Announced Inspection Report: Independent Healthcare

Service: Sapphire Clinics (Central) Ltd, Stirling
Service Provider: Sapphire Clinics (Central) Ltd (online inspection)

23 November 2021
Healthcare Improvement Scotland is committed to equality. We have assessed the inspection function for likely impact on equality protected characteristics as defined by age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex, and sexual orientation (Equality Act 2010). You can request a copy of the equality impact assessment report from the Healthcare Improvement Scotland Equality and Diversity Advisor on 0141 225 6999 or email his.contactpublicinvolvement@nhs.scot
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1 A summary of our inspection

The focus of our inspections is to ensure each service is person-centred, safe and well led. Therefore, we only evaluate the service against key quality indicators which apply across all services. However, depending on the scope and nature of the service, we may look at additional quality indicators.

About our inspection

We carried out an announced inspection to Sapphire Clinics (Central) Ltd on Tuesday 23 November 2021. The service offers treatment with cannabis-based medicinal products (CBMPs). Most CBMPs are unlicensed medicines in the UK. Treating patients with unlicensed medicines poses a higher risk than treating patients with licensed medicines, because unlicensed medicines may not have been assessed for safety, quality and efficacy (how successfully a medicine produces an intended result). There is a limited evidence base to support the use of unlicensed CBMPs. A patient may only be prescribed an unlicensed CBMP to treat an appropriate health condition if a referral is made by a hospital, GP or as a self-referral to a relevant specialist doctor on the General Medical Council’s (GMC) Specialist Register. The prescribing restrictions set out in legislation also ensures that access to these medicines is available to patients with clinical needs that cannot be met by licensed medicines while minimising the risk of misuse, harm and illegal supply.

We spoke with a number of staff during the inspection during an online video-conferencing call. We received feedback from 17 patients through an online survey we had asked the service to issue for us before the inspection. This was our first inspection to this service.

The inspection team was made up of one inspector and two clinical experts from Healthcare Improvement Scotland.

We did not request a self-evaluation from the service before the inspection.
What we found and inspection grades awarded

For Sapphire Clinics (Central) Ltd, the following grades have been applied to the key quality indicators inspected.

### Key quality indicators inspected

| Domain 5 – Delivery of safe, effective, compassionate and person-centred care | Quality indicator | Summary findings                                                                                                                                                                                                                                                                                                                                 | Grade awarded |
|---|---|---|---|---|
| 5.1 - Safe delivery of care | Processes were in place to ensure medicines were prescribed in line with current legislation and guidance. Appropriate safeguards were in place to minimise risks to patients. A range of policies and procedures helped the service to ensure care was delivered safely. The service’s medicines and prescribing policies should be updated to reflect its current practice. Action plans following audits should be produced. | ✔️ Good |

| Domain 9 – Quality improvement-focused leadership | Quality indicator | Summary findings                                                                                                                                                                                                                                                                                                                                 | Grade awarded |
|---|---|---|---|---|
| 9.4 - Leadership of improvement and change | The service demonstrated a patient-centred and proactive approach to measuring its performance and improving quality. Structures, processes and systems were in place to support good clinical governance. Healthcare Improvement Scotland must be notified of certain events, as detailed in Healthcare Improvement Scotland’s notification guidance. | ✔️ Good |
The following additional quality indicators were inspected against during this inspection.

### Additional quality indicators inspected (ungraded)

<table>
<thead>
<tr>
<th>Domain 5 – Delivery of safe, effective, compassionate and person-centred care</th>
<th>Quality indicator</th>
<th>Summary findings</th>
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<tr>
<td>5.2 - Assessment and management of people experiencing care</td>
<td>All relevant consultation and assessment information was clearly documented in the patient care record, and ongoing monitoring of patients was taking place. Information about each treatment was available for patients.</td>
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<tr>
<th>Domain 7 – Workforce management and support</th>
<th>Quality indicator</th>
<th>Summary findings</th>
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<td>7.1 - Staff recruitment, training and development</td>
<td>Policies were in place for the recruitment, induction and training of staff. Job-specific induction training and continued training and development for staff was in place. However, all relevant pre-employment safety checks must be completed, and documented, before staff start working in the service.</td>
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Grades may change after this inspection due to other regulatory activity. For example, if we have to take enforcement action to improve the service or if we investigate and agree with a complaint someone makes about the service.

