First-tier Tribunal Care Standards

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

2024-01091.EA-MOU
[2024] UKFTT 00387 (HESC)

Heard by Video Link on 29- 30 April 2024

BEFORE
Ms. M Daley (Tribunal Judge)
Ms. Rabbetts (Specialist Member)
Mr. M Cann (Specialist Member)

BETWEEN:

Mr. Ahmed Ismail

Appellant

-v-

Care Quality Commission

Respondent

DECISION

The Appeal

1. On 3 April 2024, Mr. Ahmed Ismail the Service Provider the Appellant made an application, appealing against the decision of the CQC. The Appeal was against the Notice of Decision of the CQC dated 8 March 2024 of decision of the CQC in the following terms- “that your registration as a service provider in respect of the above regulated activities has been suspended from 8 March 2024 (having commenced on 26 January 2024) until 23:59, 8 June 2024 at or from the following location: Queens Clinic 75 Wimpole Street W1G 9RT.”Directions were given by Judge Khan on 3 April 2024, for the preparation of the matter on 9 April 2024, those directions were varied by agreement and the matter was listed for hearing on 23 April 2024. The dates were varied by agreement and the matter was set down for hearing with a time estimate, for two days on 29-30 April 2024.

The Parties

2. The Appellant is a leading gynecologist with almost 50 years' experience in the field of gynecology who is a service provider for a clinic 'providing services of

Diagnostic and screening procedures, Family planning and Treatment of disease, disorder and injury. The clinic which is subject to the CQC Notice of Decision is the Queen's clinic.'

3. The Respondent is the CQC, the independent regulator of all health and social care services in England. Under section 3 of the Health and Social Care Act 2008 (HSCA 2008) the Respondent's objectives are to protect and promote the health, safety and welfare of people who use health and social care services. Under Regulation 8 of the Health and Social Care Act 2018 (Regulated Activities) Regulation, the respondent is under a statutory duty to ensure that the provider complies with the fundamental standards of care (The Standards). The CQC is also tasked with protecting the interests of vulnerable people including those whose rights are restricted under the Mental Health Act.

Attendance

4. In attendance was Mr. Ahmed registered provider and consultant doctor and on behalf of the Appellant, Mr. Leviseur - Counsel, also in attendance was Mr. Adam Smith para-legal. On behalf of the Respondent, Ms. Theresa Deignan-Counsel. Also, in attendance on behalf of the Respondent was Karolis Krukonis para- legal, Toby Buxton (Lawyer) and April Marshall-Dean.

5. Witnesses on behalf of the Respondent were Stuart Poole and Ben Millington. The Appellant the service provider, Mr. Ahmed had produced two statements, and also gave evidence.

Preliminary Matters

6. At the beginning of the hearing the Judge declared that she was acquainted with counsel Ms. Deignan, as counsel Judge Daley was also a legal assessor for the NMC. Judge Daley had exchanged mobile numbers with Ms. Deignan and had exchanged pleasantries with her in passing at the NMC although they had never socialized. Mr. Cann confirmed that he knew of Ms. Deignan professionally during his time as chair, fitness to practice although they were not personally acquainted.

7. Mr. Leviseur was stated that he would take instructions from his lay client and instructing solicitors. After an adjournment of half an hour he confirmed that his client made no objections to the Judge continuing to hear this matter along with the Tribunal as constituted.

8. The Tribunal makes a restricted reporting order under Rule 14(1) (a) and (b) of the 2008 Rules, prohibiting the disclosure or publication of any documents or matter likely to lead members of the public to identify the service users so as to protect their private lives.

Late Evidence

9. The appellant made an application to admit a further witness statement and exhibits, there was no objection to the evidence being admitted by Ms. Deignan on behalf of the CQC. The CQC also applied for late evidence to be admitted

that was, 5 Screen shots of the SEMBLE screen, by an application dated 26 April 2024. Neither party had any objections to the other parties evidence being admitted.

10. The Tribunal decided to admit the evidence in accordance with Rule 15. We noted that both parties agreed that the evidence was relevant, and raised no objection. We took account of Rule 2 the overriding objective of The Tribunal Procedure (First-Tier Tribunal) (Health, Education and Social Care Chamber) Rules 2008. We considered that it was in the interest of justice for us to consider all of the evidence which was relevant.

Background

11. That decision was appealed to the Care Standards Tribunal on 23 February 2024. Following discussions between the Tribunal and the parties, that appeal was withdrawn with no finding of fact on 29 February 2024. The suspension was due to come to an end.

12. The service was inspected on 6 March 2024 by a CQC inspector, a CQC Operations Manager and a specialist advisor in gynecology to review the service again, and to determine whether the suspension should be lifted or continued. The inspectors found that concerns existed in the following areas Regulation 12 Safe care and treatment and Regulation 17 (1) Good Governance.

