

# J.C.Michael Groups Ltd J.C Michael Groups Ltd Bexley

### **Inspection report**

189 Broadway Bexleyheath DA6 7ER

Website: www.jcmichaelgroups.com

Date of inspection visit: 11 February 2020 12 February 2020

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Ratings

### Overall rating for this service

Requires Improvement

Is the service safe?	Requires Improvement 🛛 🔴
Is the service effective?	Requires Improvement 🛛 🗕
Is the service caring?	Requires Improvement 🛛 🔴
Is the service responsive?	Requires Improvement 🛛 🔴
Is the service well-led?	Requires Improvement 🛛 🗕

### Summary of findings

### Overall summary

About the service: JC Michael Groups Ltd Bexley is a domiciliary care agency. It provides personal care and support to people in their own homes. At the time of the inspection there were 43 people receiving personal care from the service.

People's experience of using this service:

There was poor planning for care visits with staff not following care plans and working to meet people's needs. Staff rostering records showed staff were not always given enough time to travel between the calls, which impacted on their ability to arrive promptly or stay the full length of time with people as planned for. Some people were not always treated with dignity and respect. People's care was not delivered in line with their care plans. Complaints were not managed effectively. The provider's quality assurance systems were not effective, and their internal monitoring and audit process had not identified the above issues we found at this inspection.

People were protected from the risk of abuse, and risks to people had been identified, assessed and had appropriate risk management plans in place. There was a system to manage accidents and incidents and to reduce them happening again. Staff administered prescribed medicines to people safely. People were protected from the risk of infection. The provider trained staff to support people and meet their needs. The provider worked within the principles of Mental Capacity Act (MCA). Staff asked for people's consent to their care. People were supported to have maximum choice and control of their lives and staff supported them in the least restrictive way possible and in their best interests; the policies and systems in the service supported this practice.

People's needs were assessed to ensure these could be met by the service. Where appropriate, staff involved relatives in these assessments. Staff supported people to eat and drink enough to meet their needs and staff supported people to maintain good health. Staff supported people and they showed an understanding of equality and diversity and people's privacy was respected.

Care plans were person centred and contained information about people's personal life and social history, their health and social care needs, allergies, family and friends, and contact details of health and social care professionals. The provider had a policy and procedure for managing complaints and to provide end-of-life support to people.

The provider completed checks and audits on accidents and incidents, medicines management, staff training, and safeguarding. However, their audits about staff care visits, recruitment and complaints was not effective. The registered manager and the provider remained committed to working in partnership with other agencies and services to promote the service and to achieve positive outcomes for people.

Rating at last inspection: Requires improvement (report published on 13 February 2019). The service remains rated requires improvement. This service has been rated requires improvement for the last three

#### consecutive inspections.

Why we inspected: This was a planned inspection based on the last inspection rating.

#### Enforcement

We have identified breaches in relation to staff deployment, rostering and call monitoring, complaints management, dignity and respect, and effective quality assurance system and process at this inspection.

Please see the action we have told the provider to take at the end of this report.

#### Follow up

We will request an action plan for the provider to understand what they will do to improve the standards of quality and safety. We will work alongside the provider and local authority to monitor progress. We will return to visit as per our re-inspection programme. If we receive any concerning information we may inspect sooner.

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

We always ask the following five questions of services.

<b>Is the service safe?</b> The service was not always safe. Details are in our safe findings below.	Requires Improvement 🤎
<b>Is the service effective?</b> The service was not effective. Details are in our effective findings below.	Requires Improvement –
<b>Is the service caring?</b> The service was not always caring. Details are in our caring findings below.	Requires Improvement –
<b>Is the service responsive?</b> The service was not always responsive. Details are in our responsive findings below.	Requires Improvement –
<b>Is the service well-led?</b> The service was not always well-led. Details are in our well-Led findings below.	Requires Improvement –



# J.C Michael Groups Ltd Bexley Detailed findings

# Background to this inspection

#### The inspection

We carried out this inspection under Section 60 of the Health and Social Care Act 2008 (the Act) as part of our regulatory functions. We checked whether the provider was meeting the legal requirements and regulations associated with the Act. We looked at the overall quality of the service and provided a rating for the service under the Care Act 2014.

