

# 10 Harley Street

## Inspection report

10 Harley Street  
London  
W1G 9PF  
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www.botonics.co.uk

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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.

### Ratings

#### Overall rating for this location

Inadequate



Are services safe?

Requires Improvement



Are services effective?

Inadequate



Are services caring?

Good



Are services responsive to people's needs?

Good



Are services well-led?

Inadequate



# Overall summary

**This service is rated as Inadequate overall.**

The key questions are rated as:

Are services safe? – Requires improvement

Are services effective? – Inadequate

Are services caring? – Good

Are services responsive? – Good

Are services well-led? – Inadequate

We carried out an announced comprehensive inspection at 10 Harley Street on 6 July 2022 as part of our inspection programme and in response to medicines management related concerns. This service had not previously been inspected.

Mr William Green is the registered manager. A registered manager is a person who is registered with the Care Quality Commission (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.

Botonics Limited, 10 Harley Street is an independent provider and is registered with the CQC to provide diagnostic and screening procedures, surgical procedures and treatment of disease, disorder or injury in relation to cosmetic treatments where there are some exemptions from regulation by CQC. These relate to particular types of regulated activities and services and these are set out in Schedule 1 and Schedule 2 of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. The provider also provided a separate aesthetics service delivered by a clinician working in the service. This included full facial rejuvenation and anti-ageing treatments. These types of arrangements are not within CQC scope of registration; therefore, we did not inspect or report on these services.

The provider was issued with a Section 64 Information Request letter on 21 May 2021 due to concerns received by CQC in relation to their prescribing of Isotretinoin (for severe acne), which is a medicine that should only be prescribed by a specialist dermatologist or within a specialist team. This means prescribed only by a consultant dermatologist led team, prescriptions issued under the consultant's name and from a community pharmacy. The Section 64 letter contained a number of assurances the provider was asked to provide the Commission with.

There were no comment cards distributed to patients as part of this inspection and no patient interviews were carried out during the inspection. Patient feedback was found on Trustpilot online.

## **Our key findings were:**

- Staff did not have the right specialist skills to carry out their roles.
- The service did not have clear systems to keep people safe and safeguarded from abuse.
- Staff did not always have the information they needed to deliver safe care and treatment to patients.
- The prescribing systems in place were not safely managed.
- The arrangements in place for making improvements when things went wrong and learning required improvement.

# Overall summary

- We were not assured the provider always assessed needs and delivered care and treatment in line with current legislation, standards and guidance.
- The service was not actively involved in quality improvement activity.
- We saw no evidence of discrimination when making care and treatment decisions.
- Staff worked together and worked well with other organisations.
- Staff were consistent and proactive in empowering patients and supporting them to manage their own health and maximise their independence.
- The service obtained consent to care and treatment in line with legislation and guidance.
- Governance processes were not operating effectively.
- The service did not always act on appropriate and accurate information.

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 for 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:

- Consider provisions for those whose first language is not English.
- Take action to monitor the process of seeking consent appropriately prior to treatment.
- Record full complaint details to demonstrate learning from complaints.
- Implement a formal system to share meetings and implement guidance.

**Dr Sean O’Kelly BSc MB ChB MSc DCH FRCA**

Chief Inspector of Hospitals and Interim Chief Inspector of Primary Medical Services

## Our inspection team

Our inspection team was led by a CQC lead inspector, who was supported by a GP specialist advisor and a Pharmacist Specialist.

## Background to 10 Harley Street

Botonics Limited's is located at 10 Harley Street, W1G 9PF, London in the London Borough of Westminster. The registered manager operates the service full time from the headquarters and administration offices of Pump House, Plumtree Cross Lane, Itchingfield, Horsham, Sussex, RH13 0NN which is no longer registered with CQC. The provider applied to remove this address as their registered location with CQC in March 2020, as it was not a clinical location to carry out any regulated activities.

The provider is registered with the Care Quality Commission (CQC) to deliver the regulated activities of diagnostic and screening procedures, surgical procedures and treatment of disease, disorder or injury.