More information about grading can be found on our website at: [http://www.healthcareimprovementscotland.org/our_work/inspecting_and_regulating_care/ihc_inspection_guidance/inspection_methodology.aspx](http://www.healthcareimprovementscotland.org/our_work/inspecting_and_regulating_care/ihc_inspection_guidance/inspection_methodology.aspx)

Further information about the Quality Framework can also be found on our website at: [https://www.healthcareimprovementscotland.org/our_work/governance_and_assurance/quality_of_care_approach/quality_framework.aspx](https://www.healthcareimprovementscotland.org/our_work/governance_and_assurance/quality_of_care_approach/quality_framework.aspx)
What action we expect Sapphire Clinics (Central) Ltd to take after our inspection

This inspection resulted in three requirements and three recommendations. Requirements are linked to compliance with the National Health Services (Scotland) Act 1978 and regulations or orders made under the Act, or a condition of registration. See Appendix 1 for a full list of the requirements and recommendations.

An improvement action plan has been developed by the provider and is available on the Healthcare Improvement Scotland website: [www.healthcareimprovementscotland.org/our_work/inspecting_and_regulating_care/independent_healthcare/find_a_provider_or_service.aspx](http://www.healthcareimprovementscotland.org/our_work/inspecting_and_regulating_care/independent_healthcare/find_a_provider_or_service.aspx)

Sapphire Clinics (Central) Ltd, the provider, must address the requirements and make the necessary improvements as a matter of priority.

We would like to thank all staff at Sapphire Clinics (Central) Ltd for their assistance during the inspection.
2 What we found during our inspection

Service delivery

This section is where we report on how safe the service is.

Domain 5 – Delivery of safe, effective, compassionate and person-centred care

High performing healthcare organisations are focused on safety and learning to take forward improvements, and put in place appropriate controls to manage risks. They provide care that is respectful and responsive to people’s individual needs, preferences and values delivered through appropriate clinical and operational planning, processes and procedures.

Our findings

Quality indicator 5.1 - Safe delivery of care

Processes were in place to ensure medicines were prescribed in line with current legislation and guidance. Appropriate safeguards were in place to minimise risks to patients. A range of policies and procedures helped the service to ensure care was delivered safely. The service’s medicines and prescribing policies should be updated to reflect its current practice. Action plans following audits should be produced.

The service followed strict protocols for the prescribing of unlicensed cannabis-based medicinal products (CBMPs). Patients were only prescribed an unlicensed CBMP to treat an appropriate health condition if a referral was made by a hospital, GP or as a self-referral to a relevant specialist doctor on the General Medical Council’s (GMC) Specialist Register. We were told the majority of prescriptions were for chronic pain, neuropathic pain (pain in the nervous system), generalised anxiety disorder and fibromyalgia (a condition that causes widespread pain and extreme tiredness).

Patients were required to provide photo identification when a consultation was requested. All consultations took place by video call allowing the doctor to verify essential personal information about the patient such as name, address and date of birth. This helped to minimise any risk of medicines being prescribed to the wrong person.

Controlled drugs are medications that require more strict control, such as some types of painkillers. The service did not store CBMP supplies on site. We were told the private prescription blank pads for this category of controlled drugs were held securely by the service’s chief pharmacist. This was to ensure...
governance over the controlled drug process. For each individual prescription, and following a multidisciplinary team meeting, the chief pharmacist then sends an individual prescription to the prescriber within the service to sign. Completed prescriptions were then delivered directly to a CBMP pharmacy supplier (registered importer of CBMPs with a closed pharmacy service which is not open to the public). These pharmacy suppliers were then responsible for dispensing the CBMP supply to patients by registered post.