#### Inspection team

One inspector visited the service on 11 and 12 February 2020. One expert by experience made phone calls to people and their relatives to seek their views about the service. An expert by experience is a person who has personal experience of using or caring for someone who uses this type of care service. Their area of expertise is in older people and as a family carer.

#### Service and service type

This service is a domiciliary care agency. It provides personal care to people living in their own houses.

The service had a manager registered with the Care Quality Commission. This means that they and the provider are legally responsible for how the service is run and for the quality and safety of the care provided.

#### Notice of inspection

This inspection was announced. We gave the service 48 hours' notice of the inspection visit because the registered manager was often out of the office supporting staff. We needed to be sure that they would be in.

#### What we did before the inspection

We looked at all the information we held about the service. This information included the notifications that the service sent to the Care Quality Commission. A notification is information about important events that the service is required to send us by law. The provider was not asked to complete a provider information

return prior to this inspection. This is information we require providers to send us to give some key information about the service, what the service does well and improvements they plan to make. We took this into account when we inspected the service and made the judgements in this report. We also contacted the local authority commissioning and safeguarding teams for their feedback about the service. We used this information to help inform our inspection planning.

#### During the inspection

We spoke with the operations manager, registered manager, five members of field staff, and one office staff member. We looked at six people's care records, and six staff records. We also looked at records related to the management of the service, such as the complaints, accidents and incidents, medicines management, safeguarding, staff rota, call monitoring and policies and procedures.

#### After the inspection

We spoke with four people and nine relatives. We continued to seek clarification from the provider to validate evidence found. We looked at care plans sent by the provider.

### Is the service safe?

# Our findings

Safe – this means we looked for evidence that people were protected from abuse and avoidable harm.

At the last inspection this key question was rated as requires improvement. At this inspection this key question has remained the same. This meant some aspects of the service were not always safe and there was limited assurance about safety. There was an increased risk that people could be harmed.

#### Staffing and recruitment

• At our inspection on 31 May 2018, we found appropriate levels of staff were not being deployed to keep people safe and to meet their needs in a timely manner. At the 10 January 2019 inspection we found that improvements had been made. However, at this inspection, we found the provider had not sustained improvements they had made in relation to regulation 18.

• Some people were not supported by effectively deployed staff to keep people safe and to meet their needs in a timely manner. For example, one person told us, "I have got some issues with the carers, they gave me lunch today at 11.15, they turn up at all different times."

• Some people had missed calls and their needs were always not met. For example, one person told us, "Monday of this week they forgot me altogether and Tuesday and other days they have been different times and different carers. I managed with the help of my wife on Monday. I phoned them and they apologised for missing my call

• Staff did not always attend people's care calls as required. For example, on 3/2/2020 a person was scheduled a call from 8.35am to 9.05am. However, call monitoring records showed they were visited from 10.36am to 10.53am. Staff were late by over 2 hours. In another instance, staff were late by 2 hours 45 minutes.

• The service maintained an electronic call monitoring system to monitor staff attendance and punctuality. The registered manager explained when staff were running late for more than 15 minutes, they followed up by calling people and if required they arranged replacement staff. However, there were no communication record for all late calls, to show the office staff had informed people when staff were running late to their scheduled home visits. The registered manager told us "From today 12/2/2020, we shall record all late calls informed to people."

• People were not always supported in line with their agreed length of time. Call records showed that on some occasions staff had not spent the full allocated time at people's homes. For example, on 3/2/2020 call monitoring record showed, one person was scheduled for a 45 minutes call, but they were visited for 22 minutes. Another person, on 2/2/2020 was visited for 18 minutes instead of 30 minutes.

Staff rostering records showed staff were not always given enough time to travel in-between the calls, which impacted on their ability to arrive promptly or stay the full time with people. For example, we found in some cases there was no travel time allotted between two different postcodes and in some other cases the travel time allotted between two different postcodes was not enough to ensure staff arrived on time.
A member of staff told us, "It takes 7 to 10 minutes travel time from a person's home to another person's home, and for a second visit it takes from 12 to 15 minutes travel time." There was no time allocated

between these calls to people.

This was a breach of Regulation 18 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

• We looked at six staff recruitment records and found the provider carried out satisfactory background checks for five staff before they started working. These included checks on staff member's qualifications and relevant experience, their employment history and consideration of any gaps in employment, references, and criminal record checks and proof of identification. This reduced the risk of unsuitable staff working with people who used the service.

