Factual accuracy check form for the draft inspection report

Complete this form and return your submission to:

- email: HSCA_Compliance@cqc.org.uk or
- post: CQC HSCA Compliance, Citygate, Gallowgate, Newcastle upon Tyne, NE1 4PA

***Inspection number**	INS2 - 11627809541
***Location/organisation ID**	1-9187031316
Location name	Diamond Skin Care, Roundwell Medical Centre

***This is on your letter with the draft inspection report. You must record these details correctly so we can identify you and consider your comments**

What does your factual accuracy challenge relate to?	Use	Select section
Typographical/numerical errors	Section A	No
Accuracy of the evidence	Section B	Yes
Additional or omitted information we should consider – 'completeness'	Section C	Yes

Completed by name (see our privacy notice)	Dr D Rallan
Position	Director and Chief Consultant
Date	02/12/21

Section A: Typographical/numerical errors in the draft inspection report

What to list here
- typographical or numerical errors

How to complete this section
- list each error on a separate line
- if the same error is repeated, identify the first time it appears and add 'throughout the report'
- provide a brief explanation of the point you wish to make and specific reference to any supporting information

Point	Hospitals only: Location or core service	Page no	Correction	For CQC use	
				Decision Yes/No/Partial	**Response**

If you wish to add more points and need extra rows, place the cursor outside of the righthand side of the last row and press enter.

Section B: Accuracy of the evidence in the draft inspection report

What to list here
- corrections to factually inaccurate evidence used in your inspection report
- this must relate to the position **at the time of your inspection**

How to complete this section
- list each correction point on a separate line
- provide a brief explanation of the point you wish to make and specific reference to any supporting information
- for each point, **you must specify exactly** where we can find the information that supports your correction

Point	Hospitals only: Location or core service	Page no	Correction	For CQC use	
				Decision Yes/No/Partial	**Response**

1.		5	This statement and all references should be removed or modified for the following reasons: Infection prevention and control is a clear policy document. Instructions on daily infection control procedures for each venue are on the wall in each clinic room and followed by all DSC staff. The document clearly outlines the precise order of daily actions for infection prevention and control. Strict COVID management protocols have been in place since the pandemic - clearly stated in our terms and conditions on the website. Also repeated in appointment confirmations sent to every single patient. Staff awaiting completion of DBS checks only work accompanied by other staff. It is not our policy to delay induction, probation or shadowed working while awaiting the checks. Once checks are complete, staff proceed beyond probation into their full role. This is not a new practice for us and there were no anomalies in the 2 recruitments fro whom we are awaiting a DBS check. Of these 2, one had started 1 week prior to the inspection. The other employee (consultant recruited from Italy) is awaiting assignment of a national insurance number without which a DBS check apparently cannot proceed.	No	B1. Thank you for your comments. The reports states: • 'The service could not evidence safety risks were assessed and managed appropriately, for example fire safety and infection prevention and control. Risk assessments had not been completed, for example where clinical staff were working and the service had not yet received a Disclosure and Barring Service check.' When asked you did not provide evidence that infection prevention and control checks were completed and documented. When asked you did not provide evidence of a documented risk assessment where clinical staff were working, and the service had not yet received a Disclosure and Barring Service check. You were not following your own policy 'Safeguarding people who use services from abuse' Section 8, 8.1, 8.2 and 8.3. Specifically, 'A written risk assessment will be carried out by Diamond Skin Care and the member of staff directly supervised in their work until the DBS check has arrived.' You have not submitted any additional supporting evidence. We confirm no changes have been made to the final report

			The report states 3 individuals did not have complete checks. This is incorrect. The correct documentation confirming clearance of the third individual has been forwarded.	Partial	or 'should' actions in relation to your comment. B2. Thank you for your comments. The report states: • 'we identified three clinical staff who had commenced work before all recruitment checks had been received, including DBS checks and two references.' To reflect your comment, we have added a sentence to this section. 'Following the inspection, the provider submitted the DBS certificate for one of these clinicians.' This change did not affect the rating for this key question. We have reviewed the remaining evidence obtained during the inspection period and judge that it still fits the ratings characteristics for the given rating.

