obtaining of CRB and pre employment checks.

52. Mr Audreson said that outstanding CRB checks have been received. Most of the staff had been with him for 14 years. Many were known to each other as NHS employees and staff tended to refer other staff to them when necessary. Only 1 employee has joined since 2010.

Tribunal's conclusions

53. We can understand how Mr Audreson might not have focussed on this issue because of the extremely low staff turnover. However, this was a notified requirement and the information to be obtained was specified but remains outstanding. On that basis this shortfall indicates a lack of acceptance and appreciation of an appropriate requirement to ensure safe future recruitment practices. We conclude this was a failure to comply with Regulations.

Staff training and supervision

54. CQC inspectors found a lack of staff training, supervision and continuing professional development records. They found some staff had little awareness of child safeguarding and adult protection issues. Whilst Mr Audreson considers that all are extremely skilled, experienced and qualified he did not provide evidence of training and CPD nor contradict the inspection findings.

Tribunal's conclusions

55. Whilst we note Dr Dalle Valla no doubt had his own professional CPD requirements, we find for the remaining staff this was a failure to comply with regulatory requirements.

Titration

56. Mrs Alexander commented on the lack of suitable systems for titration of medicines so that an optimal dose could be reached. The clinic had a system but it was not considered satisfactory as it relied upon Service Users self reports.

57. Mr Audreson took steps to obtain a titration policy from another Service Provider although it was found not to have been put into operation by the time of the February 2015 inspection. Mr Audreson said that he had decided that he would not take new patients until the titration policy was effective although in the event, a returning patient was taken in January 2014. He made general comments about the clinic's long experience of titration for its patients but accepted the policy should be updated.

Tribunal's conclusions

58. We find Mr Audreson accepted that the titration policy should be changed and steps were taken. Whilst we consider there was sufficient time to do so, the policy was not put into effect. Although new patients were not accepted, save the single returning patient, we find this a breach that has not been addressed satisfactorily and we conclude this was a failure to comply with regulatory requirements.

Assessment records

59. Mr Audreson is concerned that judgements were made in particular by Mrs Alexander about assessment records when she did not have them. He disputes that he was asked for the doctor's records and said had she done so, they would have been sent to her. He feels her judgements were flawed as a result.

Tribunal's determination

60. We have found that the Appellant Service Provider failed to comply with Regulations as set out above. In most cases Mr Audreson said that steps were to be taken. An experienced individual was to join for the purpose of drafting development and application of relevant systems. We are conscious that some of the issues identified in inspections were addressed and were not included in the notice of proposal but the outstanding issues are of considerable importance and have clearly existed for a relatively lengthy period during which several inspections took place. Taken together they indicate severe management failings by the Provider and a lack of leadership, purpose and resources to address identified requirements. We cannot be confident that the safety, interests and welfare of Service Users and dependants is appropriately considered and addressed.

61. Mr Audreson has been reactive in circumstances where it was essential he was proactive. Effectively, the inspection reports and notices have provided time for change. We are conscious that the Service is not in operation and individuals cannot now be affected. Whilst there is no evidence that a Service User has come to harm and the Service will have provided necessary help over the years, we consider the risks in its continuation are unacceptable. Accordingly we conclude that the notice of proposal should be confirmed and that registration is cancelled.

Order

62. Mr Audreson's appeal is dismissed.

Laurence J Bennett
Tribunal Judge

Date Issued: 17 February 2016