• However, we found the sixth member staff continued working, despite their residence permit to live in the United Kingdom has expired in January 2020.

• We brought the above concerns to the attention of the registered manager, who told us they would straight away stop this member of staff from work until they provided evidence of right to work in the UK, and review staff rota for all people.

Systems and processes to safeguard people from the risk of abuse

• People were protected from the risk of abuse. A person told us, "I do feel safe. I have a key-safe and the carers let themselves in. I have been lucky with the [staff] I have had." A relative said, "My [relative] feels comfortable with carers and they had never felt unsafe with any carers." • The provider had a policy and procedure for safeguarding adults from abuse. The registered manager and staff understood what abuse was, the types of abuse, and the signs to look for. This included reporting their concerns to the registered manager and the local authority safeguarding team.

• Staff completed safeguarding training and knew the procedure for whistle-blowing and said they would use it if they needed to.

• The service-maintained records of safeguarding alerts and monitored their progress to enable learning from the outcomes when known. The service worked in cooperation with the local authority, in relation to safeguarding investigations and they notified CQC of these as required.

Assessing risk, safety monitoring and management

• People were protected from the risk of avoidable harm. Staff completed risk assessments and risk management plans that included guidance of the support staff should provide for every person who used the service. These included manual handling risks, oral care, eating and drinking and their home environment.

• However, we looked at care plan and found there was no diabetes risk management plan for a person, upon our feedback the registered manager prepared it during the inspection.

• Risk assessments were reviewed periodically and as and when people's needs changed. Staff told us these records provided them with the relevant information they needed to understand people's situation and needs. However, one relative commented, "They [staff] have left my [relative] a couple of times without their phone lead which could leave them unsafe and I don't think they are safe being hoisted by one carer on their own."

### Using medicines safely

• People were supported to receive their medicines safely. One relative told us, "They [staff] do help my [relative] with tablets every evening. As far as I know there have not been any mistakes." Another relative said, "They [staff] just put the tablets on a tray for my [relative] to take them when they are ready."

• The provider trained and assessed the competency of staff authorised to administer medicines.

Medication Administration Records were up to date and clear records kept of the medicines administered. • The service had PRN (as required) medicine protocols in place for any medicines that people had been prescribed but did not need routinely. • Regular medicines checks were carried out by the registered manager and if areas of improvement were identified these were put into an action plan and discussed with staff.

Preventing and controlling infection

• People were protected from the risk of infection. People told us staff put on gloves and would wear an apron when doing personal care.

• Staff understood the importance of effective hand washing, using personal protective equipment (PPE) such as aprons and gloves and disposing of waste appropriately, to protect people and themselves from infection and cross-contamination.

• The service had infection control procedures in place and records showed that staff had completed infection control training to ensure they knew how to prevent the spread of diseases.

Learning lessons when things go wrong

• The provider had a system to manage accidents and incidents to reduce the likelihood of them happening again. Staff completed accident and incidents records. These included action staff took to respond to and minimise future risks, and who they notified, such as a relative or healthcare professional.

• The registered manager monitored these events to identify possible learning and discussed this with staff.

### Is the service effective?

# Our findings

Effective – this means we looked for evidence that people's care, treatment and support achieved good outcomes and promoted a good quality of life, based on best available evidence.

At the last inspection this key question was rated as good. At this inspection this key question has now deteriorated to requires improvement. This meant the effectiveness of people's care, treatment and support did not always achieve good outcomes or was inconsistent.

Assessing people's needs and choices; delivering care in line with standards, guidance and the law • People's needs were assessed to ensure these could be met. Staff carried out an initial assessment of each person's needs to see if the service was suitable for them. The assessments looked at people's medical conditions, physical and mental health; mobility, nutrition and choices.

However, people's care was not delivered in line with their care plans and this required improvement. For example, a relative told us, "My relative needs to take tablets after food. They [staff] give after tea and help get ready for bed and my relative doesn't want that at 5.30pm. They [manager] told us they are not able to do 8pm call as it is very dark." Another relative said, "They [staff] have missed a call when the regular carer was off. The carer is off normally on a Sunday every 2 weeks and the problems have been with the stand ins."
Where appropriate, staff involved relatives in this assessment. Staff used this information as a basis for developing personalised care plans to meet each person's needs.

