Royal Tunbridge Wells Skin Clinic Ltd

Inspection report

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This report describes our judgement of the quality of care at this service. It is based on a combination of what we found when we inspected, information from our ongoing monitoring of data about services and information given to us from the provider, patients, the public and other organisations.

Overall summary

We carried out an unannounced focused inspection at Royal Tunbridge Wells Skin Clinic Ltd on 15 July 2020 under Section 60 of the Health and Social Care Act 2008. We returned to the practice on 17 July 2020 to complete our review of records.

The service was previously inspected in November 2018, when the practice was not rated but was found to be meeting all regulations. We carried out an unannounced, focused inspection on 15 July 2020, followed by a short notice announced inspection visit on 17 July 2020, in response to information we had received with regards to concerns about the safe care and treatment of patients and governance arrangements within the service. This report covers our findings in relation to those concerns.

Royal Tunbridge Wells Skin Clinic Ltd is an independent provider of doctor-led dermatology services and the use of Botulinum toxin (Botox) injections to treat a range of medical conditions. Services are provided from dedicated premises within the centre of Royal Tunbridge Wells.

This service is registered with CQC under the Health and Social Care Act 2008 in respect of some, but not all, of the services it provides. There are some exemptions from regulation by the Care Quality Commission (CQC) which relate to particular types of regulated activities and services and these are set out in Schedule 2 of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. Royal Tunbridge Wells Skin Clinic Ltd provides a wide range of non-surgical cosmetic interventions, for example Botox injections, facial fillers and cosmetic laser treatments, which are not within CQC's scope of registration. Therefore, we did not inspect or report on those services.

The practice is registered with CQC to provide the following regulated activity: Treatment of disease, disorder or injury.

The company chairman and director is the registered manager. A registered manager is a person who is registered with CQC to manage the service. Like registered providers, they are 'registered persons'. Registered persons have legal responsibility for meeting the requirements in the Health and Social Care Act 2008 and associated Regulations about how the service is run.

Our key findings were:

- The clinic had good facilities and was equipped to treat clients and meet their needs.
- Services were offered on a private, fee paying basis only.
- Care and treatment was not always provided in a safe way for service users.
- Treatments had been carried out by a non-registered doctor, without the required clinical oversight or authorisation by a General Medical Council (GMC)registered doctor.
- Medicines were not always prescribed, administered and supplied to patients in line with legal requirements. Some patients received treatment with no valid prescription in place to support the treatment administered.
- The service did not always ensure the proper and safe storage and management of medicines.
- The provider had not undertaken an audit of infection prevention and control procedures and some infection prevention arrangements required review. Staff had not received recent training in infection prevention and control.
- Organisational policies were not always specific to the clinic and did not clearly reflect some of the processes taking place within the service.
- Clinical record keeping and consenting processes did not always clearly document treatments received.
- Staff recruitment processes were not sufficiently robust to mitigate the risks to service users and the organisation as a whole.

The areas where the provider **must** make improvements as they are in breach of regulations are:

- Ensure care and treatment is provided in a safe way to patients.
- Establish effective systems and processes to ensure good governance in accordance with the fundamental standards of care.

(Please see the specific details on action required at the end of this report).

The areas where the provider **should** make improvements are:

- Ensure that labels on all sharps bins are fully completed at the start of use and include a date and signature.
- Provide clear opportunities for staff to regularly contribute to the review of service processes and to feel supported in raising concerns.

We are mindful of the impact of the Covid-19 pandemic on our regulatory function. This meant we took account of the

Overall summary

exceptional circumstances arising as a result of the COVID-19 pandemic when considering what enforcement action was necessary and proportionate to keep people safe as a result of this inspection. We will continue to discharge our regulatory enforcement functions required to keep people safe and to hold providers to account where it is necessary for us to do so.

Dr Rosie Benneyworth BM BS BMedSci MRCGP

Chief Inspector of Primary Medical Services and Integrated Care

Our inspection team

Our inspection team comprised a CQC lead inspector and a medicines inspector.