1. 2		5	This statement and all references should be removed or modified for the following reasons: The required vaccinations are COVID vaccinations and for individuals involved in minor surgery - Hep B vaccination. All members who have successfully completed probation have up to date immunisations as per the above. Most individuals have more than the required vaccinations through their historic working experiences. These extra vaccinations e.g. MMR, OP, DTP etc maybe stored in their files but are not essential in the current setting.	No	B3. Thank you for your comments. The report states: • The service was not able to evidence staff immunisation checks were complete and up to date. When asked you did not provide evidence of up to date immunisations in the three staff files we reviewed. Two did not contain any staff immunisation information. One contained evidence of immunisation status, with a note to follow up Hepatitis B immunisation, but this had not been actioned. You have not submitted any additional supporting evidence. We confirm no changes have been made to the final report or 'should' actions in relation to your comment.

1. .4		5	Statement should be removed - factual evidence inaccurate for the following reasons; Clinical waste collection and management is provided within the terms of the venue occupation. This is understood by the term 'use of facilities'. The agreement with the venue provider allows us use of the sharps bins and clinical waste bags they provide but does not allow us our own collection schedule or arrangement with their waste collection company. There has never been disputed by any of our venue providers since 2013. DSC does not therefore require a separate contractual arrangement with a third party for clinical waste collection in the current locations.	No	B4. Thank you for your comments. The report states: • The service could not evidence appropriate arrangements were in place for the management and oversight of infection prevention and control and management of clinical waste. Information in the safe key question: • The service advised that staff at the premises disposed of their healthcare waste. The service's policy detailed that clinical waste would be identified and labelled with Diamond Skin Care clinic details for traceability. However, the service was not able to provide any assurance this was undertaken. There was no oversight of the arrangements in place at the service to ensure the management and disposal of health care waste was safe. In addition, you were not following your own policy. Diamond Skin Care Cleanliness and Infection Control policy section 2.10 and 2.12 state (in relation to the sharp's container and clinical waste bags) 'will be identified and labelled with Diamond Skin Care clinic details for traceability purposes.' Section 3.5 and 3.7 state ((in relation to the sharp's container and clinical waste bags)

					‘will be identified and labelled with the Diamond Skin Care clinic name and address for traceability purposes.’ Diamond Skin Care Safety and Suitability of premises policy states section 4 Disposal of waste. 4.2 All clinical waste will be safely disposed of in approved containers, which will be labelled and identified with the Diamond Skin Care clinic details in order to trace the waste back to its point of origin’. You have not submitted any additional supporting evidence. We confirm no changes have been made to the final report or ‘should’ actions in relation to your comment.

1. 5		5	Statement should be removed. Medical factual inaccuracy for the following reasons. Dr Rallan was the only clinician available at the inspection and was not asked any questions about medical emergencies. Administrative and non-clinical staff are not expected to handle any medical emergencies. Only the the attending clinician can make this assessment and direct support staff as required. This is clearly stated in our policy document along with the actions to be taken. Since the start of our service in 2013, there are no 'medical emergencies' on record in our service. The phrase medical emergencies is broad and vague. There are hundreds of known medical emergencies. Specific dermatological emergencies can occur but their specialised nature dictates that only clinicians should deal these and no other staff. This position was relayed by email following the inspection. Unless clarity, logic and relevance can be shown for this statement, it should be removed.	No	B5. Thank you for your comments. Report states: • Arrangements for the management of medical emergencies were not clear and staff had not all been trained to respond to medical emergencies. We have reviewed the notes made by our GP Specialist Advisor. These reflect a discussion with Dr Rallan, relating to emergency procedures. We also note the lead inspector contacted you following the inspection to clarify the arrangements in place for the management of medical emergencies. Information in the safe key question: • Arrangements for the management of medical emergencies, which included the medicines and equipment which would need to be used, were not clear. There was no risk assessment in place to inform the decision around what emergency medicines were kept by the service, and no oversight of what emergency medicines and equipment were kept at the premises. The service was not

					able to evidence what checks were undertaken at the premises to ensure these emergency medicines and equipment were in date and fit for purpose and how these could be accessed by staff. There was no process for checking the expiry dates of emergency medicines kept by Diamond Skin Care. • Staff had not all been trained to respond to medical emergencies. We reviewed three staff files and there was no evidence these staff had completed training on basic life support. The service was not able to evidence that any staff had completed basic life support training. Following the inspection, on 15 November 2021 and 17 November 2021 the provider submitted basic life support training certificates for eight members of staff. There was one staff member who did not have evidence of this training. You have not submitted any additional supporting evidence. We confirm no changes have been made to the final report or 'should' actions in relation to your comment.