Staff support: induction, training, skills and experience

- Training records confirmed that staff had completed training that was relevant to people's needs. One relative told us, "I do think they [staff] are well trained." Another relative said, "I think they [staff] are reasonably trained. They do seem to be quite good."
- Staff told us they completed comprehensive induction training and a brief period of shadowing experienced staff, when they started work.
- The registered manager told us all staff completed mandatory training identified by the provider. Staff training records confirmed this.
- The training covered areas such as basic food hygiene, health and safety in people's homes, moving and handling, administration of medicines, infection control and safeguarding adults.
- Staff told us the training programmes enabled them to deliver the care and support people needed.
- The provider supported staff through regular supervision and spot checks to ensure people's needs were met.

Supporting people to eat and drink enough to maintain a balanced diet

- Staff supported people to eat and drink enough to meet their needs. One person told us, "They [staff] get me whatever I fancy." A relative said, "They [staff] always leave my [relative] with a glass of water and a glass of orange juice at night."
- Staff told us people made choices about what food they wanted to eat and they supported them to prepare those foods, so their preferences were met.
- People's care plans included a section on their diet and nutritional needs. This provided staff with

guidance on the level of support they should provide to ensure people's needs were safely met.

Supporting people to live healthier lives, access healthcare services and support; Staff working with other agencies to provide consistent, effective, timely care

• People were supported to maintain good health. People's health needs were recorded in their care plans along with any support required from staff in relation to this need.

• The provider had worked with local healthcare professionals including GPs, district nurses, and occupational therapists.

• Relatives coordinated people's health care appointments and health care needs, and staff were available to support people to access healthcare appointments if needed. One relative told us, "My relative, once cut their leg and staff phoned the office and got the district nurse out to dress it."

• Staff told us they would notify the office if people's needs changed and if they required the input of a health professional such as a district nurse or a GP appointment.

Ensuring consent to care and treatment in line with law and guidance

The Mental Capacity Act 2005 (MCA) provides a legal framework for making particular decisions on behalf of people who may lack the mental capacity to do so for themselves. The Act requires that, as far as possible, people make their own decisions and are helped to do so when needed. When they lack mental capacity to take particular decisions, any made on their behalf must be in their best interests and as least restrictive as possible.

People can only be deprived of their liberty to receive care and treatment when this is in their best interests and legally authorised under the MCA. When people receive care and treatment in their own homes an application must be made to the Court of Protection for them to authorise people to be deprived of their liberty. We checked whether the service was working within the principles of the MCA.

• People's capacity to consent to their care and support was documented.

• People and their relatives, where relevant, were involved in making decisions about their care. People and their relatives confirmed that staff obtained consent from them before delivering care to them.

• Staff had received MCA training and understood people's rights under this legislation. The registered manager and staff understood their responsibilities under the MCA.

### Is the service caring?

### Our findings

Caring – this means we looked for evidence that the service involved people and treated them with compassion, kindness, dignity and respect.

At the last inspection this key question was rated as good. At this inspection this key question has deteriorated to requires improvement. This meant people did not always feel well-supported, cared for or treated with dignity and respect.

Respecting and promoting people's privacy, dignity and independence

- People's privacy and dignity was not promoted. Despite some positive comments from people and relatives the overwhelming feedback from them was negative about staff.
- Some people and their relatives told us they were not treated with dignity and respect. One person told us, "Before Christmas [staff] was ok with me but the way [staff] talk to me is horrid, [staff member] mumbles and talks to themselves. I think [staff member] has lost their way as a carer." Another person said, "Some staff are quite sweet, but some are brusquer."
- One relative said, "Most of the time they [staff] are rushing my [loved one]. One of the carers even tells my [loved one] to hurry up. The carers have even banged their way out of the house a couple of times. I could hear the angry banging of the door from my bedroom."
- Another relative commented, "We are liaising with social services as we are unhappy with this agency. My [loved one] has double up visits but often they [staff] either didn't turn up or only one carer would turn up. My [loved one] has lots of different carers."