Services provided include dermatology, body treatments and plastic surgery. Isotretinoin treatment (a high-risk medicine used to treat severe acne) is provided by two General Medical Council (GMC) registered doctors who provide a combination of 6.5 hours at the service. Also employed are a registered mental health nurse and another GP. The provider is supported by two administration staff who are based in the Philippines.

The service is open between 9.00am and 5.00pm on Monday to Friday. The provider also provides telephone and email support seven days a week and hours vary between 10.00am and 7.00pm at the weekends and between 5.00am and 11.00pm on some weekdays. The provider's website can be accessed at [www.botonics.co.uk](http://www.botonics.co.uk)

The provider has a service level agreement with 10 Harley Street to hire a consultation room for their aesthetics service; Room 11 twice a week on Wednesday between 1:30pm and 5.30pm and Friday between 1:30pm and 5.30pm. All consultations relating to the prescribing of Isotretinoin are all fully remote.

Botonics Limited also has a service level agreement with a separate partner company that is based in Harley Street for the use of surgical theatre facilities. The separate location was not a condition of the provider's registration and the service level agreement allows Surgical Procedures to be carried out by it.

### How we inspected this service

Before the inspection, we reviewed a range of information regarding the service including their response to the Section 64 Information Request letter. During our visit, we interviewed staff, observed practice and reviewed documents.

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 therefore formed the framework for the areas we looked at during the inspection.

# Are services safe?

**We rated safe as Requires improvement because:**

- **The service did not have clear systems to keep people safe and safeguarded from abuse.**
- **Staff did not always have the information they needed to deliver safe care and treatment to patients.**
- **The prescribing systems in place were not safely managed.**
- **The arrangements in place for making improvements when things went wrong and learning required improvement.**

## **Safety systems and processes**

**The service did not have clear systems to keep people safe and safeguarded from abuse.**

- The service had some systems to safeguard vulnerable adults from abuse but improvement was required. Staff told us they could access provider policies online; however, there was no safeguarding lead or policy in the service to manage safeguarding processes. Staff told us no safeguarding incidents had occurred.
- The Registered Manager advised they did not generally provide any treatment to children under the age of 18. They told us they would see patients under 18 years of age in unusual cases when their condition was severe; however, this would be carried out with the parent or guardian present.
- On inspection we found not all staff had up to date safeguarding training relevant to their role. For example, one clinician had not received update training in the last three years. Following the inspection, we saw evidence the clinician had updated their level three safeguarding training.
- The provider could not demonstrate they had a safe or effective system in place for verifying the identity of patients in accordance with GMC guidelines. They told us they did not request patient identification on registration, or before offering treatment.
- The provider told us they carried out staff checks at the time of recruitment and Disclosure and Barring Service (DBS) checks were undertaken where required. (DBS checks identify whether a person has a criminal record or is on an official list of people barred from working in roles where they may have contact with children or adults who may be vulnerable). DBS certificates were not viewed on inspection.
- The provider had the expectation that the landlord who they rented their clinical rooms from managed infection prevention and control systems, therefore the service had no infection control lead. We were told that clinicians ensured they cleaned surfaces and equipment after each patient; however, we were not assured that all staff had received infection control training. After our inspection the service provided evidence that a staff member subsequently completed infection control training in October 2022.
- At the time of inspection and since the Covid-19 pandemic, all services related to Isotretinoin prescribing (used to treat severe acne) were provided fully online; for example, GPs carried out online consultations remotely; usually from their home. The management staff for the organisation were based in the offices of Horsham and two administration staff were based overseas in the Philippines. The location rooms were used for aesthetic services which were out of CQC scope of regulation and not assessed as part of the inspection.
- The provider expected that all GPs would conduct consultations in private and maintain the patient's confidentiality. Each GP used an encrypted, password secure laptop to log into the operating system, which was a secure programme.

## **Risks to patients**

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

- There were arrangements for planning and monitoring the number and mix of staff needed.
- There was an induction system for staff tailored to their role.