An adult support and protection policy was in place. Staff told us they would not prescribe CBMPs if sufficient information was not provided from the patient, their GP or if, after assessment, treatment was deemed unsuitable for their needs. We saw examples of communication between the doctor and patients where the treatment had been declined.

The service used spreadsheets to record any accidents, incidents or adverse events that had occurred, such as medication prescribing errors. Any incidents that had occurred had been dealt with by the service, in line with its own policies. We saw evidence that any learning or changes in practice to be taken forward had been clearly documented on the spreadsheet. We saw that each incident was reviewed, with documented evidence of resolution and/or action taken to prevent any similar incidents from occurring.

A range of policies and procedures were in place to help the service deliver care safely for patients and staff. A programme of regular review helped to make sure policies and procedures were kept up to date. Any changes in legislation and best practice guidance were shared with relevant staff members. A risk register and risk assessments were in place.

We saw evidence of audits being carried out with any resulting improvements identified and taken forward. This included:

- an annual audit of prescription and medicines management
- patient care records audited every 6 months, and
- clinical outcomes and adverse events reviewed every year.

The service also formally reviewed any complaints and patient feedback received. Where areas for improvement were identified, we saw that appropriate action was taken. Audit results were discussed at relevant governance groups and information shared with staff.
**What needs to improve**

Although we were assured that appropriate procedures were undertaken around medicine management and prescribing, the service’s medicines and prescribing policies did not adequately reflect current guidance or current practice.

Non-medical prescribers, such as a pharmacist prescriber, may take over the responsibility for prescribing under a shared care protocol once a patient has been stabilised. The service’s medicines and prescribing policies should include reference to the shared care arrangements that allows non-medical prescribers in the service to prescribe CBMP and describe how the arrangement works in practice.

Staff were able to explain the prescribing process from the initial decision to prescribe through to delivery of the CBMP supply to the patient. However, we found this was not clearly described that in the medicines and prescribing policies including:

- the roles and responsibilities of each person involved in the process
- how the prescription is delivered to the prescriber
- how a handwritten signature is obtained from the prescriber
- how the prescription is delivered to the pharmacy, and
- how the CBMP supply is delivered to the patient (recommendation a).

Although we saw that audits were being completed and actions taken to make improvements, we saw no evidence of action plans that formally documented the improvement work identified, who was taking forward the work and the timescales for completion (recommendation b).

- No requirements.

**Recommendation a**

- The service should ensure that the medicines and prescribing policies are updated to detail:
  a) the process in place for the use of non-medical prescribers under a shared care protocol, and
  b) the process followed from the initial decision to prescribe through to the delivery of a CBMP supply to the patient, to include the generation of patient-specific paper prescriptions and their delivery either to a pharmacy or a patient.

**Recommendation b**

- The service should produce action plans to address issues that have been identified from any audits.
**Our findings**

**Quality indicator 5.2 - Assessment and management of people experiencing care**

All relevant consultation and assessment information was clearly documented in the patient care record, and ongoing monitoring of patients was taking place. Information about each treatment was available for patients.

The patient consultation only took place once the doctor had received a ‘summary of care’ record from the patient’s GP.

We reviewed five patient care records. We found clear records that documented the patient journey from initial consultation and assessment through to the supply of CBMP delivered to the patient. We saw evidence in those records reviewed that patients who had received treatment had clinical needs that had not been met by licensed medicines. We also saw patient consent recorded showing that patients were happy for the service to contact their GP to obtain relevant information about them. If consent was not given, patients would not be treated with CBMPs.

Generally, patients received one month supply of CBMP. Further prescriptions required additional consultations. We saw evidence of ongoing monitoring of patients through video calls in the patient care records reviewed. This was to assess the patient’s response and check how they were managing side-effects.

Patients were directed to information about their treatment through patient information leaflets, videos, workshops and a frequently asked questions section on the service’s website. This was particularly important as administration of CBMPs can be more challenging than conventional treatments, for example the need to use vaporisers or very small volumes of cannabis oils.

