Caring Homes Healthcare Group Limited

Ivy Court

Inspection report

Ivy Road
Norwich
Norfolk
NR5 8BF

Tel: 08082020478
Website: www.caringhomes.org

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Ratings

Overall rating for this service	Requires Improvement

Is the service safe?	**Inadequate**
Is the service well-led?	**Requires Improvement**

Summary of findings

Overall summary

The inspection took place on 23 October 2018 and was unannounced.

We undertook this unannounced focused inspection because we had been made aware of concerns regarding the safety and leadership of the service. The team inspected the service against two of the five key questions we ask about services: is the service safe? and is the service well-led?

No risks, concerns or significant improvement were identified in the remaining key questions through our ongoing monitoring, or during our inspection activity, so we did not inspect them. The ratings from the previous comprehensive inspection for these key questions were included in calculating the overall rating in this inspection.

Ivy Court is a 'care home'. People in care homes receive accommodation and nursing or personal care as single package under one contractual agreement. CQC regulates both the premises and the care provided, and both were looked at during this inspection.

Ivy Court accommodates up to 71 people in one purpose built building. People who used the service, some of whom were living with dementia, received either residential or nursing care. Some areas of the service, such as the garden and cinema room, were shared spaces to which everyone had access. At the time of our inspection visit there were 61 people using the service, two of whom were in hospital.

The service had a registered manager in place. A registered manager is a person who has registered with the Care Quality Commission to manage the service. Like registered providers, they are 'registered persons'. Registered persons have legal responsibility for meeting the requirements in the Health and Social Care Act 2008 and associated Regulations about how the service is run.

At our last comprehensive inspection of the service, which was carried out on 8 and 9 January 2018, we rated the service as Good overall. However, we found that some improvement was required in the key question of Well-Led due to concerns about disorganised care plans and about staff culture and morale. At this inspection we found that these concerns had not been fully addressed and had significant concerns about the safety of the service. We identified poor management of some risks and of people's medicines. We also found that there were not always enough staff as people told us they had to wait a long time to have their needs met. We have judged that there are three breaches of regulation, relating to safe care and treatment, staffing and the leadership of the service. You can see what action we told the provider to take at the back of the full version of this report.

Medicines were not always managed safely. Some people failed to receive their medicines because they were not made available to them. Stocktaking and storage procedures, and records relating to medicines given covertly, required improvement. We could not be sure people always received their medicines as

prescribed.

There was a mixed picture with regard to the management of risk. Some environmental risks were well managed with regular servicing and monitoring checks of equipment and safety procedures. A variety of specific risks people might be subject to, were assessed and specific guidance was documented to help guide staff. It was not always clear what steps the service had taken to reduce future risk and respond to patterns and trends, where people were frequently falling out of bed for example. Some risks, such as those posed by hot radiators, had not been assessed. Risks and procedures relating to infection control required some attention to fully protect people, although cleaning in communal areas and kitchens was very good.

Risks were further heightened as, in recent months, people were regularly supported by agency staff who did not know them well. Although the service aimed to only use agency staff who were known to the service this was not always possible in practice. Using agency staff so regularly and having a high number of new staff, alongside some poor recording systems, increased the risk of people not receiving safe and individualised care. We received a high number of negative comments about the availability, knowledge and expertise of agency staff and this was people's main concern. The registered manager was aware of the concerns and had clearly tried to address this. They had employed new staff and we saw that key new staff were due to start. They had employed two new clinical leads and it was hoped this would reduce the pressure on the registered manager who told us they had been carrying out this role in addition to their management duties. This was clearly not sustainable and we were not clear how they could carry this role out effectively as they were not a registered nurse themselves.

Staff received safeguarding training and understood their responsibility to keep people safe from abuse. They knew how to spot and report signs of potential abuse. One safeguarding matter had not been fully addressed by the registered manager. They had not taken all the required actions to ensure people were fully protected.

We found that although the provider and registered manager had worked hard to improve elements of the service, the shortage of staff had meant that oversight of important areas of service delivery had been overlooked leading to a number of failures in monitoring. The registered manager and other senior staff were stretched and stressed. Although senior management for Caring Homes had sought to support the service, this had not been effective. We were, however, encouraged by the open and honest attitude of the management and of the provider overall. They accepted our feedback and immediately began to address our concerns, providing us with an initial action plan within days of our inspection visit. Before our inspection they had already taken the step of suspending further admissions to the service while they reviewed areas which needed improving. This demonstrated a willingness to drive further improvement and was a sensible measure designed to reduce overall risk.

