Care Standards

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

IN THE MATTER OF AN APPEAL

Before;

Judge Meleri Tudur (Tribunal Judge)
Ms Pat McLoughlin (Specialist Member)
Ms Wendy Stafford (Specialist Member)

BETWEEN:

Grafton Surgery

Appellant

V

Care Quality Commission

Respondent

[2016] 2765.EA-MoU

DECISION

1. The appeal was listed for consideration on the papers which is permissible under Rule 23 of the Tribunal Procedure (First-tier Tribunal) (Health, Education and Social Care) Rules 2008 ('2008 Rules'). Both parties consented to the hearing on the papers but the Tribunal must also consider that it is able to decide the matter without a hearing. In this case, we have sufficient evidence regarding the allegations made and the conclusions reached after investigations, and there appears to be no substantial factual dispute which might affect our decision. In the circumstances, we consider that we can properly make a decision on the papers without a hearing.

2. The Appellant appeals to the Tribunal against the decision of a Justice of the Peace dated 27 June 2016 pursuant to section 30 of the Health and Social

Care Act 2008 to urgently cancel the registration of Grafton Surgery, a registered provider of regulated activities, first registered on the 1 April 2013.

Events leading to the cancellation of registration

3. The Appellant, Dr Saida Noorah is a general practitioner and the registered manager of the practice. Grafton Surgery had a contract with Castle Point and Rochford Clinical Commissioning Group to provide a general practice healthcare and about 6,200 registered patients.

4. On the 15 June 2016, a comprehensive announced inspection took place at Grafton Surgery. At the routine inspection a number of concerns relating to patient safety were identified and the Respondent convened a management review meeting on the 16 June 2016 to consider the inspection findings. The meeting concluded that a further unannounced inspection should be undertaken on the 21 June 2016 as part of the same inspection.

5. The visit on the 21 June 2016 raised further concerns and a further short notice inspection took place on 22 June 2016 to raise the issues identified with the partners of the practice.

6. The Respondent convened two further Management Review Meetings on the 22 and 23 June 2016 to consider enforcement options in light of the findings at inspection and concluded that the concerns identified presented serious risks to patients' life, health or wellbeing and applied to the court for urgent cancellation of registration pursuant to Section 30 of the Health and Social Care Act 2008.

7. On the 27 June 2016, the application was heard at the Southend Magistrates' Court and following an oral hearing and evidence on oath, an order issued cancelling registration with immediate effect.

8. The Appellant submitted an appeal to the Tribunal under the Memorandum of Understanding provisions on the 25 July 2016, and the appeal was expedited in accordance with the Memorandum of Understanding.

Legal framework

9. The statutory framework for the registration of providers of regulated services is set out in the Health and Social Care Act 2008. Section 32 provides a right of appeal to the Tribunal against any decision made pursuant to Chapter 2 of the Act or an order made by a justice of the peace under section 30 and specifically provides as follows:

> "(4) On an appeal against an order made by a justice of the peace the Tribunal may confirm the order or direct that it is to cease to have effect."

10. Section 32 further provides:

> "(6) On an appeal against a decision or order, the Tribunal also has power—
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> (a) to vary any discretionary condition for the time being in force in respect of the regulated activity to which the appeal relates,
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> (b) to direct that any such discretionary condition is to cease to have effect,
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> (c) to direct that any such discretionary condition as the Tribunal thinks fit shall have effect in respect of the regulated activity, or
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> (d) to vary the period of any suspension."

11. When deciding whether to order urgent cancellation of registration, the test is set out in section 30 as follows:

> "1 If (a) the Commission applies to a justice of the peace for an order cancelling the registration of a person as a service provider or manager in respect of a regulated activity and (b) it appears to the justice that unless the order is made, there will be a serious risk to a person's life health or well being, the justice may make the order and the cancellation has effect from the time when the order is made."

12. The powers of the Tribunal are set out in section 32 and it stands in the shoes of the decision maker so that the question for the tribunal is whether at the date of its decision it reasonably believes that unless the order is made, the continued provision of the regulated activity by the registered provider will present a serious risk to a person's life, health or well-being.

