[2019] UKFTT 0756 (HESC)

Care Standards

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

Heard: 16, 17, 18 and 19 December 2019 at Darlington Magistrates Court
Determined: 27 December 2019

[2019] 3874.EA-MoU

BEFORE
Mr Laurence Bennett (Tribunal Judge)
Dr David Cochran (Specialist Member)
Mr John Hutchinson (Specialist Member)

BETWEEN:

Aesthetic Beauty Centre LLP

Appellant

v

Care Quality Commission

Respondent

DECISION

Appeal

1. Aesthetic Beauty Centre LLP (ABC) appeals under Section 32 of the Health & Social Care Act 2008 (the Act) against the imposition of conditions on its registration under Section 31 of the Act as a Service Provider in respect of regulated activities:
    - Treatment of disease, disorder or injury

Preliminary

2. The appeal form is dated 29 October 2019 (A1).

3. Case management decisions were made by Judge H Khan (A129-143).

4. By consent of the parties, it was ordered that the appeal should be considered outside the Memorandum of Understanding procedure.

5. In compliance with directions, the parties submitted case statements and documents relied upon.

6. The Tribunal hearing took place on 16, 17, 18 and 19 December 2019.

7. Immediately prior to the hearing, the parties submitted skeleton arguments.

8. During the hearing it was observed that the condition appealed would expire on 4 January 2020. Miss Danielle Gilmour, Counsel for CQC submitted that the Tribunal should extend the condition for a further 3 months.

9. At the hearing, the Tribunal accepted late evidence:
    - ABC Statement of Purpose 13 July 2011
    - CQC Inspection report in Decision Tree Template V3 format dated 9 December 2019

10. During the hearing it was acknowledged that Dr Dutta has appropriate qualifications and experience; this was no longer a ground relied upon by the CQC.

11. The Tribunal convened without the parties to determine the appeal on 27 December 2019.

12. Page references in this decision relate to the paginated hearing bundle.

Attendance

13. Mr Gordon Bebb, QC represented ABC. Its witnesses were Dr Ashish Dutta and Mrs Wendy Dutta.

14. Miss Danielle Gilmour, a Barrister represented CQC. Its witnesses were Mrs Jill Bullimore, Inspector, Mrs Angie Brown, Inspection Manager, Mrs Victoria Head, Inspection Manager, Mrs Sarah Dronsfield, Head of Hospital Inspection, Mr Michael Zeiderman National Professional Advisor and Dr Eliot Sykes, Clinical Advisor.

Restricted Reporting Order

15. It was noted at the hearing that a Restricted Reporting Order was not in existence, however, taking into account submissions of the parties it was considered appropriate to make an order in the following terms.

16. The Tribunal ordered that there shall be a restricted reporting order under Rule 41b of the Tribunal Procedure (First-Tier Tribunal) (Health, Education and Social Care Chamber) Rules 2008 prohibiting the publication (including by electronic means) of in written publication available to the public or inclusion in any relevant programme for reception in England and Wales of any matter likely to lead members of the public to identify any service user or patient mentioned in the appeal. For that reason service users are referred to by letter.

The decision

17. The Respondent's decision imposing conditions on the Appellant's registration is dated 4 October 2019 (B1).

18. The condition imposed in respect of the regulated activity is stated (B1): "The Provider must immediately suspend the carrying out of any surgical procedures which require local anaesthetic or sedation on service users at the location Aesthetic Beauty Centre – Newcastle-upon-Tyne, 4 Grainger Park Road, Newcastle upon Tyne, Tyne & Wear, NE4 8DP until 04 January 2020."

19. The grounds within the notice are that "any person will or may be exposed to the significant risk of ongoing harm on the basis of" procedure and anaesthesia, pre-assessment and identification of risk and practitioner's qualifications. Reference was made to patients A, B, C and D and further details of the chronology and patient history are contained within accompanying documents.