The five questions we ask about services and what we found

We always ask the following five questions of services.

Is the service safe?

Inadequate

The service was not safe.

Medicines were not managed safely. Medicines were not always given as prescribed and recording was not consistent. Procedures relating to the storage and availability of medicines were not safe.

There was a mixed picture relating to the management of risk. Some risks were well managed but staffing issues and poor recording increased the risk of people not receiving safe care. There were not always enough staff to make sure people were safe and to meet their individual needs.

Staff understood their responsibilities to keep people safe from abuse but one potential safeguarding concern had not been fully addressed.

Communal areas of the service were clean but some improvements were needed to fully protect people from the risk and spread of infection.

Is the service well-led?

Requires Improvement

The service was not always well-led.

The provider and registered manager did not have robust oversight of the service and had not taken effective action to address areas which needed improving.

The leadership of the service demonstrated a failure to prioritise the important issues facing the service.

Staff felt well supported and there were opportunities for staff, residents and relatives to help develop the service.

There was a comprehensive system of audits in place but this had not highlighted all the concerns we identified. Recording systems did not ensure a clear flow of information.

Ivy Court

Detailed findings

Background to this inspection

We carried out this inspection under Section 60 of the Health and Social Care Act 2008 as part of our regulatory functions. This inspection checked whether the provider is meeting the legal requirements and regulations associated with the Health and Social Care Act 2008, to look at the overall quality of the service, and to provide a rating for the service under the Care Act 2014.

The inspection was prompted, in part, by notification of an incident following which a person using the service sustained a serious injury. The information shared with CQC about this incident indicated potential concerns about the management of risk and the administration of medicines. As a result, we undertook a focused inspection to look into those concerns. This report only covers our findings in relation to those topics. You can read the report from our last comprehensive inspection, by selecting the 'all reports' link for (location's name) on our website at www.cqc.org.uk.

No risks, concerns or significant improvement were identified in the remaining Key Questions through our ongoing monitoring or during our inspection activity so we did not inspect them. The ratings from the previous comprehensive inspection for these Key Questions were included in calculating the overall rating in this inspection.

This focused inspection took place on 23 October 2018 and was unannounced.

The inspection was carried out by five inspectors, including a medicines inspector, and an Expert by Experience. An Expert by Experience is a person who has personal experience of using or caring for someone who uses this type of care service. Before we carried out the inspection we also reviewed other information available to us. This included statutory notifications. Notifications relating to information about specific events that the provider is required to tell us about by law.

We spoke with 15 people who used the service and we carried out a SOFI observation. This is a structured observation that helps us understand the experiences of people who are not able to communicate with us easily. We spoke with seven relatives, five members of the care staff including two senior staff members and one agency staff member, two members of the domestic staff, the head chef, two nurses, the registered manager, the regional manager and the senior operations director. We also spoke with two staff from the

local authority adult social care team and one person from the local clinical commissioning group (CCG).

We reviewed care records for ten people, 27 people's medication records, two staff files and other records relating to the quality and safety of the service.

Inadequate

Is the service safe?

Our findings

At our last inspection, which was carried out on 8 and 9 January 2018, we rated this key question as Good as we had found the service had made a number of improvements in response to the preceding inspection report. This meant that in January 2018 we judged that people who used the service were receiving safe care. At this inspection we found that these improvements had not all been sustained.

People who used the service told us they felt safe and trusted the staff to look after them. One person commented, "I feel totally safe here. I have never had cause for concern." Another person said, "I am safe here. I have nothing to worry about. They lock everywhere so people can't get in." However, we identified concerns relating to the management of medicines and of other risks.

We looked at people's Medicine Administration Record (MAR) charts and found that staff had not always signed to confirm medicines had been administered. We also found records which had been completed by staff but then deleted without explanation. We noted there were discrepancies which showed that people's medicines may not have been given to them as prescribed. For example, one person's medicines had been incorrectly labelled by the pharmacy with the name of another medicine. This had not been identified by staff giving the person their medicines and rectified. We also saw that there had been delays obtaining medicines for some people and some medicines not being given as staff could not locate them.

We noted records of medicines that had not been given to people in the mornings because they had still been asleep but no further attempts to give them their medicines later were recorded. For one person this included a medicine scheduled for a once weekly dose and therefore they missed this treatment for a week. A staff member was observed to carry round one person's medicines in a small unlabelled plastic bag in their pocket, to give to them later. This was unsafe practice. A relative told us, "Sometimes I visit and find medication left on the table. When asked, staff say [my relative] was in the bathroom."