Background to Royal Tunbridge Wells Skin Clinic Ltd

Royal Tunbridge Wells Skin Clinic Ltd is an independent provider of doctor-led dermatology services and the use of Botulinum toxin (Botox) to treat a range of medical conditions. Services are provided from dedicated premises within the centre of Royal Tunbridge Wells.

The Registered Provider is Royal Tunbridge Wells Skin Clinic Ltd.

Services are provided from:

Cobden House,

25 London Road,

Tunbridge Wells,

Kent, TN1 1DA

Opening times are Monday to Saturday 9am to 6pm and until 8pm on Wednesday and Thursday.

The service provides emergency telephone support out of hours and has a referral arrangement with a local independent GP service should additional support be required.

Services are provided by a General Medical Council (GMC) registered doctor specialising in dermatology and aesthetics, an aesthetic doctor who is a company director and the nominated individual, as well as nursing, administration and reception staff.

The provider works closely with other local services to refer patients whom it deems are outside of their scope of practice.

Patients can access services on a fee-paying basis only.

How we inspected this service

Information held by CQC about the provider was reviewed prior to our inspection.

During our visit we:

- Spoke with a range of staff, including the registered manager, a GMC-registered doctor, an aesthetic doctor and the IT director.
- Made observations of the internal and external areas of the main premises.
- Looked at information the clinic used to deliver care and treatment plans.
- Reviewed documentation relating to the clinic, including policies and procedures.

To get to the heart of patients' experiences of care and treatment, we always ask the following five questions:

- Is it safe?
- Is it effective?
- Is it caring?
- Is it responsive to people's needs?
- Is it well-led?

These questions formed the framework for the areas we looked at during the inspection.

Are services safe?

Safety systems and processes

The service did not have clear systems to keep people safe.

- The service employed one doctor who specialised in dermatology and aesthetics and who was registered with the General Medical Council (GMC). An aesthetic doctor, who was not GMC registered, provided medical laser and cosmetic injection services and some limited use of Botox to treat medical conditions such as migraines, hyperhidrosis (excessive sweating) and bruxism (teeth grinding), with authorisation and clinical oversight by the GMC registered doctor. The service provided information via their website regarding the qualifications, specialist interests and registrations of both doctors.
- The registered manager told us that despite recent restrictions and government guidance associated with COVID-19, one doctor and the registered manager had continued to provide services and treatments to some patients. Treatments had been provided during that time by the aesthetic doctor who was not registered with the GMC. The registered manager confirmed that the GMC registered doctor employed by the clinic had been absent from the service throughout that period. We reviewed patient records and found that during the period March to June 2020, eight patients had received treatment with Botox by injection, for medical conditions which included hyperhidrosis, bruxism and migraine. Treatments had been carried out by the aesthetic doctor without any clinical oversight by the GMC-registered doctor.
- Staff told us that the prescribing of Botox followed a face-to-face consultation which included medical history taking and clinical examination. A patient specific direction would then be written for the patient, which included the specific dosage prescribed and this remained valid for one year provided the medical status of the patient did not change or the required dosage did not change. However, we found that for four of those patients who had received treatment during the period March to June 2020, there was no valid prescription in place to support the administration of the injection. In all eight cases, the doctor who administered the injection had not been authorised to do so by the prescribing doctor.
- Our review of patient records also identified one patient who had undergone consultation and treatment for a skin lesion, with no clinical oversight by the GMC registered doctor and the issuing of a prescription only medicine, from the service's stock supplies, with no valid prescription.
- We reviewed processes and procedures for assessing and monitoring the risk of and preventing, detecting and controlling the spread of infection within the service. The registered manager told us that they were the lead for infection prevention and control within the clinic. We reviewed training records and found no evidence that staff had received training in infection prevention and control. The registered manager told us that no audit had been undertaken to assess the effectiveness of, or risks associated with, the service's infection prevention and control processes.
- There were some systems for managing healthcare waste, including sharps items. We saw that clinical waste disposal was available in clinical rooms which included access to clinical waste bins and sharps bins. Bins used to dispose of sharps items were signed and dated in most instances. However, we found two sharps bins which had not been signed and dated which meant that the provider could not ensure their timely removal from use. We reviewed documentary evidence and found that contractual arrangements for the collection and disposal of clinical waste from the premises, by an approved contractor, were insufficient to support the timely removal of the volume of waste generated. The registered manager confirmed that two clinical waste bags and two sharps bins were collected from the premises each month but was unable to explain how this arrangement correlated with the number of clinical waste bins and sharps bins currently in use within the premises. Outside storage facilities which provided storage for clinical waste bags awaiting collection were not fit for purpose as the lock on the container was broken.
- The registered manager told us that used vials of Botox were disposed of within orange clinical waste bin bags rather than in rigid sharps bins which would minimise the risks associated with sharps injuries to staff, service users and clinical waste contractors and ensure the safe disposal of used medicines.

