

## Apodi Healthcare Limited

# Apodi Healthcare Limited

### Inspection report

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## Overall summary

We carried out an announced comprehensive inspection on 8 January 2018 to ask the service the following key questions; Are services safe, effective, caring, responsive and well-led?

### **Our findings were:**

#### **Are services safe?**

We found that this service was not always providing safe care in accordance with the relevant regulations.

#### **Are services effective?**

We found that this service was providing effective care in accordance with the relevant regulations.

#### **Are services caring?**

We found that this service was providing caring services in accordance with the relevant regulations.

#### **Are services responsive?**

We found that this service was providing responsive care in accordance with the relevant regulations.

#### **Are services well-led?**

We found that this service was providing well-led care in accordance with the relevant regulations.

### **Background**

We carried out this inspection under Section 60 of the Health and Social Care Act 2008 as part of our regulatory functions. This inspection was planned to check whether the service was meeting the legal requirements and regulations associated with the Health and Social Care Act 2008.

This was the first inspection undertaken at this service.

Apodi Healthcare Limited provide care to patients via NHS services both in the community and hospital outpatient care. They support patients receiving medicines under specific programmes sponsored by the pharmaceutical industry. The programmes are negotiated directly between NHS providers and the pharmaceutical companies, and the latter offer Apodi Healthcare Limited's services to NHS providers to undertake the monitoring and support of patients on these programmes. The prescribing of the medicines under the programmes is undertaken only by NHS services and this is usually by consultants in NHS Acute Hospital Trusts. The provider monitors patients during treatments and this may include initiation and titration (a process of determining the correct dosage for medicines). Patients may continue on the medicines under the care and monitoring of hospital doctors or their GPs.

# Summary of findings

The programmes the provider were supporting at the time of the inspection were medicines for the treatment of heart failure, prostate cancer and multiple myeloma. In addition the service provided phone support for oncology and rheumatoid arthritis patients.

The clinical staff providing care were all registered nurses who had nurse managers overseeing their work. The nursing staff worked within community and hospital settings and the NHS services prescribed the medicines. Nursing staff from Apodi Healthcare Limited were inducted into the service where they would work in the same way as employed staff. Alongside this there were staff training and checks provided by Apodi Healthcare Limited. Patient monitoring data resulting from tests undertaken by the provider's staff were recorded directly onto the NHS services patient records within the NHS services records. Anonymised data regarding the number of patients receiving the medicines and audits during the period they were initiated onto the medicines, were sent to the pharmaceutical companies. Information was provided to patients to ensure this was understood by those receiving care under the programmes.

The provider had no premises from which they provided care. They had a head office from which the regulated activities were managed and where they locate their patient phone support service.

## **Our key findings were:**

- The provider had systems in place to identify and learn from clinical practice in order to improve services where necessary.
- Most risks associated with the provision of services were well managed. However, infection control processes should be reviewed.
- The provider did not have an appropriate system for ensuring any information related to medicine alerts was always acted on.
- The necessary checks required on staff who provided care were in place.
- Patients received full and detailed explanations of treatment including information enabling informed consent.
- The service was caring, person centred and compassionate.
- There were processes for receiving and acting on patient feedback.
- There were appropriate governance arrangements in place. The provider ensured clinicians maintained an up to date knowledge in their specialism and undertook relevant training and revalidation.
- There were systems in place to respond to incidents and complaints.

There were areas where the provider could must make improvements:

- Ensure care and treatment must be provided in a safe way for service users.

There were areas where the provider could make improvements and should:

- Review infection control processes including the potential need for audit and processes.
- Review the means by which patients individual requirements and preferences are respected and met in terms of the Equalities Act 2010 and other relevant legislation.

# Summary of findings

## The five questions we ask about services and what we found

We always ask the following five questions of services.

### **Are services safe?**

We found that this service was not always providing safe care in accordance with the relevant regulations.

We have told the provider to take action.