20. ABC's appeal application was received on 30 October 2019 (A1). Both the application and subsequent submissions include reasons for appeal, a response to the reasons provided by CQC, documentary evidence referred to and witness statement of Dr Asish Dutta, Mrs Wendy Dutta and as exhibited by Mrs Dutta, witness statements of Dr Vijay Kumar Jagannathan, Consultant Anaesthetist and Dr Farooq Ahmed Brohi, Consultant Anaesthetist.

21. The Appellant's witness statements also exhibit chronologies, relevant correspondence, research, DoH professional opinion and clinical practice.

22. CQC's response to the appeal (A131) sets out its reasons, a registration history and reference to inspections, 23 September and 4 October 2019. It includes: "The Tribunal are reminded that suspension is for a limited period of time, that period of suspension allowing the Appellant to reflect upon the issues identified within."

Background

23. The evidence indicates and it is common ground that ABC operates from 2 locations, Sunderland and Newcastle. The conditions imposed relate solely to the Newcastle location. The Tribunal was given to understand there are other current proceedings and considerations both in relation to Dr Dutta's professional registration, in respect of matters arising from the 9 December 2019 inspection and consideration of Provider registration matters.

24. Submissions and evidence at the hearing raise questions about the corporate entity operating Newcastle ABC. The Tribunal was urged to reach a conclusion on the appeal on the basis of the submissions by the parties about the appeal issues although it observes there may be a fundamental consideration in that the Registered Provider has not carried out activities or in commercial terms "traded" under its own corporate governance for some years as was stated by Dr Dutta. He cited financial advice and the formation of an alternate company which may have been the entity carrying out the registered activities during relevant periods. The Tribunal gives no further attention to this although it may be fundamental to continuation of the registration.

The Law

25. **Section 31 of the Act - 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 (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."

26. **Section 32 of the Act - Appeals to the Tribunal**

(1) An appeal against—

(a) any decision of the Commission under this Chapter, other than a decision to give a warning notice under section 29, or

(b) an order made by a justice of the peace under section 30, lies to the Tribunal.

(2) No appeal against a decision or order may be brought by a person more than 28 days after service on the person of notice of the decision or order.

(3) On an appeal against a decision of the Commission, other than a decision to which a notice under section 31 relates, the Tribunal may confirm the decision or direct that it is not to have effect.

(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.

(5) On an appeal against a decision to which a notice under section 31 relates, the Tribunal may confirm the decision or direct that it is to cease to have effect.

(6) On an appeal against a decision or order, the Tribunal also has power—

(a) to vary any discretionary condition for the time being in force in respect of the regulated activity to which the appeal relates,

(b) to direct that any such discretionary condition is to cease to have effect,

(c) to direct that any such discretionary condition as the Tribunal thinks fit shall have effect in respect of the regulated activity, or

(d) to vary the period of any suspension.

(7) In this section – "discretionary condition," in relation to registration under this Chapter, means any condition other than a registered manager condition required by section 13(1).

27. The burden of proof is upon the CQC to establish that the relevant test in section 31 of the 2008 Act is met.

28. The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 set out a number of important requirements that a Registered Provider must comply with.

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

Evidence and submissions

30. Dr Dutta's witness statement (D225) sets out the history of ABC and his own surgical rotations and background. In this and his oral evidence at the hearing, he detailed his practice as a General Practitioner and interest in plastic surgery. He had researched the designation Plastic Surgeon. He said he continues to be on the GP Register, although he has not undertaken clinical general practice for a number of years.

31. Dr Dutta confirmed that in accordance with requirements imposed by GMC he is mentored by 2 Consultant Plastic Surgeons, one in London, the other in East Grinstead. He mentioned the frequency of meetings, some of which are by telephone. He said he had discussed the events highlighted by CQC, particularly patients A, B, C and D with his mentors.