This was a breach of Regulation 10 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

• People's privacy was respected. One relative told us, "They [staff] seem fine with my relative and quite respectful for example, when we were there visiting as they came to do my relative's personal care, they asked us to go out while they did personal care and my relative seemed pleased to see them."

- Staff described how they respected people's privacy. For example, staff told us they ensured people were properly covered, and curtains and doors were closed when they provided personal care.
- People were supported to be as independent in their care as possible. One person told us, "They [staff] wash the parts I can't reach." Staff told us that they would encourage people to complete tasks for themselves as much as they were able to.

Ensuring people are well treated and supported; respecting equality and diversity

- Staff supported people and showed an understanding of equality and diversity.
- People's care plans included details about their ethnicity, preferred faith and culture.
- The service was non-discriminatory and staff told us they would always support people with any needs they had with regards to their disability, race, religion, sexual orientation or preferred gender.

Supporting people to express their views and be involved in making decisions about their care

• People and their relatives were involved in the assessment, planning and review of their care and support needs.

• People told us they had been involved in making decisions about their care and support needs. For example, one relative told us, "They [staff] tell my [relative] everything they are doing and seem really caring and thorough in what they are doing."

### Is the service responsive?

# Our findings

Responsive – this means we looked for evidence that the service met people's needs.

At the last inspection this key question was rated as requires improvement. At this inspection this key question remained the same. This meant people's needs were not always met.

Improving care quality in response to complaints or concerns

• Complaints were not managed effectively. The provider had a clear policy and procedure for managing complaints and this was accessible to people and their relatives.

• However, people and their relatives were not happy with the way their complaints had been managed. One person told us, "I always say please and [staff] shouts back 'I heard you'. We have told the manager and it improved for a while but is now worse than ever. I worry what [staff] is doing with others who don't have any family to help them."

• One relative said, "I mentioned a situation regarding the carer who is nasty to my [loved one] to the manager a couple of weeks ago. He came out to meet with us and it was mentioned that we were going to get different carer but that didn't happen. For a few days the situation improved with [staff] but then it got bad again."

• A second relative commented, "I've been in email contact with the manager. It's mainly to complain for example when no carer turns up. If you phone, especially out of hours, at times nobody answers."

• A third relative said, "The normal carer comes about 5pm to 5.30pm, and about 7pm the carer hadn't been yet on 30/01/2020. The regular carer told me they had been cancelled to come, so I phoned out of hours, they knew nothing about the cancellation at all, so they contacted the office and got someone out at 8.30pm. I sent the manager an email complaint. I wasn't happy with their response and I'm still waiting for them to get back to me."

• Following the inspection we received two complaints from relatives, and we raised a safeguarding alert with the local authority.

• There were complaints which the provider had not adequately addressed.

This was a breach of Regulation 16 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

Planning personalised care to meet people's needs, preferences, interests and give them choice and control • At the inspection of the service on 31 May 2018, we found care plans and risks to people were not appropriately identified and managed. At the 10 January 2019 inspection we found that improvements had been made. However, the rating remained 'Requires Improvement' as at the time systems and processes that had been implemented had not been operational for a sufficient amount of time for us to be sure of consistent and sustained good practice.

• At this inspection we found systems and process that had been operational had been consistent and sustained good practice.

• Care plans were person centred and contained information about people's personal life and social history, their health and social care needs, allergies, family and friends, and contact details of health and social care

professionals. They also included the level of support people needed from staff and what they could do for themselves.

• Staff told us, that before they went to people's homes, they looked at their care plans to know how to support them.

• Staff completed daily care records to show what support and care they had provided to each person.

• Staff told us they would discuss with the registered manager any changes they noticed when supporting people to ensure their changing needs were identified and met.

• The registered manager told us they updated care plans with guidance for staff when people's needs changed. Records we saw showed that care plans were up to date and reflected people's current needs.

#### Meeting people's communication needs

Since 2016 onwards all organisations that provide publicly funded adult social care are legally required to follow the Accessible Information Standard (AIS). The standard was introduced to make sure people are given information in a way they can understand. The standard applies to all people with a disability, impairment or sensory loss and in some circumstances to their carers.

• The provider had an accessible information policy in place. Most of the staff communicated with people in the way the understood, however two people told us they experienced some language issues with the staff.