- There was an effective system in place for reporting and recording significant events.
- The service had clearly defined and embedded systems, processes and practices in place to keep patients safe and safeguarded from abuse. The safeguarding policies were reviewed and contained up to date contact details for the local safeguarding team.
- There was not an adequate process for receiving and acting on medicine alerts.
- Procedures were in place for monitoring and managing risks to patient and staff safety. For example, there were arrangements to prevent the spread of infection.
- Information required for providing care to patients was shared and stored securely.

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### **Are services effective?**

We found that this service was providing effective care in accordance with the relevant regulations.

- The provider ensured patients received assessments required during their treatments.
- Monitoring of patients on specific medicines took place and also monitoring of the numbers of patients receiving care overall was monitored.
- Staff were supported to provide care and treatment safely and effectively.
- Consent procedures were in place.

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### **Are services caring?**

We found that this service was providing caring services in accordance with the relevant regulations.

- The provider was considerate towards the needs of their patients and showed compassion in the delivery of care.
- According to patient feedback, services were delivered in a caring manner and their privacy and dignity was respected.

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### **Are services responsive to people's needs?**

We found that this service was providing responsive care in accordance with the relevant regulations.

- Patients were satisfied with the time provided during consultations.
- There was a complaints process in place which contained all the information for patients to ensure they understood their rights.
- There was some consideration of the potential additional needs of patients who may require support due to cultural and spiritual beliefs.

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### **Are services well-led?**

We found that this service was providing well-led care in accordance with the relevant regulations.

- There was a clear ethos of patient centred care.
- Governance arrangements in place to enable the oversight of staff and monitoring of patient satisfaction.

# Summary of findings

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- Patient feedback was encouraged and considered in the running of the service.
  - Risks to patients were managed and mitigated.
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# Apodi Healthcare Limited

## Detailed findings

### Background to this inspection

We inspected Apodi Healthcare Limited on 8 January 2018. A GP specialist adviser and a lead inspector undertook the inspection.

We spoke with nurse managers, clinical leads and other managerial staff who worked for the service. We spoke with the registered manager. We looked at records related to patient assessments and the provision of care and treatment. We also reviewed documentation related to the management of the service. We reviewed patient feedback sent directly to us and feedback received by the service.

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?

## Our findings

We found that this service was not always providing safe care in accordance with the relevant regulations.

We have told the provider to take action (see full details of this action in the Requirement Notices at the end of this report).

The impact of our concerns is minor for patients using the service, in terms of the quality and safety of clinical care. The likelihood of this occurring in the future is low once it has been put right

In addition the provider should review infection control processes including the potential need for audit and processes to protect staff in the event of a healthcare related infection.

### Safety systems and processes

The service had clearly defined and embedded systems, processes and practices in place to keep people safe and safeguarded from abuse, which included:

- There was consideration of safeguarding procedures and requirements. Safeguarding policies were accessible to staff. Staff had completed safeguarding vulnerable adults and children training. The registered manager provided us with an example of where a safeguarding concern had been raised due to concerns with a patient which led to action by their GP.
- The provider had a chaperone policy in place. This was to support staff with defining the role of a chaperone. As staff provided nearly all their work under the management of external providers, they were required to use the relevant processes externally. None of the services provided at the time of inspection involved intimate procedures. All staff had a Disclosure and Barring Service (DBS) check (DBS checks provide background information on whether a person has committed a crime or is barred from caring for vulnerable adults or children).
- There were appropriate recruitment and staff checks undertaken by the provider to assure themselves that all staff were safe and of good character in order to work with patients. This included proof of conduct in previous healthcare roles and full employment histories.

### Risks to patients

Risks to patients were assessed and managed. There were areas of minor concern which the provider had not ensured that risks were fully mitigated.

