

Care Standards

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

Heard on the 13 May 2016 on the papers before:

BEFORE
Judge Meleri Tudur, Deputy Chamber President
Specialist Member James Churchill
Specialist Member Michele Tynan

**IN THE MATTER OF AN APPEAL
BETWEEN:**

Dr Asha Sen

Appellant

v

Care Quality Commission

Respondent

[2016] 2673.EA-MoU

DECISION

1. The Appellant is the registered provider of a General Practitioner practice who is an individual known as Dr Asha Sen, providing GP services from its main location in Plumstead, London.
2. On the 10 March 2016, the Respondent carried out a comprehensive inspection of the services at Dr Asha Sen and identified a number of breaches of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (“the 2014 Regulations”)

3. In particular, deficiencies were found in relation to safe care and treatment and governance contrary to Regulations 12, 13, 17, and 19 of the 2014 Regulations.

4. On the 18 March 2016, the Respondent issued a notice to urgently suspend the registration of the Appellant as a service provider in respect of regulated activities of diagnostic and screening procedures, family planning services, maternity and midwifery services and treatment of disease, disorder or injury, for a period of six months until the 19 September 2016.

5. The Appellant appealed to the Tribunal on the 2 May 2016 against the Respondent's decision. The appeal was admitted out of time and the response to it received on the 9 May 2016 with an amended witness statement submitted on the 11 May 2016, correcting an error in the original statement of Michelle Golden.

Legal framework

6. The appeal is brought under section 31 of the Health and Social Care Act 2008 ('the 2008 Act') against the Respondent's suspension decision.

7. Section 31 provides:

"Urgent procedure for suspension, variation etc.

(1) If the Commission has reasonable cause to believe that unless it acts under this section any person will or may be exposed to the risk of harm, the Commission may, by giving notice in writing under this section to a person registered as a service provider or manager in respect of a regulated activity, provide for any decision of the Commission that is mentioned in subsection (2) to take effect from the time when the notice is given.

(2) Those decisions are—

(a) a decision under section 12(5) or 15(5) to vary or remove a condition for the time being in force in relation to the registration or to impose an additional condition;

(b) a decision under section 18 to suspend the registration or extend a period of suspension.

(3) The notice must—

(a) state that it is given under this section,

(b) state the Commission's reasons for believing that the circumstances fall within subsection (1),

(c) specify the condition as varied, removed or imposed or the period (or extended period) of suspension, and

(d) explain the right of appeal conferred by section 32."

8. The 2014 Regulations set out a number of important requirements with which a registered provider must comply. They identify fundamental standards which must be met. The most relevant regulations to this case are summarised below:

Regulation 12 Safe care and treatment:

Regulation 13 Safeguarding service users from abuse and improper treatment

Regulation 17 Good governance

Regulation 19 Fit and proper persons employed

Evidence

9. A comprehensive witness statement was prepared by Kemi Modupe Ajayi, Inspector in the Primary Medical Services directorate, and Michele Golden, Head of Inspection for General Practice (London) opposing the appeal.

10. The statement of Ms Kemi Ajayi set out the findings of the inspection which supported the conclusion that there were inadequate systems and processes in place to protect patients from harm. The statement set out the background of the provider, who was registered with the CQC as a GP practice on the 1 April 2013 from the location of 12 The Slade, Plumstead London SE18 2 NB. The practice is run as a single-handed practice with Dr Asha Sen being the lead GP, with a patient list of approximately 3,900 patients and employs two part-time locum GPs.

11. The inspection on the 10 March 2016 was the first inspection of this General Practice run by Dr Asha Sen and was led by Ms Kemi Ajayi. The statement identified the areas of concern identified from the inspection, in particular the absence of emergency equipment and emergency medicines, no automated external defibrillator or oxygen.

12. She identified several areas of particular concern, by way of examples of the inadequacies found: inadequate systems and processes in place to protect patients from the spread of infections; against the advice from Greenwich Clinical Commissioning Group's medicines management team, Dr Sen had prescribed four medicines which had been listed as being unsuitable for prescribing in primary care in line with South East London Area Team's Prescribing Committee Interface prescribing policy; against the recommendations of Public Health England, a record of the immunisation status of all clinical staff working at the practice was absent; vaccines fridge temperatures had not been checked to ensure they remained within acceptable limits for safe storage; the recruitment procedures were not established or operated effectively and there was no evidence of training, background checks, references, photographic identification, registration with the relevant bodies or indemnity insurance for two locum GPs; staff had not received safeguarding training at appropriate intervals.

13. As a result, there were significant concerns regarding the leadership capacity of both Dr Sen and her practice manager Ms Katie Minter, the latter having disclosed that she had joined the practice as a receptionist and had been “thrown in” to the practice manager role without any training. According to the CQC submission, during the inspection feedback at the end of the inspection, Dr Sen told Ms Ajayi that she had “struggled to keep up with regulatory and contractual changes and that she would need to take a long time to make the necessary changes.” Ms Ajayi concluded that the lack of cohesiveness, ineffective communication, lack of training and lack of awareness of governance responsibilities adversely impact on the ability of Dr Sen and her practice manager to lead the practice effectively and safely.

14. The inspector concluded that the shortfalls identified represented breaches of Regulation 12, 13, 17 and 19 of the 2014 Regulations. Management review meetings were carried out on the 16 and 17 March 2016 to discuss the concerns and the decision taken that the risks were significant and posed an immediate risk of harm to patients, so the decision was made to serve an urgent notice of decision to suspend Dr Sen’s services for a period of six months in order to avoid patients being exposed to the risk of harm and in order to give Dr Sen and her staff sufficient time to put corrective measures in place to improve outcomes for her patients.