1. 6		5	Statement should be removed or modified. Factual inaccuracy for the following reasons; A stock take is carried out for every single item on a fortnightly basis. Items not in date are not counted as a usable item. New stock is replenished (at least monthly) on this basis. Out of date items are therefore not in circulation but are kept aside for safe disposal (before the January stock update). The The box of punches dated Nov 2019 is a definite over site.	No	B6. Thank you for your comments. Report states: • The service did not have a process to ensure medicines and medical equipment were in date. We reviewed a sample of medicines and equipment and found some which were out of date. Information in the safe key question: • The service had processes in place for checking stock levels of medicines, including emergency medicines they provided. However, they did not have a process to ensure medicines and medical equipment were in date. We reviewed a sample of medicines and equipment and found some which were out of date. For example, we found a box of nine disposable scalpels which had an expiry date of June 2021, patch test units which had an expiry date of August 2021 and four biopsy punches which had an expiry date of November 2019. There was nothing to clearly identify the medicines and medical equipment we found during the inspection, which were out of date. These medicines and medical equipment were available for use as they had not been clearly labelled as out of date and not to be used. The associate director

					informed the inspectors that dates should be checked when stock is checked, and they confirmed this had not been done. There was no effective process in place to check expiry dates and record this had been completed. You have not submitted any additional supporting evidence. We confirm no changes have been made to the final report or 'should' actions in relation to your comment.
1.1		7	This point and all its references should be removed or modified for the following reasons; Medical factual inaccuracy Our Care and Welfare policy states that Only medical practitioners may assess patients in an emergency. This is because handling of dermatological emergencies is specialised. However, no medical staff were asked this question. Administrative and non-medical staff were questioned on the handling of medical emergencies which is not in line with our expectations or policies. The precise actions to be taken are clearly documented in the above policy which was shared with inspectors on the day. A explanation of dermatological emergencies was also provided to aid understanding following the inspection. BLS is no considered mandatory for our staff. It is provided for their own development and in appropriate circumstances, may become mandatory in the future.	No	B7. Thank you for your comments. The report states: • Staff had not all been trained to respond to medical emergencies. We reviewed three staff files and there was no evidence these staff had completed training on basic life support. The service was not able to evidence that any staff had completed basic life support training. Following the inspection, on 15 November 2021 and 17 November 2021 the provider submitted basic life support training certificates for eight members of staff. There was one staff member who did not have evidence of this training. When asked you did not provide sufficient evidence that staff had received appropriate training, or that you had

					completed a risk assessment, to keep patients safe from harm. You had not considered national guidance https://www.resus.org.uk/library/quality-standards-cpr/primary-care You have not submitted any additional supporting evidence. We confirm no changes have been made to the final report or 'should' actions in relation to your comment.

1. 4		9	This point and all its references should be removed or modified for the following reasons; Factual inaccuracy The mandatory staff training relevant to our patients ’needs is done in house via our competency frameworks. We are not sure what records were examined but progress and completion of the required competencies is recorded live with every clinical session. This applies to Phlebotomy, aseptic techniques for sterile trolley prep, preparation of cryotherapy canister amongst others. (This is stated later in the report on page 10, point 3). Knowledge and observed practice of aseptic technique for sterile trolley management and correct procedure for scrubbing for minor procedures are mandatory and the main requirements to satisfy infection control and prevention training in DSC.	No	B8. Thank you for your comments. The report states: • The service did not have up to date records of the completion of staff training. Information in the safe key question: • The Registered Manager told us they were aware of the need to ensure staff training had been completed and to ensure there was oversight of the completion of this. An external company had been sourced to provide training deemed mandatory by the Registered Manager and it was planned that staff would begin completion of this online mandatory training imminently. • The service was not able to evidence that all staff received up-to-date safeguarding and safety training appropriate to their role, for example fire safety, infection prevention and control, safeguarding children and safeguarding adults training. When asked you did not provide sufficient evidence that staff had received

					appropriate training, or that you had completed a risk assessment, to keep patients safe from harm. You have not submitted any additional supporting evidence. We confirm no changes have been made to the final report or 'should' actions in relation to your comment.