- There was a plan for emergencies which may occur and affect the running of the service.
- Staff received resuscitation training (CPR) training. Emergency medicines and equipment were managed by the services where nurses provided care.
- Any care provided at patients' homes included a full risk assessment of the patient's home and their individual needs. There was an assessment of how easily emergency vehicles could access the premises, what medical conditions the patients had and potential risks regarding the delivery of care in every home.
- There was an infection control policy and staff were provided with training relevant to their role. In addition all staff received inductions from external providers including infection control. However, Apodi Healthcare did not undertake their own infection control audit to ensure that the standards they expected within their own policy were maintained by staff. For example, no hand hygiene audits were undertaken. No physical audit of premises could be undertaken due to there being no physical locations from which the provider delivered care directly. Staff were supported with any occupational healthcare needs by the external providers with which they worked. However, the provider had not identified the potential needs of their staff if a needle stick / sharp injury should occur and staff preferred to use Apodi Healthcare processes for accessing support.

### Information to deliver safe care and treatment

Staff were able to access medical records belonging to patients when delivering care within the NHS services they operated. Any data taken away from NHS services for care monitoring purposes was anonymised. Correspondence was shared with external professionals in a way that ensured data was protected.

Staff had access to the relevant information they needed in order to support patients with the specific medicines for which they were being supported and monitored.

### Safe and appropriate use of medicines

The provider did not prescribe medicines. They monitored and supported patients prescribed medicines under specific prescribing projects funded by pharmaceutical

# Are services safe?

companies. Staff did not administer or oversee administration of the specific medicines. The advice staff provided to patients was based on training provided on a specific medicine via the pharmaceutical companies.

The provider did not have a process for receiving medicine alerts from the MHRA. All prescribing and monitoring of patients' care was undertaken by the external providers. However, the advice provided to patients may be influenced by any medicine alerts and equipment alerts which related to other medications patients were taking alongside the medicines monitored by Apodi Healthcare.

## **Track record on safety**

There were systems to identify, assess and mitigate risks. For example:

- There was a fire risk assessment and related actions. These included regular checking of fire safety equipment including emergency lighting and firefighting equipment.

- There was some medical equipment owned by the provider which was used on home visits. However, there was not a process for ensuring the equipment was calibrated when required. Most equipment used by staff was owned and maintained by external providers.

## **Lessons learned and improvements made**

There was a formal process for recording and investigating incidents and events which may indicate required changes to practice and procedure. Staff could report incidents and investigations subsequently took place. The quality of clinical work was monitored through audit to identify any instances where patients may encounter problems with clinical work as a means to improve quality. For example, any potential breaches of data protection were reviewed and discussed with the information commissioner's office to identify if any further action was required.

# Are services effective?

(for example, treatment is effective)

## Our findings

We found that this service was providing effective care in accordance with the relevant regulations.

### Effective needs assessment, care and treatment

The provider was not responsible for assessing patients' eligibility to the programmes under which they received medicines. This was the responsibility of the external provider who was assessing and providing patient care. Apodi Healthcare Limited undertook assessments to monitor patients on the specific medicines delivered on the programmes and support patients with the medication.

- The provider ensured they adhered to the Association of the British Pharmaceutical Industry (ABPI) guidelines regarding the monitoring of patient medicines.
- Ongoing patient assessments undertaken during the initiation of medicines were recorded by Apodi Healthcare staff onto external providers' record systems that were responsible for the overall care and treatment of patients.

### Monitoring care and treatment

The provider monitored how many patients were receiving care from Apodi Healthcare staff on each separate medicine programme they were involved in. They recorded how many patients had been initiated on the programmes, continued to receive monitoring, had their medicines changed and those who had stopped taking the medicine. For example, on the heart failure project 428 patients were receiving ongoing monitoring and 49 had stopped taking the specific medicine under the programme.

Patient feedback was sought via questionnaires and surveys on the support and care provided. This was highly positive about the quality of service patients received.

The data regarding the outcomes for patients on each programme was only received by Apodi Healthcare anonymously in order for this to be shared with the relevant pharmaceutical company. No identifiable patient information was kept by Apodi Healthcare.