15. The statement of Michele Golden described the process and consideration given to the inspection findings on the 16 and 17 March 2016 by a management review meeting (MRM). The decision of the initial meeting on the 16 March 2016 was to impose Enforcement Notices on Dr Asha Sen, asking that she demonstrate compliance with the regulations with a prescribed time period. Having reflected overnight on the decision, Ms Golden convened a further MRM on the 17 March 2016 which concluded that the initial action was not sufficient to alleviate the risk for patients and on the basis of the evidence of the inspection, concluded that the appropriate action was an immediate suspension.

16. An urgent notice of decision to suspend Dr Asha Sen’s registration as a service provider was served on the 18 March 2016 and set out the reasons for the decision.

17. In her reasons for appeal, Dr Sen explained that the decision has caused severe distress to her patients, her staff and herself. She stated that she had been practising from the premises for the past 20 years and that none of her patients had come to any harm. In her view, she should be given an opportunity to rectify the points raised whilst the surgery was still operational. She confirmed that she had started the process of addressing some of the concerns raised and provided her assurance that she would endeavour to comply with the points raised as soon as possible, but suggested that the surgery should be allowed to operate to raise the capital necessary to fund the works. The Appellant

submitted no further supporting evidence other than her remarks on the appeal form and decision letter.

Tribunal's conclusions with reasons

18. The Tribunal has considered the evidence presented. From reading the grounds of appeal, it appears that there is an acknowledgement that there are a number of areas where improvements are required, but the information provided by the Appellant was scant, with no reference to an action plan or programme of work to be undertaken to support her assertion that the work had already started. The absence of any evidence in response to the allegations also meant that the Tribunal were not clear about what was accepted and whether any of the inspection findings were challenged. We concluded that the purpose of the appeal had been to seek a lifting of the suspension to generate an income to support the work to be done, without any specific challenge to the findings of the inspectorate.

19. We reminded ourselves of the test to be applied in cases of suspension and the test to be met in deciding whether the Respondent's decision should be upheld. Section 31 states that if the Respondent, and the Tribunal on appeal "*has reasonable cause to believe that unless it acts under this section any person will or may be exposed to the risk of harm,*" that enforcement action is justified. The burden of proof is on the Respondent. The standard of proof '*reasonable cause to believe*' falls somewhere between the balance of probability test and '*reasonable cause to suspect*'. The belief is to be judged by whether a reasonable person, assumed to know the law and possessed of the information, would believe that any person might be at risk.

20. We read the evidence very carefully and noted that there was a spread of concerns raised during the inspection. We noted the following particular areas where the concerns were at their greatest.

21. Firstly, we noted that there was a lack of emergency medication and equipment and the absence of a risk assessment to mitigate the need to have the emergency equipment and medicines available. We concluded that this was a serious issue and presented a risk of harm to patients attending the surgery. The appellant made no specific comment about the finding and did not offer any explanation or evidence about the steps to be taken to remedy the deficiency quickly. We concluded that this finding posed a risk of harm to patients.

22. Secondly, the inspection finding of prescription issues and the assignment by Dr Sen of a task of carrying out medicine changes and additions to an employee who does not feel competent to carry out the role and had not received relevant training is a serious issue which we conclude poses a risk of harm to patients.

23. Thirdly, the issues of infection control and fourth, lack of governance were two further issues which presented an immediate risk if suspension action was not taken.

24. We consider that some of the other issues might have been dealt with by the implementation of enforcement notices, but the four issues highlighted above we have concluded required immediate action and could not be remedied sufficiently to remove the risk of harm without a suspension of the registration. The Appellant did not provide any evidence or proposed timeline for addressing these serious issues. As a result, we have concluded that a suspension was necessary to enable the practice to take action to remove the risk of harm to its patients.

25. We noted that the suspension had been put into effect for six months. We considered whether there was evidence to support the need for such a long period of suspension. The evidence of the Respondent does not set out an explanation of the reason for concluding that a six month suspension was necessary and it would have assisted both the Appellant and the Tribunal to have that information provided.

26. On considering the evidence presented, we noted that the Appellant does not appear to challenge the findings of the inspectors, she has not set out an action plan or a timeline for carrying out the necessary improvements, and she is recorded by Ms Ajayi as having acknowledged during the inspection feedback that she had struggled to keep up with regulatory and contractual changes and that she would need to take a long time to make the necessary changes. This was not challenged in the notice of appeal, and no evidence was presented by the Appellant to show what improvements had already been carried out. As a result, we have concluded that six months is an appropriate period for all of the changes to be undertaken. However if the Appellant is able to expedite the work and ensure that the most serious of the findings are addressed, it is possible that the Respondent will review the suspension, as they are required to do by the framework and to give consideration to an earlier lifting of the suspension.

27. We were persuaded by the evidence of Ms Ajayi that there were sufficient examples of bad practice demonstrated within the inspection as to lead to the reasonable belief that persons may be placed at risk of harm unless action is taken. There were assertions made by the Appellants about the changes put in place after the inspection, but there was no evidence of a coherent and time limited action plan to identify a timescale within which the improvements were to be achieved. In our conclusion, the identification of the issues above are sufficiently serious and significant to provide reasonable cause to believe that patients may be placed at risk of harm unless a suspension is in place.

28. We are satisfied on the evidence presented that, unless the suspension continues, the low threshold that there may be a risk of harm to the patients within the practice in this case has been met and consequently the appeal against the suspension fails.

Decision

Appeal dismissed.

The notice of suspension is confirmed.

**Judge Meleri Tudur
Deputy Chamber President
Care Standards & Primary Health Lists
First-tier Tribunal (Health Education, Social Care)**

Date Issued: 18 May 2016