32. Dr Dutta has conducted a large repertoire of cosmetic procedures, initially under admitting rights at South Tyneside Hospital until December 2011 and since then using local anaesthesia and conscious sedation at ABC's Newcastle clinic. The Sunderland Clinic is not licenced for such procedures. He mentioned carrying out over 1,700 procedures.

33. Dr Dutta described his method of working with Anaesthetists who were engaged for sessions at ABC, the matters which he considered within the responsibility of the Anaesthetist and the liaison between himself and the Anaesthetist during procedures.

34. Dr Dutta responded to CQC's reasons for imposing conditions and to each of the 4 patient matters highlighted.

35. In addition to Dr Dutta's medical duties he detailed his involvement in management of the Registered Provider (and successor company). He mentioned how recommendations by existing Anaesthetists led to the engagement of Dr Jagannathan and through him, Dr Brohi.

36. Dr Dutta said that equipment was acquired on the advice of the Anaesthetist. Matters such as combination sedation and monitoring End Tidal CO_2 were matters for the Anaesthetist. He maintained conversation during procedures "through a patient privacy screen."

37. Dr Dutta gave his commentary on each of the 4 patient events. In respect of patient D, he saw a red flag arising from the patient's prescription of Clopidogrel and took a judgement call about the balance of risks. In respect of this and other inspection issues, Dr Dutta acknowledged he may have been wrong but he was willing to learn. He would respond to requirements. Dr Dutta said that he has decided that ABC will not operate on any patient taking Clopidogrel. He said that ABC is similar to clinics in which he has worked in Harley Street which have equivalent CQC registration.

38. Dr Dutta summarised that he could not provide the services within the clinic without the capacity for at least local anaesthesia and suggested that the condition appealed be varied so that it referred to minor procedures under local anaesthesia with limited anticipated blood loss.

39. In response to questions Dr Dutta accepted that he had fallen below essential standards but that he and ABC would actively improve and respond to matters highlighted by CQC.

40. Mrs Dutta is the registered manager of ABC. She is a registered nurse and was the floor nurse during the procedures under question. She detailed her duties as registered manager and the documentation she prepared. She said that management discussions were part of everyday routine, often round the breakfast table. Mrs Dutta's statement (D1) refers to policies, significant event analysis, recruitment, checks and reviews. She explained the conduct of ABC's Medical Advisory Committee that consisted of Dr and Mrs Dutta and the Anaesthetist and gave further details of the 4 patient matters mentioned.

41. Both Dr and Mrs Dutta described the physical features of ABC. The operating theatre is on the 1st floor. They detailed the location of the clean room and dirty room and air circulation. There is no lift and a trolley could not be used from the theatre. Patients left the theatre when sedation was reversed and they were able to walk.

42. Mrs Dutta gave further details regarding patient A. She acknowledged telephone calls to the emergency services were eventually made by the Anaesthetist. She did not take immediate managerial responsibility.

43. Dr and Mrs Dutta stated they did not accept the findings of 9 December 2019 inspection although they had yet to consider them in detail.

44. CQC inspection evidence was provided by Ms Sarah Dronsfield, Mrs Jill Bullimore, Mrs Angie Brown and Mrs Victoria Head. Their witness statements are within the bundle (Section B). In summary, the witnesses described the process which led them to impose the condition having taken advice from CQC Clinical Medical Advisors. They alluded to further considerations currently in course.

45. CQC witnesses referred to the lack of earlier records following the change of regulator to CQC and the provenance of some documents including Statements of Purpose and what they considered could be defined as minor procedures. It was acknowledged that the 2011 statement of purpose included the procedures under consideration but that a Registered Provider was required to be aware of changes in regulation and practice and should alter procedures in the light of such changes.

46. It was highlighted that the relevant breaches which led to the conditions related particularly to Regulations 12 Safe Care and Treatment, 15 Premises and Equipment, 17 Governance and 18 Staffing.