### Effective staffing

The provider had a system to continually assess their staff's skills and knowledge and identify what training was

needed on an ongoing basis. The staff providing care under each separate medicine programme received specific training on the relevant medicine in order to ensure the safe and effective monitoring of their care and treatment.

In addition to the inductions provided by Apodi Healthcare, each member of clinical staff providing care received an induction from the external providers to ensure they understood the policies and processes of the provider they were delivering care within.

Annual appraisals were provided to staff to ensure they could identify any additional development and training needs.

### Coordinating patient care and information sharing

There were processes for sharing information about patients' wellbeing during their initiation on medicines, including communication with GPs where necessary. The provider had means of accessing necessary information such as risk assessments when visiting patients in their homes.

### Supporting patients to live healthier lives

Patients were provided with information packs on the medicine programmes which they had accepted. This included leaflets and booklets on support they could receive and other relevant support associated with their specific conditions such as cancer support charities.

There were dedicated phone lines for patients to call with any queries or support issues related to the medicine that was being taken under programmes supported by Apodi Healthcare.

### Consent to care and treatment

Patients were fully informed by Apodi Healthcare about the medicine programmes they had been referred onto. Consent forms were individualised to each programme Apodi Healthcare supported and included reference to the way data would be used and that the programmes were funded by specific pharmaceutical companies. There was guidance and a protocol on consent available to staff. There was also a dedicated Mental Capacity Act (MCA) 2005 policy.

Staff received training on consent and specifically the MCA 2005.



# Are services caring?

## Our findings

We found that this service was providing caring care in accordance with the relevant regulations.

### **Kindness, respect and compassion**

We received eight CQC comment cards from patients who had used the service. All of the feedback we received from patients was positive regarding the services. Feedback was particularly positive regarding the professional, caring and kind nature of staff. The provider regularly sought feedback from patients on the services they received. On one programme where patients were asked to rate the service from one to 10 (10 being the most positive rating), 80% of respondents rated the service 10 out of 10, with 19% rating either eight or nine out of 10.

There were 27 patient responses from those who had used the phone support service. Of these 100% provided positive feedback.

Consultations regarding the initiation of medicines were lengthy in order to enable patients to ask any questions about the treatments they were undertaking.

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

Patient feedback suggested that patients felt treatments options and assessment outcomes were explained clearly to them.

There were patient information leaflets available and these explained the various types of treatment and what they entailed.

Feedback was sought in a questionnaire including whether patients had sufficient time to discuss their treatments and 99% of the responses stated that sufficient time was provided.

### **Privacy and Dignity**

Staff received supporting information via a policy on privacy and dignity. We saw no concerns in patient feedback or complaints to the provider regarding privacy and dignity concerns.

# Are services responsive to people's needs?

(for example, to feedback?)

## Our findings

We found that this service was providing responsive services in accordance with the relevant regulations.

The provider should review the means by which patients' individual requirements and preferences are respected and met in terms of the Equalities Act 2010 and other relevant legislation.

### Responding to and meeting people's needs

The service provided personalised care to patients including ongoing access to advice and information. For example,

- Patients were provided with a lengthy initial consultation and access to support via follow up appointments. We saw that the appointment length for an initial consultation on one medicine programme was 45 minutes where required.
- The provider had considered religious and cultural beliefs in their policies. However, there was no specific planning in how to meet the needs of patients who may have required additional support to understand information they received. For example, easy read documents for patients with learning disabilities were not made available. The registered manager informed us that when any individual needs were identified for patients they would be met including any information in specific formats.

- Home visits were organised by the provider for patients based on the requirements of the treatment programmes patients' individual needs.
- Patient feedback received by CQC indicated that patients received detailed explanations about their medicines.

### Timely access to the service

There was a dedicated phone line for patients to call and ask questions or request support from clinicians regarding the medicine programmes they were receiving treatment under. Patient feedback indicated this was a valuable resource.