1. 6		14	This point and all its references should be removed or modified for the following reasons; Factual inaccuracy The leaders in DSC with managerial roles are as below. The line management structure is internally known and completely clear. Only 2 individuals from this list were spoken to on the inspection day. Dr D Rallan (Director and Chief Consultant), responsible for creation and keeping oversight of delivery of more than 15 clinical services as listed on the website Mrs Carolynne Ward (Associate Director), responsible for HR, accounting and finance, management of suppliers, stock control and marketing and line manager for management roles. Mrs Emily Davey (Head of Client Services), responsible for patient communications, complaints, schedule management for clinics and joint line manager for all care assistants (CAs) Mrs Anelia Mihaylova (Lead Nurse), responsible for mandatory training for all staff (Including infection prevention and control), competency framework maintenance and reviews and line manager for dermatology nurses and joint line manager for Care Assistants. Each employee (senior and junior) has a written contract with clear details of their roles and responsibilities in the post. Contracts are promptly updated whenever roles are changed or promotions made.	Partial	B9. Thank you for your comments. The report states: • Leaders were not always aware of the risks and issues relating to the quality of services. They were not always clear about their roles and accountability for these areas. They had identified some issues, although steps to address them had not been fully implemented. For example, the completion and oversight of mandatory staff training. We have amended the report to: • Leaders we spoke with did not demonstrate they were fully aware of the risks and issues relating to the safety of patients and staff. They had identified some issues, although steps to address them had not been fully implemented. For example, the completion and oversight of appropriate training to keep patients and staff safe from harm. This change did not affect the rating for this key question. We have reviewed the remaining evidence obtained during the inspection period and judge that it still fits the ratings characteristics for the given rating.

			The range of risks related to our services span areas concerning		

1. 6		14	(Contd).. A.) Use of powerful immunosuppressants and potent medications with potentially serious side effects. The specific potential issues relate to prescriptions errors, blood tests labelling and transport, misinterpretation of results, delay in results, monitoring appointments availability, interruption in medication (continuity). B.) Skin cancer screening and initial management of skin cancers. The specific potential issues relate to missing skin cancers, over diagnoses (leading to unnecessary excisions), incomplete removals, wound infection, wound dehiscence, misinterpretation of histology reports, incomplete treatments following initial management. The inspectors did not to show any awareness or knowledge of the above risks and issues. They could therefore not have known how or where to inspect for evidence of their mitigation which over time has been engrained in our operative system and processes through agile management (see below). They would not have been able to appreciate the mitigation steps of calendar integrations, template management in prescriptions and clinical notes, audit trail of results review, direct access to reporting pathologists, rapid online access to blood reports, free follow up axis, same day notes to patients and GPs, contract agreements with multiple local and national pharmacies (for minimal supply of medicines). Our scrum/sprint management system (explained to inspectors) ensures all operational issues, risks and challenges are picked up on a fortnightly		Our report reflects our findings on the day of the inspection. We will review the areas detailed here at our next inspection. You have not submitted any additional supporting evidence. We confirm no changes have been made to the final report or 'should' actions in relation to your comment. This is not part of factual accuracy. If you wish to complain about the inspection team, please see information on link given: https://www.cqc.org.uk/contact-us/how-complain/complain-about-cqc Information in the well led key question:

			basis. Not only are these communicated to the group live but solutions are decided there and then and acted upon within a 2 week period. the next scrum. Iterations continue as required. The scrum/sprint methodology of agile management is not new but assessors may be unfamiliar with it. We have very successfully adopted the principles to inform live operations, risk identification, rapid mitigation and rapid review. We believe this is a far superior method compared to older slow methods of situational management.		• Staff had a range of communication systems available. These supported for example, the smooth running of clinics, the sharing of general information about the service and reminders about tasks which need to be completed. In response to your comment about 'the scrum/sprint methodology of agile management' we have reflected this using generic terms which the public would understand. You have not submitted any additional supporting evidence. We confirm no changes have been made to the final report or 'should' actions in relation to your comment. This does not affect the rating.