Are services safe?

- There were policies and procedures in place to manage the control of substances hazardous to health (COSHH). We reviewed safety data sheets for hazardous chemicals used within the service. Storage arrangements for hazardous chemicals were appropriate and sufficiently secure to reduce the risk of unauthorised access.

Safe and appropriate use of medicines

The service did not have reliable systems for appropriate and safe handling of medicines.

- We reviewed arrangements for the safe storage and use of medicines within the service. We found that emergency medicines were stored in fridges within each treatment room, when none required storage at those temperatures. This may have impacted upon the effectiveness of those medicines and resulted in painful administration due to the cold temperature if administered in a hurry. We spoke to the registered manager and reviewed the provider's policy but were unable to confirm which staff members were deemed suitably qualified and expected to perform the task of administering those emergency medicines within the clinic. The provider was unable to provide evidence that staff had received recent training in basic life support at the time of inspection. Following our inspection, we reviewed evidence which confirmed that one doctor had undergone training in emergency first aid awareness, which included basic life support, on 20 July 2020.
- We found that fridges held daily use Botox in various treatment rooms throughout the premises. Our review of fridge temperature monitoring records confirmed that fridge temperature checks had been undertaken on a daily basis from the beginning of July 2020 but had stopped after one week. The registered manager confirmed that there had been no temperature monitoring of fridges during the period 7 July 2020 to 17 July 2020. The provider could not therefore be assured that medicines had been stored within the correct temperature range and were safe for use.
- We reviewed processes for the ordering of stock prescription only medicines within the service and spoke with the service's one prescribing doctor. We found that orders of stock medicines were placed with suppliers by members of the clinic team, confirming the quantity and product required, using the provider's account number, which referenced the prescribing doctor's GMC registration number to authenticate the order. We found however, that the prescribing doctor had no input into the ordering process and no direct oversight of the distribution and use of those medicines within the clinic.
- We reviewed the provider's medicines and prescribing policies and found that the provider had not undertaken an audit of the service's use of prescription only medicines in line with the provider's policy. The policy was not wholly relevant to the services provided, did not provide clear guidance to staff and did not clearly outline some of the processes that were taking place within the service.

Risks to patients

There were some systems to assess, monitor and manage risks to patient safety.

- The provider had developed specific COVID-19 policies and procedures and had implemented appropriate arrangements to mitigate the risks associated with patients attending the service since resuming services and their usual opening hours from 29 June 2020. The service had installed a hand-sanitising station outside of the building where visitors were required to sanitise their hands and apply a face mask before ringing a bell for assistance. Prior to being admitted to the premises, visitors were asked a series of COVID-19 screening questions and had their temperature taken by a staff member. Waiting room arrangements and carefully spaced appointment times enabled social distancing. The provider had adequate supplies of PPE and cleaning products and there were safe systems to ensure the thorough cleaning of treatment rooms and equipment in between patients. However, it was unclear what arrangements had been implemented to mitigate the risks associated with COVID-19 during the period March to June 2020 when, despite recent restrictions and government guidance associated with COVID-19, one doctor and the registered manager had continued to provide services and treatments to some patients.
- We reviewed records and confirmed there were appropriate professional indemnity arrangements in place for both doctors. We noted that the practice insurance policy had been renewed in March 2020 and included appropriate employer's and public liability insurance, premises and equipment cover.