13. The concerns cited for imposing the urgent suspension are defined broadly as: • Failure to have a safeguarding policy for patients found to have Female Genital Mutilation ('FGM'); • Lack of 'recall' system to identify patients through medication and/or conditions; • Poor Record Keeping/documentation which placed patients at risk of avoidable harm; • Undertaking procedures not covered by NICE Guidelines specifically transvaginal laser therapy; • Lack of a risk assessment for the HCA assisting with operating procedures; • Absence of a Service Manager and failure of Registered Provider to understand his role in oversight of governance updates

14. On that basis, the Respondent issued an Urgent Notice of Decision, dated 8 March 2024, to extend the suspension period until 8 June 2024. In the decision letter the CQC set out that -:
The reasons for our decision are as follows: The service was inspected on 16 and 24 January 2024 by two CQC inspectors and a specialist advisor in gynecology. Following this inspection, a notice of decision to urgently suspend registration was served as there were concerns which expose service users to potential risk of harm.
Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 Regulation 17(1) Good governance
We interviewed the lead clinician/provider about whether or not changes had been made to clinical records systems following findings at the last inspection. At that time, in review of clinical records and consent forms, we had not been consistently able to ascertain what procedures had been undertaken, or what consent process had been followed, including the explanation of risks and provision of information. In some instances, attendances at the clinic were not

accompanied by a consultation note. There were also examples where it was unclear what protocols the provider had followed in providing treatment. On the inspection of 6 March 2024, we did not look at further clinical records as the service had been suspended since the last inspection visit. However, the examples 4-7 (below) detail what the lead clinician told us about records and recording. 4. CQC asked the lead clinician/provider about how informed consent and risks and benefits of procedures were reported, specifically in relation to manual evacuation of retained products of conception using manual vacuum aspiration. We further outlined that National Institute for Health and Care Excellence (NICE) guidelines which the service had said it was following as primary guidance required that risks were discussed and that there were discussions about whether procedures undertaken were required at all, and if they were whether they would be undertaken under general or local anesthetic. We asked the lead clinician why these discussions were not detailed in the clinical records to show that NICE guidelines were being followed. He reported that he did not feel that recording this level of detail was required. On the basis that this is not documented, there can be no assurance that NICE guidelines (which are the guidelines used at the service for this procedure) are being followed. The lack of detail in the record is such that there can be neither assurance the procedure is taken in line with NICE best practice, nor that the patient had provided informed consent for the procedure to be carried out. Either of these situations puts patients at risk of harm. 5. CQC asked about contemporaneous record keeping at the service. The lead clinician/provider detailed that they wrote the paper records and entered records on the electronic system at the service. They reported that on occasion they would add to records after the event if information was missing. Additions to clinical records in this way is contrary to General Medical Council (GMC) guidelines, which state that records should be made at the time the events happen, or as soon as possible afterwards. There is no provision for amendments to be made on a later date. Therefore, there can be no assurance of the accuracy, completeness and reliability of the clinical records. 6. CQC asked the lead clinician/provider if they had a protocol for sharing information with patients' GPs, and more specifically where there were potentially red flag symptoms which required follow up, even where the patient had not consented. This is required so that potentially serious issues may be followed up in the best interests of the patient. The lead clinician/provider was not able to provide a protocol detailing this. We asked why details of what had been shared with patient's GPs either with or without patient consent did not appear in the clinical record. The lead clinician did not provide a response to this. There was no formalised recording of information sharing where patients' health is potentially at risk. If risk factors had been identified and were not passed on to the service user's GP, they could potentially have been put at risk of harm. 7. The lead clinician/provider stated that he held discussions with colleagues at other services to ensure that he was following best practice. We asked if the lead clinician/provider could provide details in clinical records or elsewhere of details of these discussions and how they impacted on patient care. They told us that the service does not have minutes of these meetings. In the absence of these minutes, there is no assurance that conversations of this kind with clinicians outside of the service comply with data protection requirements in connection with patient data, or access to details for inspectors to assess quality and compliance with relevant

requirements. There is also an incomplete record of discussions determining what care ought to be provided. Both scenarios put patients at risk of harm. 8. We asked the lead clinician/provider what guidelines were followed where there were no applicable NICE guidelines. The lead clinician told us that the use of laser rather than surgery for mild stress incontinence (a procedure which is undertaken at the clinic) had been approved by NICE. This is not the case. The specific NICE guideline in this regard is "Interventional procedure overview of transvaginal laser therapy for stress urinary incontinence (May 2021, due for review in May 2024)", which states – "The evidence on transvaginal laser therapy for stress urinary incontinence does not show any short-term safety concerns. Evidence on long-term safety and efficacy is inadequate in quality and quantity. Therefore, the procedure should only be used in the context of research". On the basis that the lead clinician/provider reported that they were following NICE guidelines, they should not have been undertaking this procedure. Undertaking procedures which are not covered by NICE in the absence of any other formalised guidelines and protocols puts patients at risk of harm. 9. CQC asked whether or not the service had undertaken a risk assessment of having a healthcare assistant (HCA) assist with operating procedures rather than a regulated clinician such as another doctor or nurse, as detailed as an area that needed to be addressed in two previous CQC reports. The lead clinician/provider was not able to provide this. We asked how in the absence of care certificate accreditation, the lead clinician/provider had oversight of the work of the HCA. They told us that the HCA was accredited to undertake cannulation but was unable to detail formal mechanisms of how the work of the HCA was monitored and reviewed. The lack of formalized risk assessments and the lack of oversight of the work of staff at the service puts patients at risk of harm. 10.CQC asked the lead clinician/provider how in the absence of a service manager for the past three months the registered provider would have oversight of policies and operational governance. The lead clinician/provider told us that they were trying to recruit someone who could undertake this, and shared an interview template that had been completed in the past week. However, they gave no further information on how changes and updates had been reviewed in the past three months. The lead clinician/provider did not demonstrate an understanding of their role in oversight of governance updates, as they reported that this would be the responsibility of a newly appointed manager, rather than their role as provider. There are currently no other staff at the service that could provide this oversight of policies and operational governance, and no temporary cover arrangements are in place until a service manager is appointed. The lack of oversight of governance at the service meant that the registered provider could not demonstrate that any new guidance was being integrated into the service's systems"