47. Mr Michael Zeiderman, is the National Professional Advisor of Surgical Services with CQC. He is a Consultant Colorectal Surgeon. His statement is included at C361. Mr Zeiderman said he had reached his opinion by consultation with relevant plastic surgery and cosmetic surgery colleagues. He repeated his views were taken following their advice. He considers that each of the incidents led to concerns that were properly taken into account by the CQC and he supported their view that there is a risk to patient safety. He said that Dr Dutta's practice may have been considered appropriate some time ago but regulatory expectations have changed.

48. Mr Zeiderman confirmed that he had not spoken to any of the relevant individuals but had reviewed the notes. He has general concerns about use of combination drugs in conscious sedation, in particular the risk to airways. He considers the documentation of the clinic was poor and has concerns about what appeared to be a tendency towards unconventional clinical practice, probably as a result of practice in an environment incapable of proceeding to general anaesthesia.

49. Dr Eliot Sykes' statement (C365) gives details of his professional background as a Consultant in Anaesthesia and Intensive Care. He said that in his role as Business Unit Director he is responsible for 28 operating units in the North East. He has key responsibility in relation to governance. He has reviewed each of patients A, B, C and D's case histories from the papers and made comments. He has not interviewed either Dr Dutta, the nurse or Anaesthetist involved. In response to questions he is of the firm opinion that there is continuing ongoing clinical risk, not least in respect of the issues that arose.

50. Dr Sykes has particular concerns about the complexity and duration of procedures driven by the case mix and environment. Irrespective of the competence of the Anaesthetist, he considers that the regime in ABC inevitably would give rise to risk. He noted the duration of operations, some of which were of great complexity and which he disputed could be described as minor and the inevitable limitation of resources in a clinic such as ABC. He believes the drug doses high, especially in combination with a significantly increased risk of transiting from conscious sedation to unconscious sedation with associated risks to patients' airways. Dr Sykes suggested that the use of End Tidal CO_2 monitoring is appropriate in all cases especially in the absence of recorded awareness scores but observed it was not utilised. He spoke of the difficulties in recognising some of the written records and repeated there was a multi-faceted combination of factors. On review of the case mix he considers that the best option for some procedures would have been prearranged elective general anaesthesia.

Skeleton arguments and closing submissions

51. Miss Gilmour's skeleton argument on behalf of CQC sets out the background of events, the appropriate law and legal test and submits on consideration of the incidents, there is reasonable cause a person would or may be exposed to harm. She submits there is no cogent evidence to support the contention that the CQC's decision was based on factual inaccuracies.

52. In closing submissions, Miss Gilmour said that service users were entitled to a safe and acceptable standard and the likelihood of difficulties continues. The types of activities carried out by ABC were unsuitable and inappropriate and the Registered Provider was not fit for purpose under Regulation 15. The conditions for a limited period were to immediately protect from risk but they gave time to reflect; the position has not changed but has deteriorated.

53. Miss Gilmour submitted the conditions are reasonable and proportionate. Dr Dutta has accepted that patient safety was compromised and has himself proposed a condition. The Registered Manager has overall responsibility notwithstanding the evidence given about the duties of the Anaesthetist. Ultimately, issues for the Anaesthetist may be issues for GMC regulatory oversight.

54. Miss Gilmour commented that it was not the role of the regulator to take responsibility for the provider and to give directorial input such as suggested by Dr and Mrs Dutta. She submitted Dr Dutta's evidence in respect of changes within the 2015 Statement of Purpose acknowledged the big step from hospital procedures to clinic procedures. Whilst he is a cosmetic surgeon with years of experience, it was unthinkable he could have considered many of procedures "minor." The clinic is not a hospital and there are questions about its design and layout a lack of documentation.

55. Miss Gilmour referred to the significant event analyses JB07 and JB08 and C79-C98 showed inconsistent approaches which were not in accordance with clinical guidelines. She drew attention to Dr Sykes' evidence and conclusions. She submitted there was collective responsibility for the administration of drugs and lack of appropriate operating environment and that Dr and Mrs Dutta have limited understanding of the regulatory requirements, not least shown by Mrs Dutta stating she had met them.