1. 6		14	(Contd..) Feedback is then reported back to the group at the next scrum. The scrum/sprint methodology of agile management is not new but assessors may be unfamiliar with it. We have very successfully adopted the principles to inform live operations, risk identification, rapid mitigation and rapid review. We believe this is a far superior method compared to older slow methods of situational management.		

If you wish to add more points and need extra rows, place the cursor outside of the righthand side of the last row and press enter.

Section C: Additional or omitted information we should consider – 'completeness' in the draft report

What to list here
- additional information or information omitted from the draft report you think we should consider to inform our judgement of your service
- this must relate to the position **at the time of your inspection**

How to complete this section
- list each piece of information on a separate line
- provide a brief explanation of the point you wish to make and specific reference to any supporting information
- for each point, **you must specify exactly** where we can find the information that supports it

Point	Hospitals only: Location or core service	Page no	Additional/omitted information	For CQC use	
				Decision Yes/No/Partial	**Response**

1. 8		5	This point and all its references should be removed or clarified for the following reasons; We are a private dermatology clinic for which appointments can only be secured by full payment before attending. Enquiries made by minors are also not addressed without an adult guardian on the phone call. Correspondences are only sent to the registered legal guardian. All our on line forms and chat facility require self confirmation of age prior to direct engagement. The booking in our clinical system (writeupp) is made under the patient's name. It is not clear why an adult would pay for and bring a random minor to an appointment! Patients are called by name from a common waiting room and are fully conscious throughout any consultation or treatment. No general anaesthesia is used. Delivery of consultation or treatment to the incorrect patient is not a risk in our setting.	No	C1. Thank you for your comments. Report states: • The service did not have a system to check that an adult accompanying a child had parental responsibility and they did not check the identity of patients before offering treatment. Information in the safe key question: • The service had some systems to safeguard children and vulnerable adults from abuse. The Registered Manager advised they would not see a patient under the age of 18 without a parent/guardian being present. However, they did not have systems in place to check that an adult accompanying a child had parental responsibility. The service did not check the identify of patients before offering treatment. When asked you did not provide sufficient evidence that systems were in place to check that an adult accompanying a child had parental responsibility and to check patient's identity to keep patients safe from harm. You have not submitted any additional supporting evidence. We confirm no changes have been made to the final report or 'should' actions in relation to your comment. You have advised in your factual accuracy response, that enquiries made by minors

					are also not addressed without an adult guardian on the phone call. Staff dealing with enquiries will have contact with patients under the age of 18.

1. 11		5	This point and all its references should be removed or modified for the following reasons; Factual inaccuracy of observed activity Our daily and long term strategic infection control measures include the following. As no clinics were running at the inspected venue on the day, inspectors did not have a chance to witness the majority of the measures below. • -Alcohol wipe down of couches and chairs after each patient visit • -Wipe down of all chairs, couches, surfaces, switches and hand lights after each clinic session • -Compulsory mask use by staff in clinic environment • -Until recently, mask use was compulsory for all patients as well. This has been relaxed to allow vaccinated patients to remove the mask if they wish • -Mandatory COVID vaccination of all staff • -Transfer of majority of face to face pre-procedure consultations to telephone format to minimise close contact and crowding • -Transfer of all consent processing from paper to digital format to minimise in clinic paper and item sharing • -Alcohol cleansing of dermatoscopes before use with each patient • -Alcohol or soap based hand washing before before contacting patient skin • -Standard scrub procedure for all minor surgeries • -Use of disposable privacy gowns only • -Compulsory lateral flow testing for staff who develop any signs of COVID. Staff must also isolate and await a PCR test before returning to work	No	C2. Thank you for your comments. The report states: • The provider did not evidence they conducted safety risk assessments, for example health and safety checks. They could not evidence they had assurance that safety risks were assessed and managed appropriately, for example fire safety and infection prevention and control. They had some appropriate safety policies, however we found these did not always contain up to date information. For example, the provider advised the service was available for patients aged 12 and over. However, their Safeguarding People policy detailed they would see patients aged 0 to 12 years. Staff received some safety information from the service as part of their induction. Information in the safe key question: • There was not an effective system to manage infection prevention and control. The Registered Manager was the infection control lead. The service was not able to evidence staff had all completed infection control training, appropriate to their role. They were not able to evidence an infection control audit had been undertaken and room cleaning completed by staff was not documented. They did not have any