15. The decision was appealed on 3 April 2024.

Legal Framework

The Health and Social Care Act 2008 (“the Act”) and the Health and Social Care Act (Regulated Activities) Regulations 2014 (“the Regulations”).
Section 18
Suspension of registration (1) The Commission may at any time suspend a person's registration under this Chapter as a service provider or manager for a specified period. (2) Except where the Commission gives notice under section 31, the power conferred by subsection (1) is exercisable only on the ground that— (a) the regulated activity is being, or has at any time been, carried on otherwise than in accordance with the relevant requirements, or (b) the person has failed to comply with a requirement imposed by or under Chapter 6. (3) The suspension of a person's registration does not affect the continuation of the registration (but see sections 34 and 36 as to offences). (4) A period of suspension may be extended under subsection (1) on one or more occasions. (5) In this section “relevant requirements” has the same meaning as in section 17.
Section 31

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…The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014Safe care and treatment 12.— (1) Care and treatment must be provided in a safe way for service users. (2) Without limiting paragraph (1), the things which a registered person must do to comply with that paragraph include— (a) assessing the risks to the health and safety of service users of receiving the care or treatment; (b) doing all that is reasonably practicable to mitigate any such risks; (c) ensuring that persons providing care or treatment to service users have the qualifications, competence, skills and experience to do so safely; (d) ensuring that the premises used by the service provider are safe to use for their intended purpose and are used in a safe way; (e) ensuring that the equipment used by the service provider for providing care or treatment to a service user is safe for such use and is used in a safe way; (f) where equipment or medicines are supplied by the service provider, ensuring that there are sufficient quantities of these to ensure the safety of service users and to meet their needs; (g) the proper and safe management of medicines; (h) assessing the risk of, and preventing, detecting and controlling the spread of, infections, including those that are health care associated; (i) where responsibility for the care and treatment of service users is shared with, or

transferred to, other persons, working with such other persons, service users and other appropriate persons to ensure that timely care planning takes place to ensure the health, safety and welfare of the service users. Good governance 17.— (1) Systems or processes must be established and operated effectively to ensure compliance with the requirements in this Part. (2) Without limiting paragraph (1), such systems or processes must enable the registered person, in particular, to— (a) assess, monitor and improve the quality and safety of the services provided in the carrying on of the regulated activity (including the quality of the experience of service users in receiving those services); (b) assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk which arise from the carrying on of the regulated activity; (c) maintain securely an accurate, complete and contemporaneous record in respect of each service user, including a record of the care and treatment provided to the service user and of decisions taken in relation to the care and treatment provided; (d) maintain securely such other records as are necessary to be kept in relation to— (i) persons employed in the carrying on of the regulated [F1activity,][F2and] (ii) the management of the regulated [F3activity, F4...] F5(iii) . (e) seek and act on feedback from relevant persons and other persons on the services provided in the carrying on of the regulated activity, for the purposes of continually evaluating and improving such services; (f) evaluate and improve their practice in respect of the processing of the information referred to in sub-paragraphs (a) to (e). (3) The registered person must send to the Commission, when requested to do so and by no later than 28 days beginning on the day after receipt of the request— (a) a written report setting out how, and the extent to which, in the opinion of the registered person, the requirements of paragraph (2)(a) and (b) are being complied with…

The Hearing

17. We decided that as this matter was an appeal from the CQC decision we would hear from the CQC witnesses first, who would set out the reason for the decision that had been made.

The Evidence of Mr. Millington Inspector CQC

18. We heard from Mr. Ben Millington, an Inspector at the Care Quality Commission (CQC) who gave evidence under affirmation. Mr. Millington had prepared a witness statement comprising 57 paragraphs together with exhibits, dated 12 April 2024 which he confirmed was true to the best of his knowledge and belief.

19. In his statement he set out his relevant employment experience. He explained the role of the CQC and the relevant inspection history of the service. He set out that the service was placed in special measures following an inspection on 30 September 2022, which involved increased monitoring and a follow up inspection to review whether improvements had been made. He said that an inspection took place on 16 & 24 January 2024 to review the service, following the special measures period to see whether the services had improved.

20. In paragraph 10 to 11 of his statement he set out the outcome of the inspection. He stated that -: ". Serious concerns were found on that inspection and CQC used its powers under Section 31 of the HSCA 2008 to issue an urgent Notice of Decision, dated 26 January 2024, to suspend the Appellant's registration until 8 March 2024. 11.The Appellant appealed that Notice of Decision. The appeal was withdrawn shortly after it was made. I understand this following agreement between CQC and the Appellant that the next inspection, which by then had been announced to the Appellant, would include two CQC inspectors (or one inspector and one operations manager). 12.That inspection took place on 6 March 2024 ("the March inspection"). The suspension was due to expire on 8 March 2024 and the inspection was necessary to assess whether the Appellant had addressed the urgent concerns found at the January inspection. If the concerns had been addressed, then the suspension could have been allowed to expire. 13.At the inspection on 6 March 2024, the CQC found that its urgent concerns had not been addressed."

21. He set out that the CQC used its powers under Section 31 of the HSCA 2008 to extend the suspension.

22. Mr. Millington was asked whether having seen Mr. Ismail's two witness statements, he was satisfied that the concerns had been addressed. He told us that having read the witness statements, the concerns remained. He explained that he remained concerned about the issues concerning FGM and the Data base. However, Mr. Millington acknowledged that there was information from the service provider that he had undertaken further training and was able to use SEMBLE to extract data to show what medication his clients had been prescribed. In respect of record keeping his concerns remained.

23. He explained that Stuart Poole and a specialist adviser Anita Sanghi accompanied him. Anita Sanghi was a pediatric gynecologist. Although she was due to attend the inspection in person, she had injured her foot and attended remotely.