# Are services safe?

- Staff understood their responsibilities to manage emergencies and to recognise those in need of urgent medical attention. They knew how to identify and manage patients with severe infections, for example sepsis.
- When there were changes to services or staff the service assessed and monitored the impact on safety.
- The provider told us there were appropriate indemnity arrangements in place; however, we were not provided with evidence of indemnity arrangements for all staff.

## Information to deliver safe care and treatment

### **Staff did not always have the information they needed to deliver safe care and treatment to patients.**

- The service did not always have systems for sharing information with staff to enable them to deliver safe care and treatment. This was in relation to those patients who had more than one blood test, this was done at an interval of more than one month apart from when they started treatment with Isotretinoin. This was not in line with the British National Formulary (BNF) prescribing guidance and Medicines and Healthcare products Regulatory Agency (MHRA) guidance which recommended blood tests one month after commencing treatment, then three-monthly intervals. We saw two examples of this from patient records we viewed.
- Individual care records were handwritten and safely locked away. However, there was no evidence to show staff had received information governance training, including for administration staff based overseas.
- The care records we saw showed that information needed to deliver safe care and treatment was available to relevant staff in an accessible way. We saw evidence of a prescribing policy in place.
- The service had a system in place to retain medical records in line with Department of Health and Social Care (DHSC) guidance in the event that they cease trading.

## Safe and appropriate use of medicines

### **The prescribing systems in place were not safely managed.**

- There was no regular auditing of prescribing with Isotretinoin to ensure prescribing was in line with best practice guidelines for safe prescribing. One of the doctors told us they undertook prescribing audits in aesthetic practice and within the NHS but not Isotretinoin prescribing audits within the service, despite MHRA guidance.
- The provider used their own tailor-made tracker system for the prescribing of Isotretinoin.
- Although we saw that staff prescribed to patients and gave advice on medicines in line with legal requirements and current national guidance, we were not assured this was consistent practice within the service. We found evidence from online patient feedback that patients were prescribed medication for the duration of their treatment; for example, two patients reported to having been prescribed six months' worth of Isotretinoin. This was unsafe practice and against national guidelines whereby the GP would decide at each monthly check-up if a dosage adjustment was required.
- The provider told us administration staff prepared the prescriptions in line with the GP notes and they worked closely with a pharmacy that dispensed their prescriptions using an e-pharmacy system. They told us less than 2% of their patients opted for paper prescriptions.

## Lessons learned and improvements made

### **The arrangements in place for making improvements when things went wrong and learning required improvement.**

# Are services safe?

- Staff understood their duty to raise concerns and report incidents and near misses. Leaders and managers supported them when they did so.
- We did not find evidence where the service learned and shared lessons identified themes and took action to improve safety in the service. Two staff we spoke within inspection could not provide any specific examples of significant events that had occurred at the service. However, senior management were able to describe a significant event whereby there were spikes in a patient's biological markers, which led to the patient being prescribed a lower dose of medicine. There was no evidence this had been shared with the wider team, or if any significant event analysis took place.
- The provider was aware of the requirements of the Duty of Candour.
- When there were unexpected or unintended safety incident, the provider told us the service gave affected people reasonable support, truthful information and a verbal and written apology.
- The provider told us they were aware of safety alerts but there was no process to log, share and discuss as well as action safety alerts.

# Are services effective?

## We rated effective as Inadequate because:

- **We were not assured the provider always assess needs and delivered care and treatment in line with current legislation, standards and guidance relevant to their service.**
- **The service was not actively involved in quality improvement activity.**
- **Staff did not have the right specialist skills, knowledge and experience to carry out their roles.**

## Effective needs assessment, care and treatment

### The systems to keep clinicians up to date with current evidence-based practice required monitoring.

- The provider told us they had a secure and active forum for the service doctors to discuss patient issues such as, blood test results, side effects and dosage adjustment. However, there was no formal record of service meetings seen on inspection.
- Staff had access to the latest guidelines. We were told that individuals signed up for alerts on guidance and acted on them but there was no process for sharing this information with all relevant staff members and ensuring that the appropriate actions were being adopted and maintained.