			• -Isolation was previously required if a close staff contact had COVID symptoms while awaiting a clear PCR test. This is now relaxed following updated guidance that contacts who are double vaccinated do not need to isolate • -Clear updated statements on our terms and conditions (website) regarding infection control measures patients are required to take • -Clear statements in the appointment confirmation emails regarding measures		assurance that appropriate arrangements were in place for the oversight of infection and prevention control undertaken at the premises. The service was not able to provide evidence that there were suitable arrangements for the management of Legionella risk associated with hot and cold-water systems (Legionella is a specific bacterium found in water supplies, which if undetected can cause ill health or death). We noted the disposable curtains in the clinic room used by Diamond Skin Care were last changed in 16 August 2018. You have not submitted any additional supporting evidence in relation to infection prevention and control. The evidence submitted was a Legionella testing certificate of four water samples tested 23 October 2020. There was no oversight of the arrangements for Legionella risk management. 10/11/2021 Email Dr Rallan: Re: Fire safety policy: 'There is no separate fire safety document but this is included in the Safety and Suitability of premises policy (outcome 10). We agree to comply with the fire safety procedures of the occupied building. On the first day, new staff are shown around

					the building including the fire assembly point. This is included in the induction schedule as 'office tour' but the induction schedule does not specifically document all building areas covered.' We have reviewed Diamond Skin Care Safety and Suitability of premises policy section 7 Fire Safety points 7.1, 7.2, 7.3 and 7.4. • Fire safety equipment and appliances are in place and tested at least once per year. • Regular liaison and communication with the building landlord is maintained with regard to fire safety. • A fire risk assessment is in place and all necessary actions addressed for the benefit of patient and staff safety. You have not submitted any additional supporting evidence in relation to oversight of the arrangements in place for fire safety for your patients and staff. We confirm no changes have been made to the final report or 'should' actions in relation to your comments.

1. 11		5	(Continued from above) Patients need to take before attending. • -Facility of phone appointments if follow up patients display possible signs of infection and are not allowed to attend clinic in person • - Service is available to all ages. However, procedures are only conducted on patients 12 and over • - Legionella occurs via inhalation of aerosolised mist containing bacterium Legionella Pneumophilla. Contaminated water sources which may produce this include air conditioners, showers, fountains, humidifiers, respiratory therapy equipment, dental equipment, whirlpool spas, water baths and ice machines. We do not utilise any such equipment in our activities and rooms. We also have no authority to independently instruct Legionella risk assessment at this or any of our locations as DSCs agreements are on a pay per session/room basis (I.e. not a tenancy or leasehold). Venue selection prior to establishing services is strictly at a location with pre-existing CQC inspections. This selection criterion which is part of the business model is a fundamental mitigation practice. Safety certificates are the contractual responsibility of the landlord/leaseholder. These have been forwarded and confirm legionella and fire risk safety. Please note that the prime infection risks in our setting are wound infection from surgical procedures and transmission of COVID whilst the pandemic remains a concern. The wound infection rate is constantly monitored through an annual rolling audit (information previously supplied).		Information in the safe key question: • For example, the provider advised the service was available for patients aged 12 and over. However, their Safeguarding People policy detailed they would see patients aged 0 to 12 years. Information in background section of report: • The service is available to both children and adults. However, surgical treatments were available to children over the age of 12 and adults only. We have undertaken a further review of Diamond Skin Care Safeguarding People Policy: • It is the policy of Diamond Skin Care to see and/or treat adult patients and also patients under the age of 18 years within the following parameters: • Patients aged 0 to 12 years – consultations and prescriptions only. • Patients aged 12 to 16 years consultations. Diagnostic/screening and prescriptions only. • Patients aged 16 years and above – consultations, diagnostic/screening, prescriptions and minor procedures only. Information submitted ‘Service is available to all ages. However, procedures are only conducted on patients 12 and over’ is contradictory to your Safeguarding people policy.

					We confirm no changes have been made to the final report or ‘should’ actions in relation to your comments.