Use of IT record keeping and the SEMBLE data base system

24. Mr. Millington referred to the inspection, he stated that during the inspection the specialist adviser asked about a consultation which had taken place, and whether Mr. Ismail had carried out the inspection alone. He told us that although the record showed that Mr. Ismail had been unaccompanied. He stated that Mr. Ismail explained that he had been accompanied by Galina Burstinsca one of his Health Care Assistant. He referred to the screenshots produced, which showed that at 12.38 the original record was deleted. He stated that he had a conversation with Mr. Ismail who then agreed to upload the original document. This was completed by the receptionist. It was Mr. Millington's observation that Mr. Ismail had limited computer skills and was not able to amend the records himself. He was also concerned that the deletion and amendment of such a record" showed a fundamental lack of understanding about appropriate record keeping."

25. In respect of the records, he referred to a patient who was included within some of the service records as having a Bartolin cyst consultation on 16

December, however there was no record of this. Mr. Millington told us that there were paper records within the clinic which had not been uploaded as evidenced in photographs. In respect of the SEMBLE records he referred us to the summary field on the right in the SEMBLE and the fact that there were no notes from the date of the consultation.

26. He referred to the brevity and incomplete nature of the records as giving rise to one of his concerns. This included the notes not having enough details so that you could understand what procedure a patient had undertaken and why, or that a discussion with the patient about the rational of any treatment had taken place.

Safe guarding and Female Genital Mutilation (FGM)

27. In his witness statement Mr. Millington set out that one of CQC's concerns during the January inspection was around a failure to consider safeguarding referrals where a patient had evidence of historic FGM. He told us that the CQC had not suggested that the Appellant must make safeguarding referrals, as was suggested by Mr. Ismail in his appeal. The concern was that the Appellant has not formally considered whether a referral should be made in the relevant situation in the patient's best interests.

28. He stated that at his inspection in March 2024, he asked about changes that had been made to the policy. However, it was apparent that no changes had been made to the processes, he stated that Mr. Ismail referred him to a template which was yet to be created.

29. During questions from counsel for the CQC, and cross-examination Mr. Millington clarified the CQCs position in relation to this, he stated that he accepted that the patients seen at the clinic were all over 18 years old, and that as such there was no mandatory requirement that a safeguarding referral be made. He also agreed that the majority of Mr. Ismail's patients were likely to come from overseas, and that they would in all probability be returning and that this was relevant to the question of whether a safeguarding referral should be made.

30. He had dealt with this issue in paragraph 17 of his witness statement which set out that "…One of CQC's concerns during the January inspection was around a failure to consider safeguarding referrals where a patient had evidence of historic FGM. The CQC has not suggested that the Appellant must make safeguarding referrals, as is suggested in the appeal. The concern is that the Appellant has not formally considered whether a referral should be made in the relevant situation in the patient's best interests." He also stated that there was no evidence that Mr. Ismail had carried out a risk assessment in reaching the decision that a safeguarding referral was not necessary.

The use of Laser Therapy

31. In his witness statement, Mr. Millington set out that he had discussed the use of laser therapy with Mr. Ismail. The purpose of this was to understand the rationale for the treatment and the protocols used. He stated that Mr. Ismail told him that the treatment was approved by NICE guidelines.

32. In paragraph 38 of his statement, Mr. Millington set out that “the information provided by NICE, the guidance stated that there was insufficient evidence for this procedure being safe in the long term and that the procedure should only be used in a research context. The Appellant had been carrying out this procedure for patients on the understanding it was covered by NICE guidelines, and on that basis, I was concerned about the Appellant’s understanding of those guidelines”

33. He accepted in response to cross- examination from Mr. Leviseur, that as Queen’s clinic was a private clinic it was not covered by the NICE guidelines. However, he stated that notwithstanding this, there needed to be protocols in place to determine the long-term efficacy of the practice and he would have expected to see some study or long-term monitoring by the service provider to ensure the safety and effectiveness in the absence of guidelines. Mr. Millington accepted that there were no concerns about the use of HCA’s within the clinical setting, and that there was no issue with using health care practitioners from other jurisdictions in an HCA role he stated that- “The Appellant needs to be assured that the person assisting is a fit and proper person to do so. Where that person is a regulated professional, a risk assessment for their assistance could be fairly basic as their practice is regulated and they must come up to a certain standard to remain registered with the relevant regulatory body. Where an HCA is assisting that is not the case, and an in-depth risk assessment covering all possibilities related to the procedure should be completed in order for the Appellant to be assured that the HCA can assist safely and effectively...”

34. He stated that during the 6 March 2024 inspection, he asked Mr. Ismail if he had carried out a risk assessment for the HCA assisting with procedures. He stated that Mr. Ismail told him that he had not. He confirmed that his view of the use of HCAs as set out in the decision remained unchanged.

35. He was asked about whether at the inspection he had accused Mr. Ismail of carrying out a termination as this was set out in Mr. Ismail’s witness statement. He stated that he had not, his concern was that due to the nature of the record-keeping the CQC was unable to ascertain the nature of the procedure which had been undertaken. He also denied accusations which had been made concerning how he had undertaken his role as an inspector, in particular he denied that he had harassed Mr. Ismail.

36. In answer to questions from Mr. Leviseur concerning whether the service could benefit from a practice manager or service manager; Mr. Millington stated that the CQC was not prescriptive and that it was a matter for Mr. Ismail how he undertook governance of the service. However, the CQC needed to know that where there were policies in place they were being implemented, and that the service had appropriate policies and practices to safeguard service users.