13. The burden of proof is on the Respondent. The standard of proof is the balance of probability that a person will be at serious risk of harm if the order is not made.

Preliminary issues

14. On the 17 August, Dr Noorah sent to the Respondent and to the Tribunal a supplementary statement, stating that she had missed the deadline for submitting the evidence set by the Tribunal for 4pm on the 16 August 2016.

15. We considered at the start of the hearing whether the late evidence should be admitted. We concluded that the evidence had been served on the Respondent in sufficient time for an objection to its admission to be lodged if that was considered appropriate, and none had been sent. We concluded that the information contained in it would assist the Tribunal in reaching its conclusions. We concluded that there would be no prejudice to the Respondent if the evidence was admitted and proceeded to admit the evidence.

Findings

16. The Tribunal had before it a bundle of documentary evidence consisting of the evidence presented in support of the original application at the Southend Magistrates Court on the 27 June 2016, supplementary evidence in the form of witness statement and documentary evidence from the Appellant, including several character references from medical colleagues. The Respondent also submitted a skeleton argument and evidence of an Interim Order made against the Appellant by the Medical Practitioners Appeal Tribunal imposing conditions on her registration from the 5 August 2016. The Tribunal also considered the Appellant's own supplementary statement admitted as late evidence.

17. The evidence of the Respondent relied on breaches to Regulation 12 of the Health and Social Care Act (Regulated Activities) Regulations 2014, Safe care and treatment and Regulation 17, good governance. Other concerns related to a failure to maintain appropriate records, a bullying culture, inadequate recording of significant events, no evidence of infection control audits since 2012, Patient Groups Directives not signed by a manager or prescriber, no evidence of audits driving improvements, incomplete training records, no Disclosure and Barring Service checks for some staff, patient satisfaction below average, many policies and procedures out of date, ad hoc staff appraisals, staff unable to locate first aid kit and no system of reporting accidents at work.

18. In her notice of appeal, Dr Noorah admitted some of the most serious concerns and initially indicated that the practice should have been allowed a two month period to implement all the necessary improvements. She acknowledged that a new practice manager, in post some four weeks prior to the inspection had warned that the practice would probably be put under special measures and that there should be preparation for another inspection in six months' time. She confirmed that she, her partner Dr Ramjan, the Practice Manager and the Practice Nurse were confident that they could deal with each complaint and concern.

19. The following concerns were admitted:

a) Inappropriate monitoring of patients receiving Methotrexate
b) Patients on Azathioprine not having regular blood tests and prescriptions being issued by non clinicians
c) Inappropriate monitoring of patients on ACE/A2RB
d) Actioning MHRA and safety alerts were not satisfactory
e) Lack of follow up for cervical smear patients due to incorrect coding
f) Inaccurate recording of appointments with diabetic treatment and inaccurate recording of diabetic foot checks
g) Significant events not adequately recorded and not driving improvements
h) Infection audit controls not formally recorded
i) Some patient group directives not signed by a manger or prescriber

j) No evidence of audits driving quality improvement
k) Patient satisfaction survey results below average.
k) Staff appraisals below standard and ad hoc
l) Staff unable to locate a First Aid Kit
m) No system for reporting accidents at work.

20. The Appellant specifically disputed the allegations of a bullying and blame culture, that minor surgery procedures were carried out inappropriately, inappropriate complaints handling, incomplete staff training records, recruitment and DBS check issues and policies and procedures.

21. In the supplementary statement, the Appellant amended the wording relating to the MHRA and safety alerts stating that the actions were not documented in a satisfactory manner. She further qualified the assertions relating to regular blood tests and prescriptions monitoring to the extent that the data had not been checked. She further amended her position in relation to the length of time required to address the issues identified stating that it would require two months to begin to address the issues. She also produced copies of her own training certificates in response to the minor procedures allegations.

22. The Appellant acknowledged that action was necessary to remedy the deficiencies identified and proposed that two months would be required to start the process of putting right the concerns. She provided a description of the action required in relation to the monitoring of prescriptions and drugs but did not include a detailed action plan for remedying the issues.