The appointment scheduling and clinics were determined by external providers and therefore Apodi Healthcare had no determination in how these were organised other than providing the appropriate staff time and resource.

### Listening and learning from concerns and complaints

The provider had a complaints policy which set out the process for dealing with complaints. This included timeframes for acknowledging and responding to complaints with investigation outcomes. We reviewed an ongoing complaint regarding provider requests for feedback on their services. Changes to process were being adopted as a result of the complaint.

# Are services well-led?

(for example, are they well-managed and do senior leaders listen, learn and take appropriate action?)

## Our findings

We found that this service was providing well-led services in accordance with the relevant regulations.

### Leadership capacity and capability;

The provider had the experience, capacity and capability to ensure patients accessing the centre received high quality assessment and care. It was evident that the leadership within the service reviewed performance frequently. The leadership team included the relevant mix of clinicians and business expertise required to deliver the services and monitor their performance.

### Vision and strategy

The provider had an ethos of identifying new and innovative means for delivering care and treatment which would enhance patient outcomes. The provider was clear that they did not intend to become involved in the research of new treatments or medicines. The delivery of care to patients reflected the provider's ethos.

### Culture

There was an open culture. This was reflected by incident and significant event reporting where staff were open about any concerns they had. Nursing managers who oversaw the various medicine programmes were enabled to support and lead the nursing staff on the projects with the full support of the provider. Staff were complimentary about the provider.

The provider had a policy in place to comply with the requirements of the Duty of Candour.

### Governance arrangements

The service had suitable governance frameworks with which to support the delivery of services. Specific policies and procedures were in place and easily accessible to staff. For example,

- There were policies covering specific areas of service delivery including safeguarding, whistleblowing and significant event reporting.
- There were regular clinical governance meetings where outcomes regarding the care provided and patient outcomes were discussed.
- We found that a process for investigating and identifying actions resulting from significant events was in place.

- However, the provider did not have a system for ensuring medicine alerts were received and acted on. In addition they had not identified all the potential infection control measures which may be required.

### Managing risks, issues and performance

The service had systems to effectively identify, assess and manage risks related to the service provided. The risks associated with the treatment provided were assessed and well managed via ongoing assessment and periodic review of their treatment outcomes. For example, the provider had a system for risk assessing home visits when they were required.

### Appropriate and accurate information

Patient assessments, treatments and medications, including ongoing reviews of their care, were monitored by the NHS providers under whom the treatment programmes were delivered. The clinical staff responsible for monitoring patients' care were able to access this information.

The provider had policies for the safe sharing of information and they were registered with the information commissioner's office (ICO).

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

The service encouraged and valued feedback from patients. They acted to improve services on the basis of this feedback.

- Comments and feedback were encouraged. These were reviewed and considered by the provider.
- There were many examples of compliments received by the service. For example, we saw several compliments related to the caring and professional nature of staff and the clear explanations around proposed treatments, risks and outcomes.

### Continuous improvement and innovation

There were systems to identify learning outcomes and implement improvements where necessary.

- The provider monitored their performance through patient and NHS provider feedback. This was nearly always positive. Where any feedback required amendment to process this was identified and acted on.

## Are services well-led?

(for example, are they well-managed and do senior leaders listen, learn and take appropriate action?)

For example, the provider was in the process of changing how many feedback forms were provided to patients during their interactions on treatment programmes.

## 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> <p>Care and treatment must be provided in a safe way for service users</p> <p><b>How the regulation was not being met:</b></p> <p>The registered persons had not done all that was reasonably practicable to mitigate risks to the health and safety of service users receiving care and treatment. In particular:</p> <ul style="list-style-type: none"><li>• The monitoring of patients on medicines was not aligned with the potential risks which may be identified via a system of receiving and acting on medicine alerts and recalls.</li></ul> <p>This was in breach of regulation 12 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.</p>