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 previously carried out a focused inspection at Royal Tunbridge Wells Skin Clinic Ltd on 15 and 17 July 2020, in response to information we had received with regard to concerns about the safe care and treatment of patients and governance arrangements within the service. We found breaches against Regulation 12 (Safe care and treatment) and Regulation 17 (Good governance) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 and issued warning notices to the provider.

We carried out this inspection of Royal Tunbridge Wells Skin Clinic Ltd, on 11 September 2020, at short notice to the provider, to confirm that the clinic was meeting the legal requirements in relation to those breaches of regulations. This report only covers findings in relation to those requirements. The service was not rated as a consequence of this inspection.

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.

At this inspection we found the practice had made some improvements including:

- Patients treated for medical conditions were treated by, or with the clinical oversight of, a GMC registered doctor.
- Revised prescribing processes promoted the safe care of patients requiring treatment involving prescription only medicines.
- There was improved oversight of the ordering and use of prescription only medicines within the clinic.
- There were safe and secure arrangements for the storage of emergency medicines.
- Processes to prevent, detect and control the spread of infection had been reviewed. Staff had undergone training in infection prevention and control.
- There were improved arrangements for managing healthcare waste, including sharps items.
- Recruitment checks were undertaken as required and in a timely manner.

We found the provider had not made sufficient improvement in providing safe services, in particular:

- Medicines which required refrigeration were not appropriately monitored to ensure their safe storage and use.
- There was a lack of risk assessment, guidance and training for staff in the administration of emergency medicines. Staff with the appropriate training were not always present within the clinic.

We took enforcement action and issued a warning notice against the provider in relation to Regulation 12(1) Safe care and treatment.

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

The areas where the provider should make improvements are:

- Arrange a clinical review of the patients treated by an unregistered doctor, by the General Medical Council (GMC) registered doctor, at their next clinic attendance.
- Document courtesy calls made, to identify any patient concerns arising from treatment by the unregistered doctor, within the patients' clinical record.

We are mindful of the impact of the Covid-19 pandemic on our regulatory function. This meant we took account of the exceptional circumstances arising as a result of the COVID-19 pandemic when considering what enforcement action was necessary and proportionate to keep people

Overall summary

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 clinic 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 clinic 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, the clinic manager 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 always have clear systems to keep people safe.

- At our previous inspection on 15 and 17 July 2020 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 were carried out by a non-registered doctor without any clinical oversight by a GMC registered doctor. 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 with no valid prescription. On 11 September 2020 we looked but could not find, records to demonstrate the practice had taken action to ensure clinical review of those patients, in order to identify any possible adverse effects of those treatments and minimise any ongoing risks to the patients. However, the registered manager confirmed that those patients had received a courtesy call from the clinic to identify any patient concerns arising from treatment which may require further clinical review. We reviewed patient records but could not find details of those calls documented within each patient's individual clinical record. However, we reviewed a separate document which listed each patient affected and noted their comments made during the calls. We found that none of the patients contacted had raised any concerns about their treatment outcomes. Our review of patient records on 11 September 2020 confirmed that patients treated for medical conditions since our last inspection, had been treated by, or with the clinical oversight of, the GMC registered doctor and with a valid prescription.
- At our previous inspection 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. This 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 eight cases, the doctor who administered the injection had not been authorised to do so by the prescribing doctor. At our inspection on 11 September 2020 we found that the provider had implemented revised processes to ensure the safe care and treatment of patients requiring treatment involving prescription only medicines. New patients were allocated an appointment with a prescriber for a full consultation and assessment before treatment. The prescriber was required to take a full medical history and assess the patient's suitability for treatment. If treatment was designated to an authorised injector, the injector was required to attend the consultation with the patient and prescriber. The injector was then required to work strictly in accordance with the patient specific direction given by the prescriber which was valid for six months from the start date. At the time of our inspection on 11 September 2020 we noted that the GMC registered doctor/ prescriber was absent from the clinic for an extended period. In order to adhere to their revised processes, the provider had ensured that no new patients who required treatments involving prescription only medicines were seen or treated during that period of absence.
- We reviewed processes and procedures in place for assessing and monitoring the risk of and preventing, detecting and controlling the spread of infection within the clinic. At our previous inspection 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. At this inspection we found that staff had completed training in infection prevention and control. A new lead for infection prevention and control had been identified. The provider had developed a revised policy document which provided updated guidance to staff. An audit of infection prevention and control processes had been initiated.

Are services safe?