37. Mr. Millington agreed that Mr. Ismail did not need to have a computerized database in order to comply with good governance, however, he stated that this was the system that Mr. Ismail had told the CQC was used for record keeping. Given this, if the system was in use, it should be fully functional. He was asked about whether the additional training on SEMBLE gave the CQC some reassurance that matters were moving in the right direction. Although Mr.

Millington agreed that this could provide some reassurance, he stated that the CQC would need to see that this was being implemented in practice.

38. Mr. Millington was asked by us about the gap in inspections between 2012- 2020, he stated that there had been a change in the inspection regime following legislative changes brought about by the 2014 legislation. This meant that inspections of private clinics were now undertaken on a regular basis. In answer to a question from us about the database and whether it was sufficient that others within the service could use the database and provide Mr. Ismail with information rather than Mr. Ismail being proficient. Mr. Millington stated that whilst this may be acceptable, it would present some difficulty if the information which was needed was of a clinical nature.

Evidence of Mr. Stuart Poole Operations Manager, CQC

39. We heard from Stuart Poole who's witness statement which was dated 16 April 2024, comprised 34 paragraphs which he confirmed was true to the best of his knowledge and belief, he gave his evidence under affirmation. In his statement, Mr. Poole set out that-" I am employed by CQC as an Operations Manager. I lead a team of inspectors and assessors to deliver assessment activity, managing system-based assessment activities and taking part in decision making meetings where concerns are found during on-site assessments. I have held this role, which was previously referred to as Inspection Manger, since I joined CQC in January 2016."

40. He was asked about his opinion of Mr. Millington's competence as an inspector. He stated that he had worked with Mr. Millington over several years and he had no reason to question his competence or capability as an inspector. He stated that the issue was what if the principal for the service was not around? Could someone step into the service and deliver safe and effective care? He said that the inspection carried out by the CQC was about looking at what is happening within the service such as systems and processes rather than clinical care.

41. He confirmed that even though the principal of the service Mr. Ismail was considered to be an eminent practitioner, this did not provide the reassurance needed by the CQC, " He cited the purpose of the CQC as a regulator, and said that an organisation, such as the service "did not get to mark its own homework" He told us that the purpose of the March inspection was to assess the current position in the light of any changes that the service had made, to see whether it was no longer in breach of the standards.

42. He referred to the findings of Mr. Millington in his report, which had been set out in the Notice of Decision which dealt with each of the concerns that had been raised in the report. He set out that he agreed with the conclusions reached by Mr. Millington following the inspection.

43. In his statement, he explained that following the inspection a meeting took place with Mr. Millington, the Deputy Director Antoinette Smith, amongst others and himself. He set out how the Enforcement Decision Tree (which was

included within the bundle) was used to inform the decision-making process. Mr. Poole set out the factors which were taken into account, that is, that there was a history of concern about the service as set out in the chronology. In paragraph 25 and that changes which had been made were not sustained. Mr. Poole stated that "The meeting considered the likelihood of the urgent concerns recurring if the suspension was to be lifted. On the basis of the concerns about the Appellant's understanding of guidelines, knowledge of the content of his own policies, and understanding around the responsibility for governance, we considered that the likelihood of recurrence was Probable."

44. At paragraph 27, of his statement he set out the range of options which was available to the CQC, which included cancellation of the registration, or imposing conditions.

45. Mr. Poole set out-: "…that the key decision for the meeting was which of these options would have had the most effective impact to keep patients safe, while also balancing that with the inconvenience caused to the Appellant. In general, CQC wants to give providers the opportunity to address urgent concerns and resolve the situation where possible. 29.The meeting considered the possibility of imposing conditions on the Appellant's registration. Conditions are most effective where there are very specific areas of concern that can be targeted by tailored conditions. Given the wide-ranging concerns in areas such as governance, we did not feel that conditions would be workable. Even if potential conditions could have been identified, the urgent concerns were at such a level that we could not see a level of enforcement that would allow the clinic to resume operating under the current level of risk. 30.On the other hand, the level of concern was not at a level where we felt that the Provider should not have the opportunity to address the concerns. That would have been the outcome of using CQC's Section 30 powers to effect immediate cancellation. That option was discounted."

46. He explained that the CQC was left with the option of extending the suspension.

47. Mr. Poole was asked about the two witness statements which had been produced by Mr. Ismail and whether this gave him some assurance that a suspension was no longer necessary. He told us that although Mr. Ismail had set out some changes that had been made, and some which were on-going, his assurances were insufficient. There was history which indicated that where changes had been made in the past, they had been not sustained, given this the lack of consistency was a concern.

48. His position had not changed since the 6 March 2024. He was asked what sort of information could assure him in the absence of patients being treated. Mr. Poole stated that if systems were in place which others, apart from Mr. Ismail, could pick up, and the CQC could see that the policies and protocols established were workable that would give some reassurance. He stated that the CQC would look to inspect before the end of the suspension period to see what improvements have been made. He said that in all probability they would

ask inspectors who had not previously inspected the service to carry out the inspections as it would be good for fresh eyes to consider what was happening, to see if there was a need for a continued suspension. Mr. Poole told us that the CQC did not want to cancel any registration, it genuinely wanted to work with service providers to improve the service, and when this occurred, this was counted as a successful intervention rather than a situation where the registration had to be cancelled.

49. Ms. Deignan on behalf of the CQC, told us that this concluded the evidence for the CQC.

The Appellant's Case

Evidence of Mr. Ahmed Ismail service provider

50. Mr. Ahmed Ismail had prepared two statements, the first of which was dated 18 April 2024 and comprised 102 paragraphs and the second witness statement dated 29 April 2024, comprising 38 paragraphs. He confirmed that his statements were true to the best of his knowledge and belief. He also gave evidence under affirmation.