1. 4		6	This point and all its references should be removed or modified for the following reasons; Where a direct contract exists between DSC and and a clinical waste collection provider, all bags and sharps bins would require our (DSC) labelling. At current venues, this contract is between the landlord and the collection provider who expects to see labelling tracing back to their registered client (i.e, Roundwell Medical Centre in this case). A DSC label should not appear on these bags and bins at this location. Future venues may require DSC to have an independent clinical waste collection arrangement where this policy would apply.	No	C3. Thank you for your comments. The report states: • The service advised that staff at the premises disposed of their healthcare waste. The service's policy detailed that clinical waste would be identified and labelled with Diamond Skin Care clinic details for traceability. However, the service was not able to provide any assurance this was undertaken. Please see response in section B4 as this is repeated information.
1. 10		6	This point and all its references should be removed or modified for the following reasons; Medical factual inaccuracy Management of medical emergencies is described in our Management of Medicines Policy. Emergency medicines and equipment for general medical emergencies are not kept at any of our venues. None are require with regard to the current set of services offered. The introduction of a type of allergy testing called prick testing will require that a stock of emergency medicines is kept.	No	C4. Thank you for your comments. The report states: • Arrangements for the management of medical emergencies, which included the medicines and equipment which would need to be used, were not clear. There was no risk assessment in place to inform the decision around what emergency medicines were kept by the service, and no oversight of what emergency medicines and equipment were kept at the premises. The service was not able to evidence what checks were undertaken at the premises to ensure these emergency medicines and equipment were in date and fit for

					purpose and how these could be accessed by staff. You have not submitted any additional supporting evidence. We confirm no changes have been made to the final report or 'should' actions in relation to your comment.
1. 1		9	This point and all its references should be removed or modified for the following reasons; Medical factual inaccuracy There is no known causal link between isotretinoin use and suicidal ideation. The written information supplied (official British Association of Dermatologists patient information leaflet) details all proven and unproven considerations for potential users. Patients are asked to sign confirmation that they have read and understood this leaflet prior to commencing isotretinoin. This level of safety is not widely available to patients using Isotretinoin in the UK.	Partial	C5. Thank you for your comments. The report states: • Arrangements were in place to discuss and document risks from specific treatments, however, we identified one patient who had been commenced on a medicine which can have a serious side effect, and lead to changes in mood and behaviour, although rare. There was no documentation in the patient's notes that low mood, suicidal ideas or any other mental health problems had been specifically discussed with them. We have amended the report to: • Arrangements were in place to discuss and document risks from specific treatments, however, we identified one

					patient who had been commenced on a medicine which can have a serious side effect, and lead to changes in mood and behaviour, although rare. There was a lack of detail in the patient's notes that low mood, suicidal ideas or any other mental health problems had been specifically discussed with them. We have reviewed our records. We identified one patient whose notes state under 'Management' 'Isotretinoin leaflet and advise.' This patient had a signed and dated isotretinoin consent form – oral contraceptive, which related to pregnancy risks only and not that they had read and understood the Isotretinoin patient information leaflet. This change did not affect the rating for this key question. We have reviewed the remaining evidence obtained during the inspection period and judge that it still fits the ratings characteristics for the given rating.

1. 2		9	This point and all its references should be removed or modified for the following reasons; Factual inaccuracy We have confirmed that these checks are included in the annual appraisals. Medical and nursing staff are required to undergo mandatory annual appraisal. Our appraising body (MEDSU) has confirmed that a certificate of appraisal is not granted without valid registration. The inspector and the CQC manager were uncertain on this point but we have confirmed the checks are part of the annual appraisal.	No	C6. Thank you for your comments. The report states: • Checks of registration with General Medical Council and Nursing and Midwifery Council were completed at recruitment, however there was no process to check this on an ongoing basis. Information in the effective key question: • Relevant professionals (medical and nursing) were registered with the General Medical Council (GMC)/ Nursing and Midwifery Council. Checks of registration were completed at recruitment, however there was no process to check this on an ongoing basis, as appropriate. The Registered Manager advised they planned to develop this area and have increased involvement with nurse revalidation. The report reflects accurately the findings on the day of the inspection. You have not submitted any additional supporting evidence. We confirm no changes have been made to the final report or 'should' actions in relation to your comment.