56. Mr Bebb's skeleton argument for ABC addressed the background of fact. He submitted that the Newcastle premises are equipped with a fully approved and functional theatre with rooms for recovery and changing. Dr Dutta's qualifications are appropriate. He referred to a response by the Anaesthetists in respect of patients A, B and C drawing attention to the Anaesthetist's evidence and relevant guidelines. Regarding patient D, he submitted the evidence shows that risks were explained and a clinical judgement made. Overall, it is submitted that suspension of all surgical procedures by local anaesthetic or sedation is "entirely disproportionate."

57. In his closing remarks, Mr Bebb repeated Dr Dutta has over 30 years' experience, registration documents are clear, at the time of registration CQC was satisfied with the operation of the provider and that its permitted procedures were appropriate as set out in the letter dated 20 November 2011 (D237). Mr Bebb referred to subsequent inspections in 2015 and 2017 (C699) which note the regulated

activities. Although there were 2 serious incidents in 2019, they must be considered in the perspective of a provider carrying out some 300 procedure per annum. He made detailed submissions in respect of the events during each procedure.

58. Mr Bebb submitted that the Section 31 notice is a draconian step as it would effectively close the provider and deprive the public of the service. In the present circumstances, a further 3 month condition in similar terms would "finish" the clinic.

59. Mr Bebb submitted that events surrounding patients A and D showed problems had occurred, they did not show a continuing risk of harm. The notice appealed referred to Dr Dutta's lack of qualification and that procedures were outside the scope of registration; it also mentioned the assessment of risk which the evidence suggests arose from "pushing out the boundaries." The issue of qualification has now been accepted. The activities undertaken had been accepted by CQC at an earlier stage and within registration. In each case relied upon, appropriate conscious sedation had taken place and they had remained conscious and it was disproportionate to impose conditions because of these events. Little had changed since 2017.

60. Mr Bebb described Dr Dutta as having been placed on a regulatory treadmill. He submitted if it was found appropriate to impose conditions, they should be varied to specify procedures not exceeding 2 hours under local anaesthetic.

61. Further evidence and submissions are referred to below.

Tribunal's conclusions with reasons

Credibility

62. We note CQC inspectors largely relied on specialist clinical advice. Their own evidence was relatively factual. We have no reason to doubt the evidence of the inspection and decision process they followed.

Mr Zeiderman

63. We have some difficulties with Mr Zeiderman's evidence. Although his statement described his personal expert opinion it transpired during intense cross examination by Mr Bebb that this opinion was in fact based on the opinion of experts in cosmetic and plastic surgery canvassed by Mr Zeiderman during telephone conversations. Whilst it is positive that Mr Zeiderman recognised his specific lack of expertise in cosmetic surgery in effect his opinion was an amalgam of unrecorded and unnamed opinions he had personally received. We were not told what details those consulted were given or their experience and expertise. We are satisfied when he expressed concerns based on his own direct knowledge that his opinions were more reliable e.g. the classification of procedures as minor or intermediate.

Dr Sykes

64. Dr Sykes was direct in his evidence. His opinions did not vary despite persistent questioning. He has a depth of experience and relevant current responsibilities. We found his evidence cogent and credible. He addressed specific risks illustrated by particular individual incidents and the overall risk inherent in the clinical organisation and range of procedures undertaken at ABC. We attach considerable weight to his opinions.

Dr Dutta

65. Dr Dutta acknowledged that he has a history of involvement with his professional regulators. His comments were reflective to some extent. He provided explanations when asked and admitted shortcomings. We found his answers factual but there was a vagueness and apparent lack of knowledge in relation to matters such as governance and to an extent, the risks highlighted by Dr Sykes. We found his evidence credible.