51. In his first statement, Mr. Ismail provided details of his professional qualification he set out that "I became a Consultant Gynecologist in 1980 and I have been a member of the Royal College of Obstetricians and Gynecologists [RCOG] since that time, as well as a fellow of the RCOG since 1997. I am also an International Associate Member of the American College of Obstetrics and Gynaecology and I am registered with the Egyptian Medical Council and other Egyptian bodies. I am also a member of the European Gynaecology and Obstetrics Society. Over the years, I have also attended, lectured at and helped arrange a number of international medical events."

52. He set out that he established the Queen's clinic in 1983. This was a clinic which provided services as a private clinic based in London. It provided a range of female health services including gynecology, fertility, pregnancy, maternity and sexual health services to patients. Prior to registration with the CQC, Mr. Ismail had registered with the CQC's predecessor the Health Care Commission.

53. He set out that his current complement of staff was 5. which included two HCA's, a receptionist/ admin officer, and a social media manager. The practice had previously had a service manager/practice manager who was a doctor who had put in place some of the policies. The service had recruited an interim practice manager who was appointed on 26 April 2024.

54. He was asked by his counsel about the concern that records had been altered. He told us that he had viewed the 5 screenshots. He told us that although you can add to records, he was aware that medical records must not be deleted. He told us that he had "never deleted records in his entire life." He told us that he understood this to be illegal. It was possible to make a retrospective entry after the event has happened. However, he stated that the requirement was to make an immediate record.

55. Mr. Ismail told us he had not appreciated that the notes were allegedly deleted. He emailed all members of staff and told them that they should not under any circumstances delete notes. He set out what had occurred. Mr. Ismail told us that there was a time when the inspectors said there is a gap in the notes, and it appeared that he had conducted a procedure on his own. He stated that this was not the case as he always had a chaperone with him. He had checked the records and realized that Galena was with him on that occasion. He had asked her to upload her name onto the system and had gotten an extra piece of paper which he added onto the paper records as a continuation sheet with her name and the assistant's name.

56. He told us that he had not realized that the allegation related to the SEMBLE system having been altered by a deletion and when he had he immediately reinstated the original. He told us that he had not realized what was being alleged until he saw the screen shot taken by the CQC.

57. This was challenged by Ms. Deignan in cross-examination, she referred us to the screenshots and the deletion of the record and the reinstatement which occurred in Mr. Millington's presence.

58. In relation to FGM in his statement he set out that "I dispute entirely the concept of an FGM patient being in my care. Adults' resident in the UK who have suffered FGM in the past might attend the Clinic for treatment. In some cases, FGM may have occurred abroad, decades earlier. There is no mandatory reporting required in such instances and one has to be sensitive to the circumstances and the wishes of each individual patient."

59. Accordingly, he told us that he had never done a referral to safeguarding, although in his clinic he displayed a prominent poster with the number for the Local Authority Safeguarding officer. (The LADO) so that any patient who wanted to, could self- refer.

60. He stated that he had checked his records and had a total of 9 patients who had had FGM. As a physician he abhorred the concept and appreciated that the CQC concern was also for the wider family of the woman who had FGM, however he told us that the majority of his clients came from overseas, and some had come specifically for treatment. Given this it was not appropriate to make a referral.

61. In paragraph 7 of his second witness statement, he stated that he was in the process of developing an FGM flow chart, however he did not accept that because he did not use a written risk assessment that he had not undertaken a risk assessment in a structured way. He told us that he used his knowledge and experience as a clinician to carry out a risk assessment on each of his patients.

62. He stated that the CQC had never provided him with the name of the specific patient whose records they had examined which made it difficult to comment specifically about this.

63. In relation to record keeping, he stated that he did not agree that he had told Mr. Millington that primary record keeping was SEMBLE. He relied upon

personnel with more IT Knowledge than himself.

64. In respect of the SEMBLE records and the ability to cross refer by medication type he had taken the following action as set out in his first witness statement “The CQC also raised concerns regarding the lack of recall systems at the Clinic. I entirely dispute this claim and refer to the implementation of `SEMBLE' that is used to recall patient data. SEMBLE was introduced at the Clinic in 2023, and training and understanding of the digital platform is ongoing. There was a training session for all staff immediately following the January 2024 inspection. Both Lina and Galina are also in constant contact with the training provider to ensure any updates can be translated to the staffing team. 40. SEMBLE allowed the Clinic to identify patients through: DOB, patient name and postcode. Following the inspection in January 2024, we queried with Semble... the system can now identify patients through: DOB, patient name, certain diagnosis (i.e., specific to the patient's problems such as fertility, gynecology, sexual health), postcode or address, email and gender preference.” He referred us to a screenshot of SEMBLE.”

65. We asked him about the record keeping, he told us that the consents for treatment were always signed by the clients and that this was a paper-based record, as was the consent for the charges. The receptionist created the initial record on SEMBLE, and during consultation if it was a small entry he would use SEMBLE himself, however longer records would be done by hand and he would either input them himself or ask the receptionist to undertake this, he would try to do this daily.

66. He considered the main record system to be SEMBLE, although he told us that paper records were made, and that these would be kept for 7 years.

67. In relation to the Laser therapy, he denied that he had said that he used the NICE Guidelines in relation to Laser treatment. He said that he had said that they were mentioned in the NICE guideline. However, he told us that he used Laser therapy for stress incontinence and vagina dryness and that there was literature and other published studies which confirmed the efficacy of the treatment. He stated that he had carried this treatment out for a number of years and that there had never been any issues concerning it.