1. 14		14	This point and all its references should be removed or modified for the following reasons; Factual inaccuracy The services have been provided to the population of East Anglia (and beyond) since 2013. We have completed 8 years of service whilst doubling most years and nearly quadrupling in the last year (patient volume). This indicates a quality which our patients are happy to recommend to family and friends. Not a single incident has been recorded (albeit we are a small operation). The complaint rate is below 1% per annum, the wound infection rate is below 5%. Not a single skin cancer has been missed or inadequately treated. We have data on number of refunds and number of word of mouth recommendations along with client retention rates. In a commercial setting, these constitute quantifiable data to assess the 'quality' of a service as evidenced by the end user behaviour - inspectors did not enquire after this. We have one 1 star review and 48 5 star reviews on google reviews (Norwich) with Colchester reflecting a similar trend. There are hundreds of handwritten reviews for perusal as well as majority of our patients prefer to avoid digital display of gratitude. High quality care is reflected in the above quantitative and qualitative measures. A clear definition of 'high quality sustainable care' is required to leave this statement in the report in light of the above. If this is not a quantifiable criterion, then other contextually comparative services to ours should be quoted to exemplify what is meant by this. The above results exceed the majority of providers of dermatology in the UK as far as we are aware and are obviously not random luck. They are not	Partial	C7. Thank you for your comments. The report states: • The service focused on the needs of patients and supported them with their expectations and preferences for treatment. However, they did not have the systems and processes in place to support the delivery of high-quality sustainable care. We have amended the report to: • The service focused on the needs of patients and supported them with their expectations and preferences for treatment. However, they did not always have safe systems and processes in place. This change did not affect the rating for this key question. We have reviewed the remaining evidence obtained during the inspection period and judge that it still fits the ratings characteristics for the given rating.

			possible, sustained over an 8 year period, in our risk environment, without highly effective risk identification, mitigation, resolution		

			(contd..) and constant iteration. The data and evidence is overwhelming. Patients seek our service and chose to self pay as a last resort, (not as a first port of call) following a series of failures from other public and private sectors. Their problems are therefore complex requiring a high standard input of science, skill and service.		
1. 5		15	This point and all its references should be removed or modified for the reasons stated above	No	C8. Thank you for your comments. The report states: • Structures, processes and systems to support good governance and management were not always clear, understood and effective. The governance and management of joint working arrangements and shared services was not effective. This included arrangements for the management of medical emergencies, infection prevention and control, medicines storage and safety, and fire safety. We identified staff who had not had a completed Disclosure and Barring Service check before commencing work and no risk assessment had been completed. This did not follow the service's 'Safeguarding people who use services from abuse' policy. You have not submitted any additional supporting evidence. We confirm no changes have been made to the final report

					or ‘should’ actions in relation to your comment.
1. 6		15	This point and all its references should be removed or modified for the reasons stated above	Partial	C9. Thank you for your comments. The report states: • Staff were not all clear on their roles and accountabilities. We have amended the report to: • Leaders we spoke with did not demonstrate they were fully aware of the risks and issues relating to the safety of patients and staff. This change did not affect the rating for this key question. We have reviewed the remaining evidence obtained during the inspection period and judge that it still fits the ratings characteristics for the given rating.
1. 9		15	This point and all its references should be removed or modified for the reasons stated above. A robust system has been in place for at least 1.5 years to identify and mitigate risks, resolve issues and iterate rapidly where required.	No	C10. Thank you for your comments. The report states: • The service could not evidence they had systems and processes in place to assess, monitor and mitigate the risks relating to the health, safety and welfare of patients and others who may be at risk. For example, health and safety risk assessments and checks were not undertaken. There was no oversight that fire risk assessments had been

					undertaken and managed appropriately in the buildings where staff worked. You have not submitted any additional supporting evidence. We confirm no changes have been made to the final report or 'should' actions in relation to your comment.
1. 10		15	This point and all its references should be removed or modified for the reasons stated above	No	C11. Thank you for your comments. The report states: • There was not an effective process to identify, understand, monitor and address current and future risks including risks to patient safety. You have not submitted any additional supporting evidence. We confirm no changes have been made to the final report or 'should' actions in relation to your comment.

If you wish to add more points and need extra rows, place the cursor outside of the righthand side of the last row and press enter.