### We were not assured the provider always assessed needs and delivered care and treatment in line with current legislation, standards and guidance (relevant to their service), as gaps were identified.

- We saw evidence that for six out of the 10 patient records we reviewed on inspection, clinicians prescribed Isotretinoin according to evidence-based guidance and there was evidence to show they consulted the British National Formulary (BNF) and other nationally published resources. The clinicians were able to discuss the NHS and National Institute for Health and Care Excellence (NICE) guidance in relation to undertaking blood tests prior to, during and after treatment of Isotretinoin and ensuring the dose was titrated according to BNF limits and we saw evidence of this in some of the patient records.
- However, we found areas where guidance was not being followed; for example, the clinicians were not following the MHRA guidance around the initial consultation being carried out face to face wherever possible. The provider told us all their consultations for Isotretinoin prescribing were fully online and this was because they did not want to prejudice those living close by with those living further away and they wanted to have the broadest geographical reach. However, this rationale was not in line with national guidance that gave an exception for patients at risk of Covid-19 infection.
- Patients' immediate and ongoing needs were not always assessed. Where appropriate this included their clinical needs and their mental and physical wellbeing. For example, in seven of the nine female patient records we reviewed, we found evidence of pregnancy tests provided before and during treatment but there was no evidence found in two of the nine records, which only recorded proof of contraception methods.
- When we reviewed the assessment of their mental wellbeing, we found gaps in their processes. For example, the GPs told us they carried out a psychological assessment of the patient's mental health to ensure they were stable before being taken under care due to the known psychological risks of this medicine. Patients were monitored for signs of suicidal ideation and changes in mood and behaviour at each review. However, we found appropriate action was not taken when a patient made a disclosure regarding their mental health history. For example, we found one of the 10 records we reviewed had a patient disclose a prior history of mental health problems which they were fully recovered. There was no evidence an appropriate psychiatric evaluation by a psychiatrist had been conducted on this patient prior to prescribing Isotretinoin, or that the recommended standard mental health screening tool had been implemented prior to prescribing as per recommended guidelines. Particular care needs to be taken in patients with a history of depression and the risk of psychiatric disorders for each patient should be considered as part of the benefit-risk assessment at the initial prescribing appointment and during each follow-up appointment.



# Are services effective?

- We saw no evidence of discrimination when making care and treatment decisions. The provider showed us evidence that between July 2021 and June 2022, over 1,000 patients sought Isotretinoin treatment with them. Of those patients, 29% had acne severe enough to be accepted under care for Isotretinoin therapy. For patients who were not eligible for treatment, the provider told us they were prescribed topical acne treatments where possible.

## Monitoring care and treatment

### **The service was not actively involved in quality improvement activity.**

- The service did not effectively use information about care and treatment to make improvements. When asked, we were told the service had not completed any audits such as those for prescribing or quality of records but rather used patient feedback to assess how well they were doing.