The service’s patient information leaflet provided to each new patient states that the products are unlicensed and that the clinician will discuss the unlicensed nature of the medicine and explain the side-effects with the patient.

The majority of patients who responded to our survey told us they had received adequate information, including benefits and risks of treatment and expected outcomes. They also stated they had been involved in decisions about their care and treatment and were given sufficient time to reflect on treatment options before making a decision.
We saw that patients were required to provide their GP details so that the prescriber could share information with them. We saw evidence of information being shared between the service and patients’ GPs.

Patient care records were held on the server of the service’s custom-built IT system. A privacy policy had been developed and was available on the service’s website. This ensured patients knew what information and data was kept. Role-based access control to the database was in place to minimise the risk of unauthorised access to confidential information about patients.

- No requirements.
- No recommendations.

**Domain 7 – Workforce management and support**

High performing healthcare organisations have a proactive approach to workforce planning and management, and value their people supporting them to deliver safe and high quality care.

**Our findings**

**Quality indicator 7.1 - Staff recruitment, training and development**

Policies were in place for the recruitment, induction and training of staff. Job-specific induction training and continued training and development for staff was in place. However, all relevant pre-employment safety checks must be completed, and documented, before staff start working in the service.

The service had a recruitment and selection policy, induction policy, and a learning and people development policy.

Corporate and job-specific induction checklists were used to record staff induction training. Each staff member completed a ‘day one’ induction. This included topics such as human resources policies and procedures, essential elements of health and safety, fire safety, and a schedule of meetings and visits. An organisational induction took place over 4 weeks and included key topic areas, meetings with key personnel and an invite to an induction training day.

One-to-one meetings with staff were in place to support individuals through induction. These were held every week and at the end of the individual’s probationary period. Learning needs were discussed and recorded in a personal development plan. Each staff member participated in an annual appraisal.
Each staff member had an ongoing training plan which included mandatory training topics such as information governance, fire safety, and health and safety.

Each clinical staff member’s training plan included additional training topics such as:

- public protection (safeguarding) adults and children, completed every 3 years
- infection prevention and control completed every 3 years, and
- basic life support, resuscitation and first aid completed every 2 years.

We reviewed three files for staff employed in the service. We saw that each staff member had a contract of employment in place. We saw that some background safety checks had been completed, including identity and reference checks.

We also reviewed two files of staff members that had a consultant agreement in place. Staff with consultant agreements are not employed directly by the provider but given permission to work in the service. We saw that each consultant had a contract in place with the provider that set out the responsibilities of both parties in the agreement. We saw that some background safety checks had been carried out, for example identity checks, reference checks and indemnity insurance checks.

**What needs to improve**

The service provided us with a spreadsheet containing the reference numbers of the Disclosure Scotland Protecting Vulnerable Groups (PVG) checks that had been completed for clinical staff. However, it was not clear from this record who had carried out the checks, the date it had been completed, or whether the individuals could work with protected adults or children. For two staff members that were employed to work in the service, we saw no record of Disclosure Scotland background checks completed (requirement 1).

Although we saw some evidence of background safety checks completed for staff with consultant agreements, we saw no evidence of professional registration checks, copies of qualifications, proof of immunisation status or a copy of the individual’s annual appraisal from their substantive NHS post. For one staff member employed to work in the service, we saw no evidence of professional registration checks completed (requirement 2).
We saw no evidence of ongoing professional registration checks being completed for staff that had been granted consultant agreements (recommendation c).

**Requirement 1 – Timescale: by 1 March 2022**
- The provider must ensure that all staff roles are risk assessed to make sure that appropriate Disclosure Scotland background safety checks are completed before staff start working in the service.

**Requirement 2 – Timescale: by 1 March 2022**
- The provider must ensure that all staff working in the service have appropriate, and documented, safety checks completed.