23. The statement of reasons for the decision by the Respondent set out the evidential basis for the conclusions drawn.

24. The first statement of Greg Rielly, Enforcement Inspector dated 27 June 2016, confirmed in the signed statement to the Tribunal dated 10 August 2016, set out the inspection findings. At paragraph 14, he described the drug Methotrexate and its use, the recommendation by the British National Formulary that blood count and renal and liver function tests should be carried out every two to three months on patients receiving Methotrexate and stated that serious risks from not appropriately monitoring patients on Methotrexate can include death, liver cirrhosis, bone marrow suppression and pulmonary toxicity amongst other side effects. There were 36 patients currently prescribed Methotrexate by the practice. 10 patient records were examined and six of the ten showed that there was a lack of monitoring.

25. Mr Rielly went on to describe the position in relation to Azathioprine, in respect of which the British National Formulary recommends that patients should be monitored for toxicity weekly for the first four weeks and thereafter at least every three months because of the risk of suppression of the bone marrow and liver impairment and kidney impairment. Seven patients were currently

prescribed Azathioprine and one patient checked showing the last prescription as the 2 June 2016 and the monitoring on the 3 December 2015.

26. In relation to ACE/A2RB drugs used to treat raised blood pressure, the recommendation is that patients should have renal monitoring every 12 months because of the danger of kidney damage. 925 patients in the practice were prescribed ACE/A2RB drugs and 250 had been identified in the course of the inspection as not having received appropriate monitoring.

27. In relation to the MHRA and patient safety alerts, he explained that these are sent to practices to alert them to risks from medication or equipment and it is the responsibility of the provider to ensure that the risks are mitigated. In 2012, a MHRA alert was issued highlighting the risk of the contraindication of high dose simvastatin and amlodipine. 24 patients were still receiving active repeat prescriptions for simvastatin 40mg or 80mg and amlodipine.

28. In February 2016, a MHRA alert was issued highlighting the risks of the contraindication between ACE/A2RB medication and Spironolactone because of risks of severe hyperkalaemia. 18 patients were still prescribed Spironolactone and ACE/A2EB medication within the practice.

29. Mr Rielly confirmed that he had attended all of the Management Review Meetings on the 16, 22 and 23 June 2016 and exhibited a copy of the handwritten minutes to his statement of the 10 August 2016. He confirmed that the concerns about the risk to patients' life, health or well-being were so serious that the meeting determined after considering lesser sanctions that the only option was to apply for urgent cancellation of the registration.

30. The handwritten minutes of the initial inspection feedback summary on the 22 June 2016 as compiled by Ms P Styles, recorded that Dr Noorah stated that staff were prompted to check for blood results and that she assumed the secretary was making checks, but confirmed that the Azathioprine monitoring wasn't undertaken. Dr Noorah was also recorded as confirming that ACE/A2RB patients had blood tests completed. The minutes further recorded Dr Noorah's acknowledgement that she should not undertake minor surgery around the eyes, but had decided otherwise in a case drawn to her attention and stated that she always sends for histology. The minutes record that Dr Ramhjan expressed concern that it will take more than 3 months to address the issues mentioned and that he acknowledged that many areas of clinical and non-clinical input need to be improved.

31. A witness statement by Dr Sally Dilley signed on the 11 August 2016, set out her findings following her two visits to the Grafton Practice on the 15 and 21 June 2016. She had questioned the two doctors about the unusual achievement of 100% of the available Quality and Outcomes Framework points and because they had not been able to provide clear answers had interrogated the practice

computer system. The data obtained in relation to cervical smears and diabetic patients raised concerns about both the reliability of the medical records and the level of routine preventive care provided to patients with chronic diseases in addition to whether systems were in place to ensure regular reviews for patients prescribed repeat medications. She confirmed that no training certificates were available in respect of minor surgery on the day of the inspection, but even if the certificates were available, she continued to share her concerns identified in Dr Starey's witness statement that there was no evidence in one case of histology being requested, that two lesions were removed from the face of another patient, that a third patient should have been referred to the hand surgeon rather than having a lesion removed by the GP and another patient who had a lesion excised but was not referred to a dermatologist between 28 September 2015 and 4 March 2016 although continuing to present at the practice with the same complaint. She concluded that to suggest that the concerns could be remedied within two months was unrealistic because of the large number of patients requiring review, as well as ongoing provision of care to other patients.