- There were 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 and were not over-filled. At our previous inspection 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. At this inspection we reviewed the provider's revised contractual arrangements for the collection and disposal of clinical waste from the premises. The provider had increased the frequency of clinical waste collections and the number of units of waste collected. We found that arrangements were now appropriate to support the number of clinical waste bags and sharps bins currently in use within the premises. Outside storage facilities which provided storage for clinical waste awaiting collection had been repaired since our last inspection and were now safe and fit for purpose.
- At our previous inspection staff told us that used vials of Botox were disposed of within orange clinical waste bin bags rather than in rigid sharps bins. At this inspection we confirmed that the provider had reviewed their processes for the disposal of used vials of Botox. Used vials were now disposed of in rigid sharps bins in order to minimise the risks associated with sharps injuries to staff, service users and clinical waste contractors and ensure the safe disposal of used medicines.

Safe and appropriate use of medicines

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

- On 11 September 2020 we reviewed arrangements for the safe storage and use of medicines within the service. We found that fridges held Botox that was used daily in various treatment rooms throughout the building. Our review of fridge temperature monitoring records confirmed fridge temperature checks had been undertaken daily in the period since our previous inspection on 15 and 17 July 2020. However, clinic staff had consistently recorded temperatures outside of the minimum and maximum recommended temperature ranges in some fridges, during July 2020 and the whole of August 2020. This included the clinic's main fridge in which all Botox for injection was stored before being moved to the individual fridges. No action had been taken to rectify the temperatures recorded or to ensure the safety of the medicines in use. All of the medicines stock stored at temperatures outside of the recommended range had been used at the time of our inspection on 11 September 2020.
- At our previous inspection 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. At this inspection we found the provider had established revised arrangements for the storage of emergency medicines. We saw that a supply of emergency medicines was now stored in wall mounted, locked cabinets located in each treatment room.
- At our previous inspection on 15 and 17 July 2020 we reviewed the provider's medicines management policy. We were unable to confirm which staff members were deemed suitably qualified and expected to perform the task of administering emergency medicines within the clinic. There was a lack of risk assessment, guidance and training for staff in the administration of emergency medicines. On 11 September 2020 we found no evidence of records to demonstrate the provider had undertaken a review of guidance and processes to support the administration of emergency medicines. There remained a lack of clarity to staff on how and when emergency medicines could be used and by whom. The registered manager confirmed that there was no risk assessment in place to mitigate risks associated with emergency care arrangements when the GMC registered doctor was not present within the clinic. They told us that two aesthetic practitioners could administer emergency medicines within the clinic. However, we could not be assured that those staff were suitably trained and competent to administer emergency medicines, such as adrenaline injections, if the need arose.
- At our previous inspection 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 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. At this inspection we reviewed documented processes which enabled clinic staff to track and audit their use of Botox. Botox stock supplies were now tracked to show which supplies were administered to individual patients by injecting practitioners. Revised processes provided some assurances and oversight of the ordering and use of prescription only medicines within the clinic.

Are services well-led?

Managing risks, issues and performance

Processes for managing risks, issues and performance were effective.

- At our previous inspection on 15 and 17 July 2020 we found that 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. Patients had received treatment carried out by the non-registered doctor without any clinical oversight by the GMC-registered doctor. For some patients there was no valid prescription in place to support the treatment administered. On 11 September 2020 we found that those patients had received a courtesy call from the clinic since our last inspection, to identify any patient concerns arising from treatment which may require further clinical review. The provider had taken steps to improve processes to ensure the safe care of patients requiring treatment involving prescription only medicines. New patients were allocated an appointment with a prescriber for a full consultation and assessment before treatment. The prescriber was required to take a full medical history and assess the patient's suitability for treatment. If treatment was designated to an authorised injector, the injector was required to attend the consultation with the patient and prescriber. The injector was required to work strictly in accordance with the patient specific direction given by the prescriber which was valid for six months from the start date.
- At our previous inspection we found 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. On 11 September 2020 we reviewed the recruitment records of three new staff members employed by the clinic since our previous inspection. We found that all required checks had been undertaken at the time of recruitment. Disclosure and Barring Service (DBS) checks were undertaken where required.

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 provider was unable to demonstrate effective systems and processes to ensure the safe management of medicines. In particular:** • Medicines which required refrigeration were not appropriately monitored to ensure their safe storage and use. • There was a lack of risk assessment, guidance and training for staff in the administration of emergency medicines. **This was in breach of regulation 12 (1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.** **Warning Notice issued.**