## Effective staffing

### **Staff did not have the right specialist skills to carry out their roles.**

- Although the service had registered General Medical Council (GMC) doctors, there were no consultant dermatologists working in the service to prescribe Isotretinoin as per national guidelines.
- Two GPs prescribed Isotretinoin for the service, some of which held a junior doctor post. There is no legislative requirement for Isotretinoin to be prescribed by a dermatologist on the specialist register at the GMC; however, the MHRA guidelines state Isotretinoin is to be prescribed by, or under supervision of consultant dermatologists who have expertise in the use of systemic retinoids and a complete understanding of the risks of therapy and monitoring requirements. Guidelines also state that it was not illegal for a GMC registered prescriber to prescribe Isotretinoin as long as adequate safeguards were in place. However, we were not assured of adequate safeguards in place as prescribing was not carried out under a consultant led team and prescriptions were not issued under the consultant's name. Therefore, the provider could not demonstrate that the clinicians signing the prescriptions had undergone appropriate training, or that they had the scope of practice congruent with the prescribing of this high-risk medicine.
- There was a registered mental health nurse in post; however, they were not involved in the prescribing of Isotretinoin and this was consistent with patient records we viewed on inspection.
- We found the provider website misleading in relation to stating that consultations were with a cosmetic dermatology specialist. The provider website also stated consultations and check-ups were carried out by GMC registered specialist doctors and although the doctors were indeed registered with the GMC, they were not on any specialist register. Doctors we spoke with confirmed they had no specialist skills for prescribing Isotretinoin in accordance with national guidance. This was consistent with several complaints received by CQC in relation to the lack of specialist doctors working at the service.
- Doctors we spoke with told us they had the support of all the previous doctors and dermatologists who provided the processes and policies assurance for the provider; however, there was no evidence any of these dermatologists were working in the service.
- Other relevant professionals were registered with the Nursing and Midwifery Council (NMC) and up to date with revalidation.
- The provider told us staff received annual appraisals and clinicians we spoke to received annual NHS appraisals and were up to date with their revalidation. We were not provided with evidence to support this on inspection.
- There were gaps in mandatory training including information governance and equality and diversity. Although we saw evidence where staff were provided with protected time to undertake training, we did not see a mandatory training schedule.

# Are services effective?

## Coordinating patient care and information sharing

**Staff worked together and worked well with other organisations, to deliver effective care and treatment, except for monitoring of patient care.**

- Before providing treatment, we were not assured that doctors at the service always ensured they had adequate knowledge of the patient's health, any relevant test results and their medicines history. For example, we reviewed a sample of 10 patient records from three of the prescribing GPs consultations and found four out of the 10 patient records we reviewed showed these patients had elevated cholesterol levels. However, we were not provided with any further information about what action was taken or how these patients were further monitored, or whether their NHS GP was informed. According to the prescription tracker log provided, these patients were still due to continue treatment with their Isotretinoin. This placed them at risk of harm as elevated cholesterol levels are a contraindication of this medicine.
- Patients received coordinated and person-centred care. Staff referred to and communicated effectively with, other services when appropriate. For example, the provider worked closely with a neighbouring provider carrying out laser treatment and received referrals from them. They told us 10 patients diagnosed with acne scarring had been referred to them so far for treatment.
- The provider also worked closely with a blood test laboratory to create their postal blood test kits and undertake their blood tests.
- All patients were asked for consent to share details of their consultation and any medicines prescribed with their registered GP when they used the service. We saw that clients were given documentation to give to their registered GP. The provider told us a third of their patients consented for their information to be shared with their GP.
- The provider had risk assessed the treatments they offered. They told us, if there were potential unsuitable patients, then they would not prescribe isotretinoin but offer alternative treatment.
- Where patients agreed to share their information, we saw evidence of letters sent to their registered GP in line with GMC guidance. When we requested evidence, following the inspection, the provider provided evidence of where they audited 100 random patients and found that 25% of these patients requested the service inform their GPs, compared to 75% who declined their GP being informed.
- Patient information was shared appropriately (this included when patients moved to other professional services).

## Supporting patients to live healthier lives

**Staff were consistent and proactive in empowering patients and supporting them to manage their own health and maximise their independence.**

- Where appropriate, staff gave people advice so they could self-care. This included provision of a product information brochure on the type of medicine and potential side effects.
- Where patients needs could not be met by the service, staff redirected them to the appropriate service for their needs.

## Consent to care and treatment

**The service obtained consent to care and treatment in line with legislation and guidance.**

- Staff understood the requirements of legislation and guidance when considering consent and decision making.
- The provider told us consent forms were completed prior to treatment. Patients were sent Isotretinoin treatment information and Isotretinoin patient product information brochures, which included potential side effects, -prior to their first consultation so they could provide informed consent.