**Recommendation c**
- The service should ensure that an annual professional registration check is completed and recorded for all relevant staff working in the service.
Vision and leadership

This section is where we report on how well the service is led.

Domain 9 – Quality improvement-focused leadership

High performing healthcare organisations are focused on quality improvement. The leaders and managers in the organisation drive the delivery of high quality, safe, person-centred care by supporting and promoting an open and fair culture of continuous learning and improvement.

Our findings

Quality indicator 9.4 - Leadership of improvement and change

The service demonstrated a patient-centred and proactive approach to measuring its performance and improving quality. Structures, processes and systems were in place to support good clinical governance. Healthcare Improvement Scotland must be notified of certain events, as detailed in Healthcare Improvement Scotland’s notification guidance.

We saw that a quality assurance programme had been developed and implemented. This included:

- a number of multidisciplinary team meetings each week
- regulatory compliance meetings twice a week
- weekly management meetings
- weekly operations meetings
- a compliance audit programme, and
- a clinical and research audit programme.

Multidisciplinary team meetings were held each week to discuss individual patient case reviews including recommendations for the suitability for treatment with cannabis-based medicines. This meeting was also used to disseminate and discuss clinical and non-clinical governance matters.

Management meetings were used to discuss areas such as strategy, recruitment, complaints, education, training, partnerships and feedback. The weekly operations meeting was held to discuss operational and day-to-day aspects of running and managing the service.
The service engaged with staff in a variety of ways, including through staff clinical meetings, case-based discussions, multidisciplinary team meetings, journal clubs and group meetings. Staff were valued and given opportunities to lead and develop in the organisation. We saw recent examples where staff had been supported to develop, resulting in promotion into new roles.

A staff survey had recently been completed. We saw that a formal review of the feedback had been completed, with actions identified. The latest survey identified that lines of communication could be improved, particularly due to current home working arrangements. In response to feedback from staff, the service had introduced a monthly staff meeting to discuss what was going well, what could be improved and priorities for the next month.

Staff successes were celebrated through a staff recognition programme, special recognition awards and staff virtual celebrations. For example, the team celebrated promotions, progress and positive feedback, and a staff member had been awarded the first special recognition award.

The provider had developed and implemented a quality improvement plan. This focused on the service’s contribution to research with the collection of outcomes in patients prescribed CBMPs. The service had established the UK Medical Cannabis Registry which supported this work.

The service took part in ‘Grand Rounds’ with an international clinic where interesting and complex cases for multidisciplinary team teaching and learning were presented. This provided the opportunity to benchmark clinical care at the service against leading organisations and clinicians in countries with greater experience of medical cannabis treatments. We saw that this had resulted in improvements in process and individual patient outcomes.

The provider had established the Society of Cannabis Clinicians UK Chapter and hosted or took part in monthly committee meetings and international peer discussions.

The service had introduced a peer support network for Scottish patients with a small number of patients so far participating. The service told us about the positive feedback received from patients about their experiences of the network.

It was clear that leadership, governance and culture in the service was used to drive and improve the delivery of high-quality person-centred care.
What needs to improve
Healthcare Improvement Scotland’s notifications guidance is a list of specific events and circumstances which services are required to report to Healthcare Improvement Scotland. We saw there had been medication prescribing errors recorded on the service’s incident tracker spreadsheet. Healthcare Improvement Scotland had not been formally notified of these events (requirement 3).

Requirement 3 – Timescale: immediate
- The provider must notify Healthcare Improvement Scotland of specific events that occur, as detailed in Healthcare Improvement Scotland’s notifications guidance. This must include any retrospective notifications.
- No recommendations.
Appendix 1 – Requirements and recommendations

The actions that Healthcare Improvement Scotland expects the independent healthcare service to take are called requirements and recommendations.

- **Requirement**: A requirement is a statement which sets out what is required of an independent healthcare provider to comply with the National Health Services (Scotland) Act 1978, regulations or a condition of registration. Where there are breaches of the Act, regulations, or conditions, a requirement must be made. Requirements are enforceable at the discretion of Healthcare Improvement Scotland.