Mrs Dutta

66. Mrs Dutta presented her evidence quietly. Some of her answers lacked detail and she could not identify particular documents that would support. Her evidence indicated that she has many roles within the registered organisation. We did not find her evasive but felt her evidence was limited and tentative in certain respects, perhaps reflecting her understanding of a manager's responsibilities and her own personality and style.

Findings

67. The evidence over the 4 day hearing was detailed. Much of it related to an analysis of the 2 clinical events that led to referral by the receiving hospital and 2 further events found on examination of records by CQC. There is no dispute that the events occurred or the factual circumstances. The issue is whether the explanation for these events reflects defective procedure and thus risk of harm.

68. We have carefully considered carefully each of the patient histories quoted. Mr Bebb suggested that we overlook Registered Provider identify issues although the Tribunal heard direct evidence by Dr and Mrs Dutta that the Registered Provider has not operated for some years. Whilst both parties seem content that we should overlook the issue, it is a matter of fundamental importance. The evidence is that the underlying activity is that of a company which is not registered. It follows that the evidence relied upon within the Section 31 notice might be considered evidence about the individuals involved but not of the Registered Provider. It is beyond the scope of this appeal to determine registration matters of this nature, they may fall within the scope of criminal proceedings and/or cancellation of registration. Having noted this, we find it appropriate to consider whether or not conditions upon registration are appropriate, assuming that the Registered Provider had been in operation throughout.

69. The immediate reason for CQC's consideration arises from clinical events reported by a receiving hospital. The underlying medical events seem agreed. There is little factual dispute about the drugs administered, pre-operative procedures and availability of equipment for example End Tidal CO_2 monitors. The evidence we heard largely relates to responsibility, governance and procedure and clinical management and judgement. Mrs Dutta is the registered manager and Dr Dutta is the clinical supervisor.

Patients B and C

70. The Tribunal was not in a position to fully analyse the clinical events, particularly in respect of the 3 patients who were given conscious sedation. We did not have the opportunity of hearing from the Anaesthetists save for written statements. The nature of the evidence and submissions shows there is some difference of professional views about matters such as combination therapy, depth of sedation and monitoring for example, in respect of patients B and C. We observe a

difference of professional opinion between Dr Sykes and the relevant Anaesthetist. This is compounded by later clarification of records when viewed as a desk exercise by Dr Sykes. We accept as for all procedures there will be an element of risk but are not persuaded the individual risk in these 2 procedures was such that clinical considerations fell outside the proper exercise of judgement by the Anaesthetist involved.

Patient A

71. We have considered patient A. That patient underwent a significant cardiac event. There are issues regarding the completeness of the pre-operative assessment in that it failed to identify a previous collapsed lung. This was not disclosed by the patient and emerged after the events. The procedure, Bilateral Gynecomastia is not explicitly stated in the statement of purpose or registration letter and we observe clearly had the potential for complications. In those circumstances we would expect pre-assessment to be of some rigour.

72. Taking into account the evidence we heard about the operation of the clinic, we form the view that the pre-assessment would have been routine and not of the detail required for a procedure of this nature. Accordingly, we consider there was a shortfall that placed patient A at risk and in the event, that risk materialised. This illustrates underlying breach of Regulations 12 and 15.

Patient D

73. Dr Dutta was frank in his response. He said that he had made a clinical judgement but was in error. He used the phrase “guilty as charged.” This is further demonstrated by his decision not to undertake procedures on any patient in future taking Clopidogrel. We find this highlights the inherent risk and difficulties in the provider’s procedures. The problem which materialised was that of bleeding. Whilst the risk of operating might have been appropriate in a hospital where it could be mitigated, the Registered Provider did not have facilities to reverse or meet the bleeding, such as a blood transfusion or relevant drugs. We find this a breach of Regulations 12, 15 and 17.