Are services well-led?

Culture

The service did not always demonstrate a culture of high-quality sustainable care.

- We were not assured that staff were routinely supported in raising concerns or were encouraged to do so. We found that the prescribing doctor within the service had no input into the ordering process for prescription only medicines and no direct oversight of the distribution and use of those medicines within the clinic. We found that for four patients who had received treatment during the period March to June 2020, there was no valid prescription in place to support the administration of a prescription only injection. This was not in keeping with the provider's policy which staff told us ensured that a patient specific direction would be written for each patient, which included the specific dosage prescribed and that this remained valid for one year provided the medical status of the patient, or the required dosage did not change. Governance arrangements surrounding the ordering and prescribing of medicines within the service had recently undergone review in response to concerns raised by a member of staff employed by the provider for a short period of time prior to our inspection. However, it was not clear if other staff within the service, including the two doctors, had highlighted similar concerns prior to that review.
- We found that the provider had been responsive to those recent concerns raised. We reviewed the comprehensive minutes of a meeting held on 5 July 2020 to discuss prescribing practices within the service. The meeting had been attended by several members of the clinic team and an external consultant advisor. A number of agreed revisions to prescribing practices resulted from the meeting, including a reduction in the length of prescription validity to six months, the implementation of an alerting system on the patient's electronic record when a prescription was about to expire and the recruitment of a second prescribing doctor within the service to ensure full time cover.

Governance arrangements

There were not always clear responsibilities, roles and systems of accountability to support good governance and management.

- The provider had established some policies, procedures and activities to promote safety, but these were not always effective or accurate. We reviewed a range of the provider's policies which had been developed by an external compliance service. We found that some of the content within the policies was not wholly relevant to the services provided, did not provide specific guidance to staff and did not clearly outline some of the processes that were taking place within the service. For example, the provider's medicines and prescribing policies did not provide clear and specific guidance to staff on the ordering and use of prescription only medicines, medicines storage, the administration of emergency medicines and repeat prescribing processes. The policies provided guidance on caring for patients in care homes and made reference to a crash trolley, a doctor's bag and a team of 'fully trained administrative prescription clerks', none of which applied to this service and could be misleading for staff. The infection prevention and control policy made reference to patients who were treated by the practice in their own home and patients who transferred from one care setting to another which were not relevant to the services provided.
- Individual care records were not always written and managed in a way which kept patients safe. We reviewed the records relating to eight patients who received treatment during the period March to June 2020. Consent forms were in place for all eight patients. The practice used a form entitled 'Combined consultation and informed consent form for patients requesting treatment with Botulinum Toxin for cosmetic use and hyperhidrosis'. Patients who received treatment with Botox for migraines or bruxism gave their consent using the same form. The form contained comprehensive information about the uses of Botox and adverse reactions, side effects and contraindications associated with treatment. However, the specific purpose of the treatment and the patient's consent to treatment for that purpose, was not clearly indicated on the form or elsewhere in the patient's records. Clinical consultation records were scant, not always fully complete and records did not always clearly indicate a diagnosis or document details of the treatment provided.

Managing risks, issues and performance

Processes for managing risks, issues and performance were not always effective.

Are services well-led?