## Are services effective?

- We saw evidence from patient records where consent to share treatment with GP was sought. Of the 10 patient records we reviewed, we found four had consented to sharing treatment with their GP.
- The provider told us no treatment was provided without written consent. However, we did not find evidence to show how the service monitored the process for seeking consent appropriately.

# Are services caring?

**We rated caring as Good because:**

- **Staff treated patients with kindness, respect and compassion.**
- **Staff helped patients to be involved in decisions about care and treatment.**
- **The service respected patients' privacy and dignity.**

## **Kindness, respect and compassion**

### **Staff treated patients with kindness, respect and compassion.**

- The service sought feedback on the quality of clinical care patients received.
- We did not speak to patients directly during inspection but online feedback from patients was positive about the way staff treat people. Patients were requested to provide feedback after consultation and we saw the service was rated five stars on the Trustpilot reviews. Patients were complementary about the treatment they received.
- Staff understood patients' personal, cultural, social and religious needs. They displayed an understanding and non-judgmental attitude to all patients.
- The service gave patients timely support and information.

## **Involvement in decisions about care and treatment**

### **Staff helped patients to be involved in decisions about care and treatment.**

- The provider did not have provisions in place for those whose first language was not in English. They assured us they would register with language line following the inspection.
- Staff communicated with people in a way that they could understand,

## **Privacy and Dignity**

### **The service respected patients' privacy and dignity.**

- Staff recognised the importance of people's dignity and respect.
- Where patients were required to send in pictures, we saw they were appropriately redacted so as not to protect their confidentiality.

# Are services responsive to people's needs?

**We rated responsive as Good because:**

- **The service organised and delivered services to meet patients' needs. It took account of patient needs and preferences.**
- **Patients were able to access care and treatment from the service within an appropriate timescale for their needs.**
- **Although complaint information was required, we saw evidence action was taken to resolve patient complaints.**

## **Responding to and meeting people's needs**

**The service organised and delivered services to meet patients' needs. It took account of patient needs and preferences.**

- The provider understood the needs of their patients and improved services in response to those needs. Patients were under the care of the same doctor throughout their course of treatment, including when they received their check-ups.
- Reasonable adjustments had been made so that people in vulnerable circumstances could access and use services on an equal basis to others for example, the provider described where they made provisions for a patient who was hard of hearing to communicate with them via email.

## **Timely access to the service**

**Patients were able to access care and treatment from the service within an appropriate timescale for their needs.**

- Patients had timely access to initial assessment, test results, diagnosis and treatment.
- Waiting times, delays and cancellations were minimal and managed appropriately.
- Patients with the most urgent needs had their care and treatment prioritised.
- Patients reported that the appointment system was easy to use. Service response times were within 24 hours and appointments were booked in 30-minute slots.

## **Listening and learning from concerns and complaints**

**The service took complaints and concerns seriously and responded to them appropriately to improve the quality of care; however, further information was required.**

- Information about how to make a complaint or raise concerns was available. Staff treated patients who made complaints compassionately.
- Staff told us when reporting complaints, patients were asked to write or email the service with any complaints and comments and these would be discussed at a service meeting.
- The service informed patients of any further action that may be available to them should they not be satisfied with the response to their complaint.
- The service had complaint policy and procedures in place. However, we were not assured how the service learned lessons from individual concerns, complaints and from analysis of trends. For example, we saw evidence of a complaints log which showed a timely response to patient complaints, contact with them and when the complaint was resolved and closed. However, the provider did not provide specific details of what the complaints were about; therefore, we could not make a full assessment on how learning from these complaints took place.

# Are services well-led?

**We rated well-led as Inadequate because:**

- **The service had a clear vision but the values in place did not support a credible strategy to deliver high quality care and promote good outcomes for patients.**
- **There were gaps in governance processes.**
- **There was no clarity around processes for managing risks, issues and performance.**
- **The service did not always act on appropriate and accurate information.**

## **Leadership capacity and capability;**

**Leaders had the capacity and skills to deliver high-quality, sustainable care; however, monitoring was required.**

- Leaders were knowledgeable about issues and priorities relating to the quality and future of services. They understood the challenges in relation to patient access to Isotretinoin treatment within the NHS, including where treatment was cancelled due to the Covid-19 pandemic and were addressing them by providing the service. However, we were not assured of the values in place in relation to how their services were advertised and following recommended national guidelines.
- Leaders at all levels were visible and approachable. There was a clear reporting structure with all staff having access to the registered manager, who would often hold informal discussions with the clinicians on a daily to weekly basis.
- The provider had processes to develop leadership capacity and skills.