Management

74. Noting the evidence in respect of each of the incidents we find shortcomings in the response by Dr and Mrs Dutta. Evidence was given about future operation. The element of learning seems purely reactive to the individual events and not an overall review of procedures. By way of example, the management decision following patient D is that patients with that particular drug will not be accepted. The wider issue would be full contingency planning and thorough root cause analysis. Another example is that in relation to pre-operative assessment. We have not identified any significant changes to methodology and procedure. This is applicable to all patients and a fundamental matter to be assessed by CQC when considering Regulation 12.

75. Dr Dutta mentioned the involvement of external advisors to provide quality assurance work and advice. We were not given details of resultant changes or improvements and cannot at this stage judge whether there will be any quantitive difference in risk.

76. We gain the impression from Dr Sykes’ evidence that he considers surgical procedures of the nature under consideration are inappropriate in less than a fully

equipped and staffed hospital. We find this an ideal but looking at his reasoning, we accept his view of the raised level of risk because of the overall nature of the ABC practice model. The combination of patients requiring elective cosmetic procedures at a day clinic, the requirement that the procedures are not undertaken by general anaesthesia, the resultant need to prolong conscious sedation until such time as the procedure is complete with increasing danger and discomfort and the demanding nature of some of those procedures leads to an unusual level of risk. We find that level of risk unacceptably high.

77. Dr Dutta mentioned other clinics comparable to ABC carrying out similar procedures have not been subject to regulatory imposition. We have insufficient evidence about those clinics but we observe ABC is a private operator, it is not part of a large group and its management is, in effect, its practitioners. Against that background we are persuaded by Dr Sykes' overall judgement. We observe this overall judgement was initially informed by the clinical incidents but takes into account wider circumstances appropriate when considering the categories of procedures and anaesthesia.

Summary

78. In summary, we have found that the Registered Provider placed persons at risk of harm and will or may expose them to the risk of harm.

Conditions

79. Having reached our conclusion, it is necessary to consider whether to confirm or amend the decision imposed by CQC. We observe by the time this decision is received, the condition will have expired. We also draw attention to the relevance of any condition against the Registered Provider bearing in mind the entity operating the facility.

80. Following 78 we have not found within the evidence reasons to consider that risk to patients has since been reduced. It follows that we accept it appropriate to continue a restriction. We were invited to extend the conditions for a further 3 month period. The evidential reason given for the length of the condition was time to reflect. There has been time for reflection. In this case in the current circumstances we do not consider this is an appropriate purpose. In our view, any extension must give sufficient time for fresh procedures to be put in place and a full inspection. However, the period of 3 months was mentioned by both parties and despite some reservations that this might not be long enough and a further extension may be required. We find this appropriate.

81. We have considered the specificity of the restriction. Bearing in mind the elements of risk we determine that the condition should relate to sedation of service users. We have separately considered whether the restriction should continue in relation to use of local anaesthesia. Patient D was administered local anaesthetic only. The element of risk related to wider issues than the local anaesthetic and they continue to pertain. We accept there is a significant diminution of risk when conscious sedation is not used, nevertheless, because of our concerns regarding the overall procedures for patients' safety, we consider that prohibition should continue.

82. We have considered whether further conditions should be imposed. Bearing in mind the different nature of the risk involved in cosmetic procedures not requiring any form of local anaesthetic or sedation, we find it would be disproportionate to

impose such restrictions. We conclude the restrictions which we have stated will continue should be specified in the terms within the notice of 4 October 2019 but for a period to 4 April 2020. We judge this necessary and proportionate to the risks we have found.

83. For the above reasons, ABC's appeal is dismissed and the condition imposed upon the provider in respect of regulated activity shall continue for a further period until 4 April 2020.

Order:

84. The conditions imposed upon the Registered Provider shall be extended to 4 April 2020 in similar terms.

Judge L Bennett
Care Standards
First-tier Tribunal (Health Education and Social Care)

Date Issued: 06 January 2020