- The provider had failed to assess the risks to service users in enabling their access to treatments provided by one doctor who was not registered with the General Medical Council (GMC) during the period March to June 2020. The registered manager confirmed that the only GMC registered doctor employed by the clinic was absent from the service throughout that period. We reviewed patient records and found that during the period March to June 2020, eight patients had received treatment carried out by the non-registered doctor without any clinical oversight by the GMC-registered doctor. We found that for four of those patients who had received treatment by the unregistered doctor, there was no valid prescription in place to support the administration of the injection. In all eight cases the doctor who administered the injection had not been authorised to do so by the prescribing doctor. Our review of patient records also identified one patient who had undergone consultation and treatment for a skin lesion with no clinical oversight by the GMC registered doctor and the issuing of a prescription only medicine with no valid prescription.
- The provider had failed to assess, monitor and mitigate the risks to service users in the recruitment of a key staff member without undertaking required recruitment checks or risk assessment. The registered manager told us that a concern had been recently raised with the Information Commissioner's Office (ICO) in relation to a recently employed member of staff who had now left their employment. The registered manager confirmed that no recruitment checks had been completed prior to employing this person. They told us that attempts to contact the employee's previous employer had been unsuccessful. We saw evidence to confirm that one employment reference had been sought in relation to the staff member on 16 July 2020, the day following our first inspection visit to the location. Concerns raised with the ICO included the removal of confidential documents from the provider's records.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

The table below shows the legal requirements that the service provider was not meeting. The provider must send CQC a report that says what action it is going to take to meet these requirements.

Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance • The registered person had failed to 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 care and treatment provided. • The registered person had failed to maintain securely such other records as are necessary to be kept in relations to the management of the regulated activity. Written policies and procedures were not always relevant to the service, did not provide specific guidance to staff and did not clearly outline some of the processes that were taking place within the service This was in breach of regulation 17(1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

This section is primarily information for the provider

Enforcement actions

Action we have told the provider to take

The table below shows the legal requirements that the service provider was not meeting. The provider must send CQC a report that says what action it is going to take to meet these. We took enforcement action because the quality of healthcare required significant improvement.

Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment **The registered person did not do all that was reasonably practicable to assess, monitor, manage and mitigate risks to the health and safety of service users. In particular:** • Patients were treated by an unregistered doctor without the clinical oversight of a GMC-registered doctor. **The provider was unable to demonstrate effective systems and processes to ensure the safe management of medicines. In particular:** • Patient specific directions were not properly authorised. Some patients were treated without a valid prescription. • Processes for the ordering, distribution and use of stock prescription only medicines within the service lacked oversight by the prescribing doctor. • There was no process for the auditing of the service's use of prescription only medicines in line with the provider's policy. • There was a lack of risk assessment, guidance and training for staff in the storage and administration of emergency medicines. • Staff had not received training in basic life support. • Fridge temperature monitoring processes were not consistently implemented. • Medicines management and prescribing policies did not provide adequate guidance for staff. **The provider was unable to demonstrate effective systems or processes to assess the risk of, and prevent, detect and control the spread of, infections, including those that are health care associated. In particular:**

This section is primarily information for the provider

Enforcement actions

- Contractual arrangements for the collection and disposal of clinical waste from the premises were insufficient to support the timely removal of the volume of waste generated.
- Outside storage facilities for clinical waste bags awaiting collection were not fit for purpose as the lock on the container was broken.
- Used medicines vials were not disposed of in line with guidance.
- The provider had not undertaken an audit of infection prevention and control processes.
- Staff had not received training in infection prevention and control.

This was in breach of regulation 12 (1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance **The registered person had systems or processes that were operating ineffectively in that, they failed to enable the registered person to assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk. In particular:** • Patients were enabled to access medical treatments provided by one doctor who was not registered with the General Medical Council (GMC). **The registered person had systems or processes in place that were operating ineffectively, in that they failed to enable the registered person to maintain securely such records as are necessary to be kept in relation to persons employed in the carrying on of the regulated activity or activities. In particular:** • A key staff member had been recruited without undertaking any required recruitment checks or risk assessment. **This was in breach of regulation 17(1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014**