There was some supporting information available for staff to refer to when handling and giving people their medicines. There was personal identification, information about known allergies and medicine sensitivities and notes about how people prefer to have their medicines given to them. However, some people's information about their medicine sensitivities was recorded inconsistently which could have led to error.

Information about medicines which were given only when required (PRN) was not detailed enough. Records did not document the exact circumstances of when to give medicines to relieve a person's anxiety or pain. This meant there was a risk that a person's pain or anxiety would not be well managed.

There were additional records in place for people who were prescribed a controlled drug which was delivered via a skin patch. These records showed where on a person's body each patch was applied and noted when a patch had been removed. Placing patches too frequently in the same place presents a risk of the skin breaking down and the medicine not working effectively. Staff had not always completed these records and records were not in place for everyone using these patches. We found one record was in use for a person who was not actually prescribed the medicine. This could have led to confusion and error.

Some medicines were crushed or dissolved and hidden in food or drink, to help people, who were living with dementia or often refused medicines, to take them safely. It was not always clear how people, or their representatives, had consented to this. We saw that, although relatives and healthcare professionals had been involved in any decision to give medicines in this way, there was no record of an initial assessment of the person's capacity to make this decision.

We also noted that pharmacists had not always been consulted about the suitability of administering some medicines in food or drink. For one person, a pharmacist had been consulted in 2017 about the suitability of preparing two medicines in food or drink. However, staff had not consulted a pharmacist about more recently prescribed medicines for this person. Staff could not be sure the medicines would remain safe and effective if administered in this way.

Medicines were not always stored safely. Records to show that medicines were stored at the correct temperature, were not routinely completed by staff and there were many gaps. Some records could not be located. Although there were air-conditioned medication rooms with secure facilities to keep medicines, we noted one medicines trolley was left unattended with the keys in it, in a corridor. We also found that a fridge storing medicines was left unlocked. This meant that unauthorised people, including people who used the service, could access medicines. This placed them at potential risk of harm.

This was a breach of Regulation 12 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

We also identified some concerns relating to the management of other risks. We observed a moving and handling manoeuvre which was not safe and which was not in line with the person's care plan. We fed this back to the registered manager who told us they would address this with the individual staff members concerned. We noted that there were problems with the heating in some rooms and oil filled radiators had been provided. These radiators were hot to touch and the additional risk had not been assessed. We discussed this with the registered manager who agreed to assess any associated risks as a matter of priority. We also found that one person's call bell was broken. They told us, "If I need help I bang on the wall." This clearly posed an additional risk for this person and it was not clear to us what action had been taken in response to this fault.

These issues constituted a further breach of Regulation 12 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

People's risk of falling was assessed and identified in their care plan and falls booklets were promptly put in place for people who had sustained frequent falls. These books gave a good overview of a person's current risk. The service referred people promptly to the falls team when a pattern of falls was detected. We saw that people who were at risk were provided with soft mattresses next to their low rise beds to reduce the impact of any fall. We also noted, however, that none of the people assessed as being at high risk of falling had been given bedrails. The registered manager and regional manager told us initially that it was not company policy to provide bedrails. However, they subsequently told us that bedrails had been provided to people in the past and could be made available. We were not assured that people's individual needs and preferences had been considered with regard to keeping them safe from falls from a bed.

We counted a high number of incidents where people had fallen from their beds, although we assumed beds were on their lowest setting to reduce possible injury. We sampled incident records for eighteen people and found 30 incidents of people falling from their beds in the last year. Some people had fallen or 'rolled out' on several occasions. For example, one person had rolled out twice in July, twice in August and

once in September. It was not clear why the provision of bedrails had not been considered for this person and for others, whose records we viewed. Staff also told us that one person may have attempted to harm themselves deliberately by falling from their bed. This information was not recorded and no steps had been taken to establish if this was the case and what could be done to reduce any future risk of possible self-harm.

However, we also observed some good practice in assessing and managing risk. A variety of potential risks had been assessed and action put in place to reduce these. Risks assessed included, among others, those relating to choking, the development of pressure ulcers, people's allergies and their likelihood of falling. We saw that staff worked in line with people's assessed risks and sought to ensure people were cared for safely, although some pressure ulcer documentation was not always completed. We noted some good practice. For example, one person's care plan outlined how drinking alcohol increased a person's risks relating to their mobility and gave staff guidance.