• The registered manager told us if people required information in different formats, they would make this available in line with the Accessible Information Standard.

#### End of life care and support

- The provider had a policy and procedure to provide end-of-life support to people. The registered manager was aware of what to do if someone required end-of life care.
- Staff received training to support people if they required end-of life support. However, no-one using the service required end-of-life support at the time of our inspection.

### Is the service well-led?

# Our findings

Well-Led – this means we looked for evidence that service leadership, management and governance assured high-quality, person-centred care; supported learning and innovation; and promoted an open, fair culture.

At the last inspection this key question was rated as requires improvement. At this inspection this key question has remained the same. This meant the service management and leadership was inconsistent. Leaders and the culture they created did not always support the delivery of high-quality, person-centred care.

Managers and staff being clear about their roles, and understanding quality performance, risks and regulatory requirements.

- At this inspection, we found the provider had not sustained the improvements they had made in relation to regulation 17 that we had identified at the last inspection of 10 January 2019.
- The provider had not always monitored and analysed staff rostering, travel time between calls, short calls, or late visits, so patterns could be identified, and improvements made. Some staff recruitment checks were not robust.
- People were not treated with dignity and respect and complaints were not being managed effectively.
- The provider's quality assurance systems were not effective; their internal monitoring and audit process's had not identified the issues we found at this inspection.

This was a breach of regulation a breach of Regulation 17 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

• We brought this to the attention of the registered manager. Following the inspection, the registered manager developed an action plan to show how improvements would be made.

How the provider understands and acts on the duty of candour, which is their legal responsibility to be open and honest with people when something goes wrong

- The service had a registered manager in post. They demonstrated knowledge of people's needs and the needs of the staffing team. They were aware of the legal requirement to display their current CQC rating which we saw was displayed at the office.
- The provider had a duty of candour policy and the registered manager understood their role and responsibilities.
- Staff were encouraged to report all accidents, incidents or near misses and to be open and honest if something went wrong.

Promoting a positive culture that is person-centred, open, inclusive and empowering, which achieves good outcomes for people

• The registered manager demonstrated willingness to provide good quality care to people. The registered manager and staff worked as a team. There was a clear staffing structure in place and staff understood their roles and responsibilities. However, their efforts aren't yielding results.

• The provider was making efforts to promote a positive culture in the service. People and their relative's opinions were sought to make service improvements.

• The telephone monitoring carried out by the service found areas where improvement was required. The registered manager said improvements had been made in relation to people's communication with the office staff, their involvement in decision making. However, the weekend staff were not always aware of people's needs.

Engaging and involving people using the service, the public and staff, fully considering their equality characteristics

• The registered manager encouraged and empowered staff to be involved in service improvements through meetings. Areas discussed at these meetings included call monitoring, staff training, medicines management, staff supervision and coordinating with health and social care professionals to ensure continuity of care.

• We observed staff were comfortable approaching the registered manager and their conversations were professional and open.

Continuous learning and improving care

• The provider completed checks and audits on accidents and incidents, staff training, medicines management and safeguarding. As a result of these checks and audits the provider made improvements, for example, care plans and risk management plans were updated, staff refresher courses had been arranged, and daily care records improved.

Working in partnership with others

• The registered manager and the provider remained committed to working in partnership with other agencies and services to promote the service and to achieve positive outcomes for people.

• They worked closely with local authority commissioners and healthcare professionals.

### This section is primarily information for the provider

### Action we have told the provider to take

The table below shows where regulations were not being met and we have asked the provider to send us a report that says what action they are going to take.We will check that this action is taken by the provider.

Regulated activity	Regulation
Personal care	Regulation 10 HSCA RA Regulations 2014 Dignity and respect
	People were not treated with dignity and respect.
Regulated activity	Regulation
Personal care	Regulation 16 HSCA RA Regulations 2014 Receiving and acting on complaints
	Complaints were not managed effectively.
Regulated activity	Regulation
Regulated activity Personal care	Regulation Regulation 17 HSCA RA Regulations 2014 Good governance
	Regulation 17 HSCA RA Regulations 2014 Good
	Regulation 17 HSCA RA Regulations 2014 Good governance The provider's quality assurance systems were
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Personal care	Regulation 17 HSCA RA Regulations 2014 Good governance The provider's quality assurance systems were not effective