68. In his statement he said that that he “would add that it is also wrong to suggest that there is no NICE guidance relating to transvaginal laser therapy. NICE published Interventional procedures guidance [IPG696] on 26 May 2021 (Exhibit AI/43) in relation to Transvaginal laser therapy for stress incontinence. Alongside the NICE Guidelines, I also rely on guidance from the Royal College of Obstetrics and Gynecology, American College of Obstetrics and Gynecology, European society of Human Reproduction and Embryology.”

69. In respect of the HCA, Mr. Ismail told us that both HCA were qualified in another jurisdiction, Gelena was a doctor in the Ukraine and his other colleague was a qualitied nurse in Ghana. Mr. Ismail did not accept that there was no competency framework in relation to their practice.

70. He told us that all of the necessary employment checks were in their HR folders, and that they had completed all mandatory HCA training, they had also

been provided with induction. He told us that there were regular staff meetings in which policies were discussed and presented by different members of staff. In his statement he referred to Mr. Millington, he had set out that he felt threatened and harassed by him. However, he now accepted that this related to his feeling vulnerable during a period of ill health and the suspension of his service rather than “acts of harassment” by Mr. Millington.

71. He stated that he felt disrespected and unsupported by the CQC. Each time the service was criticized for something different. There was no basis to be critical of clinic in relation to FGM.

72. Both Counsel addressed us in closing, and also provided us with their written skeleton arguments which we have considered in our decision below.

The Tribunal’s conclusions with reasons

73. We carefully considered all of the evidence including the bundle of 1257 pages. Both Counsels were careful to set out, that this case was not about the clinical competence of Mr. Ismail as a clinician, an approach which we adopted and agreed with. This appeal was solely concerned with the regulatory concerns which had arisen at the premises known as Queen’s Clinic.

74. We noted the power’s open to the Tribunal, which are that it considers this matter afresh and makes its own decisions on the merits based on the evidence before it at the date of the hearing. This means that we considered all evidence which may not have been available to the CQC at the time it made its decision.

75. We considered the breaches of the regulation as set out below-:

Regulation 12 Safe and Effective Care

Failure by the Appellant to follow his own safeguarding policy in relation to FGM

76. We heard from Mr. Ismail that the issue of safeguarding does not arise in practice in relation to the patients that he sees. Both he and his counsel in the outline submissions and before us, set out all of the reasons that Mr. Ismail was not required to do a safeguarding referral. However, as we understood the issue in relation to safeguarding, the issue of safeguarding arose because Mr. Ismail referred to using his safeguarding policy in relation to patient’s who had FGM. His safeguarding policy stated that “a full documented assessment was needed in order to determine whether there was a risk”. Given this, it was agreed by the CQC that it was not necessary to make a referral. However, it was necessary for the service to establish that it had a documented, risk assessment, which was available to explain the rationale where an assessment had not taken place.

77. Mr. Ismail explained the risk assessment which he performed in making a decision that an assessment was not necessary. Although we had no issues with the rationale used by him, this was not documented within the patient notes or elsewhere within the service. Mr. Ismail had stated in his first witness

statement that a template was in the process of being developed. There was no template before us at the time of the hearing. This had not occurred.

78. Regulation 12 (1) of The health and Social Care Act 2008 set out that care and treatment must be provided in a safe way for service users, this included (a) assessing the risk to the health and safety of service users and (b) doing all that is practical to mitigate any such risks.

79. Given this, we find that although it is not necessary for the treatment of those with historic FGM to be referred, Mr. Ismail stated that a fully documented assessment was needed to determine the risk. This policy has not been varied to include the unwritten rationale used by Mr. Ismail, and at the hearing there was no template or flow-chart which was proposed to be used in place of this policy.

80. We also had sight of Mr. Ismail's FGM policy in section D of the bundle in which it was recognized that there were circumstances where it was not necessary to report; "It's important to note that professionals are not required to report directly to the Police in relation to a risk or suspected cases or where the woman is over 18. In these cases, we will follow our usual safeguarding procedures and reporting protocols…"

81. However, there was no demonstration that an assessment had been undertaken, other than Mr. Ismail's' assurance that he mentally made an assessment of the risks. As this was not documented, we could not be satisfied that Mr. Ismail had demonstrated that he is no longer in breach of this regulation. As he has not shown us that he has followed his policy or documented how the policy as now been changed.

82. We found that there was no new evidence before us that undermined the findings made by the CQC at the date of this Appeal; although there was further information on FGM as produced by the Department of Health, there was no information to suggest that the service's policy had been amended, or a new policy had been adopted which would demonstrate that the risks for patients with FGM or their wider family members, had been properly considered. There was nothing to suggest that Mr. Ismail had checked and established where (the country) the FGM had been undertaken, and as such we could not be satisfied that patients were receiving safe and effective care.

Lack of recall system to identify patients and record keeping

83. We decided it was appropriate to consider both issues together.

84. We accepted that the records that had been deleted on the SEMBLE system had been deleted by accident however this raised wider issues concerning governance which are considered below.

85. In relation to recall of patients using the data base, in written submission on behalf of Mr. Ismail counsel stated that Mr. Ismail had a small number of patients and that it was therefore easy for him to identify when safety alerts arose in practice and that the SEMBLE system which was in use could not identify patients by medication. In his witness statement, Mr. Ismail told us that

updated training had taken place and that as such it was now possible to identify patients by their diagnosis, which we consider is an important step towards being able to recall patients in the event of medication recall. Having heard from Mr. Ismail we had wider concerns about the efficacy of the system given the delays in uploading information. We heard from Mr. Ismail that he did his best to transfer information to the system on a daily basis. However, we heard and accepted Mr. Millington's evidence that records were incomplete and that a full record was not available in one contemporaneous, or continuous record for each patient.