## **Vision and strategy**

**The service had a clear vision but the values in place did not support a credible strategy to deliver high quality care and promote good outcomes for patients.**

- The provider had a clear vision of their business strategy but the values in place did not always reflect on this vision. Improvement was required to ensure they had an effective and credible strategy to promote good outcomes for their patients.
- Staff were aware of and understood the vision and their role in achieving them.

## **Culture**

**The service did not always have a culture that supported high-quality sustainable care.**

- We were not always assured that leaders and managers acted on behaviour and performance inconsistent with the vision and values. We found evidence where rulings by the Advertising Standards Agency (ASA), an external body against the provider in relation to advertising prescription only medications (POM) and the use of using 'influencers' on their website and social media to advertise Isotretinoin to the general public had not been rectified by the provider.
- We also found the practice website misleading in relation to advertising dermatology specialists where they employed GMC registered doctors only without specialist training in dermatology. They could not assure us that these doctors were part of a consultant led team who led in the prescribing of this medicine to ensure patient safety.
- Staff felt respected, supported and valued. They felt the provider was thorough and supportive to all patients.
- The service focused on the needs of patients in relation to prescribing Isotretinoin.
- Not all staff we spoke with were aware of a whistleblowing policy or arrangements but stated they would feel comfortable to raise any concerns.

# Are services well-led?

- The provider was aware of the requirements of the duty of candour.
- Staff told us they could raise concerns and were encouraged to do so. They had confidence that these would be addressed.
- There were some processes for providing all staff with the development they need. This included appraisal and career development conversations. All staff received regular annual appraisals in the last year. Staff were supported to meet the requirements of professional revalidation where necessary. Clinical staff, including nurses, were considered valued members of the team. They were given protected time for professional time for professional development and evaluation of their clinical work. However, we found gaps in mandatory training provision for staff to ensure they remained up to date with their practice.
- There was a strong emphasis on the safety and well-being of all staff.
- The service actively promoted equality and diversity. It identified and addressed the causes of any workforce inequality. Staff felt they were treated equally. However, we did not see evidence of equality and diversity training for staff.
- There were positive relationships between staff and teams.

## Governance arrangements

### There were gaps in governance processes.

- There were weaknesses in governance systems in relation to the ineffective monitoring and supervision of GPs without dermatology specialist skills when prescribing Isotretinoin.
- There were gaps in governance processes such as mandatory training procedures and health and safety risk assessments for remote workers.
- We were not assured staff were clear on their roles and accountabilities in relation to ensuring their Isotretinoin prescribing practice was carried out as per the national recommended guidelines. This included where clinicians failed to refer to psychiatrists where patients disclosed a history of mental health conditions as per the national guidance.
- Leaders told us they had established proper policies, procedures and activities to ensure safety and assured themselves that they were operating as intended. Although we saw evidence of their Isotretinoin prescribing processes, we were not shown any operational policies which included a safeguarding, clinical supervision, mandatory training policy and governance policy.
- There were robust arrangements in line with data security standards for the availability, integrity and confidentiality of patient identifiable data, records and data management systems.

## Managing risks, issues and performance

### There was no clarity around processes for managing risks, issues and performance.

- The systems to identify, understand, monitor and address current and future risks including risks to patient safety were not embedded within the practice. Although we saw documented processes in place to act on abnormal test results, clinicians did not always act on abnormal test results and this placed patients at risk of harm due to poor monitoring processes. Performance of clinical staff could not be demonstrated through documented clinical supervision, prescribing audits or formal quality improvement audits of their consultations. Identifying and acting on risk would have a positive impact on quality of care and outcomes of patients.
- Leaders did not have effective oversight over safety alerts and incidents that enabled them to share and improve their practice. Complaints provided by the provider did not provide any information on what the complaints entailed.
- Provider had a business contingency plan in place but it was not clear if this was shared with staff.