Tribunal's conclusions with reasons

32. We considered first of all those areas of concern where the Appellant had admitted the concerns, albeit with a caveat that she had not revisited the data after the inspection. In her grounds of appeal and her supplementary statement, Dr Noorah confirmed that some of the concerns were not disputed and clarified which of the issues were fully disputed.

33. The concerns admitted related to the monitoring of patients with chronic conditions and the absence of appropriate clinical oversight, as well as systems and processes to adequately monitor patients receiving Methotrexate, Azathioprine and ACE/A2RB medication. In total, 1,002 patients in the practice were prescribed these medicines, with a significant percentage not appropriately monitored. We accepted the evidence of Mr Rielly regarding the recommendations for monitoring of the three types of drugs and the admission by Dr Noorah that the practice did not carry out the recommended clinical monitoring. The impact of such a failure is a serious risk to patients' life, health or well-being and satisfies the test for implementing an urgent cancellation of registration for the service provider. The prescription of various drugs without monitoring by way of blood count, liver function test and renal monitoring as recommended by the British National Formulary, we are satisfied has potentially serious and fatal outcomes.

34. The Appellant's final position in relation to the MHRA alerts and patient safety alerts was that the actioning of such alerts was not sufficiently documented. The evidence from the inspection confirmed that to be the case and we accept Mr Rielly's evidence that the evidence of taking action following MHRA alerts was absent. Without any record of the action taken, and the evidence of practice contrary to the recommendations of the patient safety alerts,

we conclude that patients were at serious risk to their life health or well-being. A failure to ensure that MHRA alerts and patient safety alerts are actioned and can be accurately checked as actioned through an effective documentary system presents a very serious risk to the life, health and well being of patients

35. The Appellant also acknowledged the weaknesses in recording of information within the practice. We consider this to be demonstrated by the concerns described by Dr Dilley arising from the inaccurate or non-recording of information. We were impressed by the evidence of Dr Sally Dilley and the double checking of the data obtained through the practice system and concluded that the inaccurate recording of information in several different areas, including the diabetic foot checks and the cervical smear tests were sufficient to satisfy the tribunal that the health and well-being of patients was at serious risk.

36. Having considered the evidence and the admissions made by the Appellant, we concluded that the test of serious risk to a person's life, health or well-being had been met and that there was no need to consider the other broader and disputed concerns raised by the Respondent. We were concerned at the reported lack of engagement by the Appellant both in the inspection process and in seeking to resolve the issues once identified. Her indication in the original grounds of appeal that she considered the issues could be resolved in two months were reflective of her lack of insight into the extent of the problems faced by the practice and reflected an inability to provide a clear action plan to deal with the concerns raised. In those circumstances, we concluded that the Appellant could not be relied upon to engage in a process of remediation effectively, and to identify effective processes for improving the situation. We shared the conclusion of the Respondent, on the evidence of the numbers of patients affected by the breaches identified, a fixed term suspension of registration would not be effective in resolving the issues.

37. We noted that in the order issued by the justice of the peace, the order records that "the registration of Dr Noorah as a service provider/manager" in respect of the regulated activities listed be cancelled forthwith. We specify however for the avoidance of any misunderstanding, that the order should specify that the service provider and manager's registration which are cancelled.

Decision

The appeal is dismissed.

The order of the justice made on the 27 June 2016 is confirmed and the registration of the service provider, Grafton Surgery and Dr Noorah as Registered Manager, in respect of the regulated activities is cancelled.

Judge Meleri Tudur
Ms Patricia McLoughlin
Ms Wendy Stafford

First-tier Tribunal Care Standards
Health, Education and Social Care Chamber
Date Issued: 24 August 2016