Other environmental risks were well managed with regular health and safety checks, servicing and monitoring of equipment such as fire systems, electrical appliances, hoists, slings, stepladders and lifts. The risks posed by legionella bacteria had been assessed and there were measures in place to reduce the risks posed by legionella through regular testing of the water system.

We asked people about the staffing levels at the service. We received negative feedback about the availability of staff from people who used the service and their relatives. Eight relatives and twelve people who used the service were concerned about the numbers of staff and the use of agency staff, while only three people made neutral or positive comments.

One person who used the service said, "A couple of nights ago I called for help as I wanted to go to bed. The girl came and said she would have to get someone to help her…. I waited for an hour and she didn't return so I managed to get myself to bed….I don't want an apology, I just want help when I need it.". Another person said, "If you ring the bell, especially at night, they don't always come very quickly." One person told us that their relative had needed the toilet and needed two carers to help them. Staff pointed out to them that their relative had an incontinence pad on. The relative felt that the implication of this was that staff wished for the person to relieve themselves in their incontinence pad rather than to try and find another staff member to help the person go to the toilet. They felt that this compromised their relative's dignity saying, "[My relative] knows what's going on and that is not fair."

People told us they felt that the high use of agency staff added to their concerns about agency staff. A relative told us, "It is important that [my relative] sees the same faces – there are too many changes of staff." A person who used the service echoed this saying, "I don't like the agency staff. They don't know us and what we need." Another relative said, "Agency staff can be problematic – …..[my relative] needs support when sitting and eating. They don't always know." However, this relative also acknowledged that things had definitely improved in recent weeks and felt able to raise any staffing concerns with the registered manager.

We observed the impact of using staff who were unfamiliar with people's needs. For example, one person told us that the service had run out of their night catheter bags. We found out that the service had not in fact run out of them but the staff member did not know where to find them and had believed they had run out when in fact there were plentiful stocks. This meant the person had been unnecessarily disturbed throughout the night as staff changed the daytime catheter bags as these were all they could find. We also found that an agency nurse was working in accordance with an out of date care plan as they were unaware there was a more current version was in place.

Staff also felt that staffing levels were inadequate at times with one staff member describing the team as being 'run ragged.' They also told us that it was difficult for newer or agency staff to find the right information as records were not always clear. One person said, "Our charts are not consistent….if there was another nurse who was permanent that would help." We noted that the service tried to use the same group of agency staff to help maintain continuity. This was not always possible however, and led to some of the comments we received.

At the time of our inspection visit there was no clinical lead in post on either unit where people received nursing care. We asked who was carrying out supervision of the nurses, especially those new and agency nurses regularly on shift. The registered manger told us that they had been carrying out this role in addition to their many other duties. They told us, "I have been leading the nurses." However, the registered manager was not a registered nurse and it was not clear to us how they could have been giving clinical and professional guidance to the nursing staff.

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

The registered manager told us that they had a recruitment programme in place and new staff, including two new clinical leads, were due to start soon. A new deputy manager had started work earlier in October and it was hoped that this would help the registered manager bring about the changes and improvements they told us they wished to make.

The recruitment process was robust and aimed to ensure staff were suitable and safe to work in this type of service. The service carried out an interview and conducted comprehensive checks of people's eligibility to work in the UK, past employment history, references and Disclosure and Barring Service (DBS) checks. The DBS carries out checks to see if people have any criminal history which might make them unsuitable to work in a care home. Staff can also be referred to the DBS if there is evidence that they may place others at risk. During our inspection visit we became aware of one situation which had not been appropriately and promptly referred to the DBS.

Staff received training in how to keep people safe from abuse and knew how to spot and report potential signs of abuse. Staff were able to tell us what action they would take if they suspected someone was at risk of harm. However, the high number of agency staff increased the risk of staff not being able to spot the signs of changed behaviour or mood, due to them not knowing people well enough.

We found infection control was mostly well managed in terms of the cleanliness of communal areas of the service and staff demonstrated good practice. The kitchens were clean and staff had clear cleaning schedules to follow which were monitored by the head chef. Staff had received infection control training. However, we noted that some people's bedrooms were not sufficiently clean. The shower drains in the ensuite bathrooms were not part of the cleaning schedule and needed a deep clean. One relative said, "Occasionally the room needs a good clean." Another person who used the service had a health condition which was not well managed in terms of infection control. We would have expected a more robust cleaning and infection control regime in place for this person to ensure their health did not deteriorate.

Requires Improvement

Is the service well-led?