# Are services well-led?

## Appropriate and accurate information

### The service did not always act on appropriate and accurate information.

- We were not assured the provider always acted on information provided to them. We saw examples where operational information was used to ensure and monitor performance. This was in relation to the number of patients accepted for Isotretinoin treatment and how many of those patients were of childbearing age and eligible for the pregnancy prevention programme. However, there were examples where they did not act on the information that was provided to them. For example, despite an external ruling against the provider that stated prescription only medicines were not to be advertised online, the provider continued to advertise Isotretinoin treatment on their website instead of acting on this information.
- There were no quality improvement audits carried out.
- Performance information was combined with the views of patients.

## Engagement with patients, the public, staff and external partners

### The service involved patients, the public, staff and external partners to support high-quality sustainable services.

- The service encouraged and heard views and concerns from patients.
- Staff could describe to us the systems in place to give feedback.
- The service was transparent, collaborative and open with stakeholders about performance. They were open about the challenges patients faced to access Isotretinoin treatment and their growing reputation where they were trying to provide the service on a nationwide scale.

## Continuous improvement and innovation

### The systems and processes for learning, continuous improvement and innovation required monitoring.

- There was a focus on continuous learning and improvement.
- We were not assured the service made complete use of external reviews and complaints. This was in relation to their advertising standards on their website.
- It was unclear whether learning was shared and used to make improvements in relation to significant events and patient complaints.



## Requirement notices

### Action we have told the provider to take

The table below shows the legal requirements that were not being met. The provider must send CQC a report that says what action they are going to take to meet these requirements.

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	<p>Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment</p> <ul style="list-style-type: none"><li>• The provider could not demonstrate they had a safe or effective system in place for verifying the identity of patients. Patient identification was not requested on registration.</li><li>• There was also no safeguarding lead or policy in the service to manage safeguarding processes.</li><li>• There was no process in place, or evidence of process to log, discuss and share and action safety alerts.</li><li>• We were not provided with evidence of indemnity arrangements.</li><li>• The service did not always have systems for sharing information with staff to enable them to deliver safe care and treatment.</li></ul> <p><b>This was in breach of Regulation 12 (1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014</b></p>
Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	<p>Regulation 18 HSCA (RA) Regulations 2014 Staffing</p> <ul style="list-style-type: none"><li>• There were gaps in mandatory staff training. Staff had not received training in areas such as information governance, equality and diversity and health and safety training.</li></ul> <p><b>This was in breach of Regulation 18 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014</b></p>

## Enforcement actions

### Action we have told the provider to take

The table below shows the legal requirements that were not being met.

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	<p>Regulation 17 HSCA (RA) Regulations 2014 Good governance</p> <ul style="list-style-type: none"><li>• We were not assured the provider always assessed needs and delivered care and treatment in line with current legislation, standards and guidance. This was in relation to lack of face to face consultations, actioning of abnormal test results and taking further action where patients disclosed a history of mental health problems, where blood tests identified high cholesterol.</li><li>• The service was not actively involved in quality improvement activity, such as auditing prescribing or treatment.</li><li>• There was no baseline face to face consultations as per national guidance.</li><li>• Staff did not have the right specialist skills to carry out their roles. The provider's website was misleading in relation to stating that consultations were with a cosmetic dermatology specialist. The provider website also stated consultations and check-ups were carried out by GMC registered specialist doctors and although the doctors were indeed registered with the GMC, they were not on any specialist register.</li><li>• There was no evidence of interaction with a patient's NHS GP when blood test results were outside of normal ranges, in particular high cholesterol.</li></ul> <p><b>This was in breach of Regulation 17 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014</b></p>