86. We remained concerned that the only way to demonstrate improvements to the database system was to inspect this in practice. However, we accepted Mr. Poole's evidence that this issue was whether in the absence of the principal an alternative clinician could provide care. We also reminded ourselves of the standard set out in regulation 17 (c) and (d).

87. Having heard evidence from Mr. Ismail we concluded that there was a hybrid system of SEMBLE and paper-based records in operation at the service. We were not satisfied that systems and processes were in place which operated effectively in compliance with regulation 17.

Clinical Guidelines the use of Laser Surgery

88. We heard from Mr. Millington in his evidence he stated that he asked Mr. Ismail about the use of Laser treatment. He stated that Mr. Ismail told him that this was approved by NICE guidelines. We heard that he was presented with the NICE publication Transvaginal laser therapy for Stress Incontinence. A copy of which was included within the bundle. We noted that Mr. Millington's concern was that the recommendations at 1:1 set out that "The evidence on transvaginal laser therapy for stress urinary incontinence does not show any short-term safety concerns. Evidence on long-term safety and efficacy is inadequate in quality and quantity." It suggested further research be undertaken under the NICE guidelines.

89. In his response on behalf of Mr. Ismail, Mr. Leviseur set out that "…The NICE guidance is unusual because it acknowledges that there is considerable evidence that there is no short term risk to patients in using it. The Appellant has been using the CO2 laser in surgery since 1993 and for non-surgical procedures for the past 10 years. He has never had any short- or long-term harm reported to him by any of his peers who have also been using the procedure in the last 25-30 years. The data from the manufacturer supports this. There are studies in the literature in the bundle which likewise indicates that this is not a long term risk to patient and is more effective than estrogen therapy."

90. We heard from Mr. Ismail that he had considerable experience in the use of the procedure, and its benefits. He had undertaken his own research into the efficacy of the treatment and had undertaken training and had no adverse reports from his previous patients, concerning the treatment. However, as we set out in the decision, the issues are not about Mr. Ismail's skills as an Obstetric and Consultant Gynaecologist.

91. The CQC was concerned about whether the service could provide evidence that it was carrying out safe and effective care, We heard and accepted Mr. Millington's evidence that his concern arose out of Mr. Ismail's reference to following the NICE Guidance. We accepted that as a private clinic the service is not bound by the NICE guidance. However, we would expect to see that the service has developed guidance that is based on all of the evidence that Mr. Ismail referred to, at the hearing.

92. Although Mr. Ismail provided documentation such as the consent form with appropriate warnings to patients and study papers which dealt with the efficacy of the treatment, we would expect to see a policy which sets out the rational that Mr. Ismail intends to apply in determining whether to use the treatment on any given patient. We accepted that as a private clinic he can develop his own guidelines which would demonstrate that there is research undertaken on the efficacy of the treatment. Given this our concern was not that the treatment was being carried out, but that we could not be satisfied that the service in the absence of written guideline on the rationale for using laser treatment for any given patient.

93. Accordingly, we find that there was no evidence to undermine the findings of the CQC in respect of a breach of the standard in relation to Regulation 17(1).

Whether the service had undertaken a risk assessment of having a health care assistant assist with operating procedures rather than a regulated clinician.

94. We heard from Mr. Ismail that both of the HCAs were qualified in other jurisdictions. We heard that Mr. Ismail had carried out appropriate checks in relation to their employment. We considered that notwithstanding their competence, and their impressive CV's and record of experience, this did not amount to a framework for their role as HCAs. We heard that the CQC's concern was that "…on the matter of Healthcare Assistants ("HCAs"), the grounds of appeal do not accept that extra supervision is required where HCAs are assisting with clinical procedures… The Respondent's concern related to both oversight and risk assessments for HCAs assisting with procedures. It is unusual for a person assisting in this way not to be a regulated clinical professional, and the Respondent's position is that a HCA should be supervised, or if not, their attendance should be fully risk assessed."

95. We accepted that the lack of a framework or appropriate assessment gave rise to concerns about governance. Although there was a job description for HCA/ Chaperones, it was vague and non-specific. We were concerned that the job description did not set out the perimeters of this role. We were concerned that where a service uses practitioners in a role for which they are over qualified there is a danger that without a framework the limits of the role will be unclear.

96. We were further concerned, that Mr. Ismail set out that there was information about the scope of the role which was in the HR files which had not been given to the CQC. We would have expected this to be provided by the service. We find that there is no new evidence which undermines the decision

of the CQC, in respect of good governance.

97. We heard that the CQC were concerned that although the service had appropriate policies they were not always applied by the service. Evidence of this was Mr. Ismail's knowledge that records should not be deleted when this was not applied uniformly by others in his service. We were also concerned that although Mr. Ismail may use his knowledge and experience to provide safe and effective care, this could not be confirmed in the absence of policies and procedures which underpinned that care. We also considered that in Mr. Ismail's absence, it would be difficult for another principal to carry out care were there were serious issues with record keeping and a lack of consistency in applying policies were the use of the policies was inconsistent and unclear

98. The Tribunal noted that nothing set out by the service in the Appeal undermined the seriousness of the breaches that had been reported by the CQC or which the Tribunal had subsequently found proved on the evidence before it.

Decision

i. The Tribunal therefore confirms the Order made under Section 30 of the Health and Social Care Act 2008.
ii. The Appeal is therefore dismissed.
iii. The Order made on 8 March 2024 is confirmed and registration of the service provider, Queen's Clinic and Mr. Ismail, as registered manager is suspended.

Tribunal Judge M Daley

First-tier Tribunal (Health Education and Social Care)

Date Issued: **16 May 2024**