- **Recommendation**: A recommendation is a statement that sets out actions the service should take to improve or develop the quality of the service but where failure to do so will not directly result in enforcement.

### Domain 5 – Delivery of safe, effective, compassionate and person-centred care

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<th>Recommendations</th>
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| a  | The service should ensure that the medicines and prescribing policies are updated to detail:  
|   | a) the process in place for the use of non-medical prescribers under a shared care protocol, and  
|   | b) the process followed from the initial decision to prescribe through to the delivery of a CBMP supply to the patient, to include the generation of patient-specific paper prescriptions and their delivery either to a pharmacy or a patient (see page 10). |
|   | Health and Social Care Standards: My support, my life. I have confidence in the organisation providing my care and support. Statement 4.11 |
| b  | The service should produce action plans to address issues that have been identified from any audits (see page 10). |
|   | Health and Social Care Standards: My support, my life. I have confidence in the organisation providing my care and support. Statement 4.19 |
## Domain 7 – Workforce management and support

### Requirements

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<th>Description</th>
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| 1           | The provider must ensure that all staff roles are risk assessed to make sure that appropriate Disclosure Scotland background safety checks are completed before staff start working in the service (see page 14).  

**Timescale** – by 1 March 2022  

*Regulation 9(2)*  
*The Healthcare Improvement Scotland (Requirements as to Independent Health Care Services) Regulations 2011*** |
| 2           | The provider must ensure that all staff working in the service have appropriate, and documented, safety checks completed (see page 14).  

**Timescale** – by 1 March 2022  

*Regulation 8*  
*The Healthcare Improvement Scotland (Requirements as to Independent Health Care Services) Regulations 2011*** |

### Recommendation

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| c              | The service should ensure that an annual professional registration check is completed and recorded for all relevant staff working in the service (see page 14).  

Health and Social Care Standards: My support, my life. I have confidence in the organisation providing my care and support. Statement 4.24 |
### Domain 9 – Quality improvement-focused leadership

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<td><strong>3</strong> The provider must notify Healthcare Improvement Scotland of specific events that occur, as detailed in Healthcare Improvement Scotland’s notifications guidance. This must include any retrospective notifications (see page 17).</td>
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Timescale – immediate

*Regulation 5(1)(b)*

*The Healthcare Improvement Scotland (Applications and Registration) Regulations 2011*

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Appendix 2 – About our inspections

Our quality of care approach and the quality framework allows us to provide external assurance of the quality of healthcare provided in Scotland.

Our inspectors use this approach to check independent healthcare services regularly to make sure that they are complying with necessary standards and regulations. Inspections may be announced or unannounced.

We follow a number of stages to inspect independent healthcare services.

Before inspections

Independent healthcare services submit an annual return and self-evaluation to us.

We review this information and produce a service risk assessment to determine the risk level of the service. This helps us to decide the focus and frequency of inspection.

During inspections

We use inspection tools to help us assess the service.

Inspections will be a mix of physical inspection and discussions with staff, people experiencing care and, where appropriate, carers and families.

We give feedback to the service at the end of the inspection.

After inspections

We publish reports for services and people experiencing care, carers and families based on what we find during inspections. Independent healthcare services use our reports to make improvements and find out what other services are doing well. Our reports are available on our website at: www.healthcareimprovementscotland.org

We require independent healthcare services to develop and then update an improvement action plan to address the requirements and recommendations we make.

We check progress against the improvement action plan.

More information about our approach can be found on our website: www.healthcareimprovementscotland.org/our_work/governance_and_assurance/quality_of_care_approach.aspx
Complaints

If you would like to raise a concern or complaint about an independent healthcare service, you can complain directly to us at any time. However, we do suggest you contact the service directly in the first instance.

Our contact details are:

Healthcare Improvement Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh
EH12 9EB

Telephone: 0131 623 4300

Email: his.ihcregulation@nhs.scot