Our findings

At our last inspection this key question was rated Requires Improvement. At this inspection we found that the service still had not put all the required improvements in place in order to be awarded a rating of Good for this key question. Disorganised information in care plans had been identified at the last inspection in January 2018 and remained a concern at this inspection. Other areas, such as the engagement with relatives and staff, had improved, although issues relating to the staff culture continued to be a challenge.

The service had a registered manager in post and they told us that the service had had ten managers, although not all had been registered with CQC, since first opening in July 2015. In addition to frequent changes of manager in recent years, we also noted that the current staffing picture meant that there were no clinical leads (although they were due to start) and that there had been times when there was also no deputy manager. This placed additional responsibility on the registered manager who told us they were acting as clinical lead at the time of our inspection visit, even though we judged they did not have the skills and qualifications to carry out this role.

It was clear to us that the registered manager was very stretched and we found that they did not have clear oversight of the whole service. This is likely to have impacted on the quality of the service overall. Although the provider had put measures in place to support the registered manager, these had not ensured the service was operating safely at all times. We also noted an escalation of issues of poor practice had coincided with a recent period of the registered manager's annual leave. During this period management at the service was described as being 'overwhelmed'.

Although the current registered manager had a clear vision for the future of the service and was aware of which issues placed the service at highest risk, they had not been able to ensure this vision became a reality. Prior to our inspection the provider had decided to put a voluntary stop on new admissions to the service while changes, designed to drive improvements, were put in place. This was a sensible response and demonstrated a willingness to examine the current issues facing the service and decide on the best way forward.

A regional manager supported the registered manager and visited the service several times a month to provide additional support. The provider had also ensured that other managers from nearby Caring Homes Healthcare Group services provided informal help and support to the registered manager. Despite this additional support the response was not effective in achieving the required standards of quality and safety. A 'mock CQC inspection' had been carried out by an external company in September 2018. Concerns with staffing levels and culture, medicines, care plan and leadership were identified. We found these concerns remained at the time of our inspection.

The registered manager had plans in place to address the staffing concerns at the service, reduce agency and improve the staffing culture. However, we noted that, at times, the focus was on minor issues rather than the more substantial problems which needed addressing. During our inspection senior staff at the service spent considerable time explaining to us how they tried to address some poor relationships within

the staff team. Although the problems were clear, the registered manager had not always taken proportionate and prompt action to investigate issues and, if required, performance manage individuals and therefore the problems continued.

Similarly, we noted a great deal of time and effort on behalf of senior staff of all levels was taken up with managing the concerns of one particular person who used the service. Strategies to deal with this person's issues were not effective and staff appeared stressed, even distressed, at times. This response again may have been a symptom of how overstretched some of the staff felt.

Although we received some negative feedback from staff about staffing levels, other feedback was positive. Staff felt well supported and found the registered manager approachable and caring. There was a recognition, amongst staff and relatives, that the registered manager was very visible at the service and was doing their best to improve the quality of the service. One relative said, "[The registered manager].. is always about and very compassionate. I can bring anything up with him." They held regular staff meetings with all the various teams of staff including meetings for nurses, for heads of department and other staff. These meetings provided an opportunity for the provider to communicate with staff and for them, in turn, to question current thinking and offer up their own suggestions. Meetings for residents and relatives gave them similar opportunities and the registered manager told us they had an open-door policy. This was confirmed by the people we spoke with.

There was regular engagement with people who used the service, relatives, staff and other stakeholders to invite feedback. The provider sent surveys out which covered all aspects of the service from people's safety and comfort to the meal experience. We viewed the results of the most recent surveys which were analysed by the group quality manager. Where the service was found to fall short in any area a six week action plan was put in place but we did not view these.

The registered manager also ensured that key data about incidents, accidents, infections, wounds, safeguarding and expected and unexpected deaths was reported to the provider on a monthly basis. This was then analysed. Although this reporting system demonstrated oversight from the provider, it was not always clear how patterns and trends had been addressed by the service. The most recent data for falls, for example, demonstrated that falls often occurred at 14.00 and 19.00. We could see no response to this particular piece of information and the total number of falls from May to September 2018 had actually increased.

The regional manager told us that they visited the service at least monthly, sometimes several times a month, and carried out a monthly comprehensive audit. We viewed the most recent audits and found that they covered a variety of areas but had not picked up on all of the concerns we identified during our inspection. The September audit had identified that care plans needed reviewing and archiving, that staff felt they were too stretched and that there were issues with the supply of medicines. None of these issues had been addressed robustly in the weeks leading up to our inspection. We identified the same issues, alongside further issues relating to risk and the administration of medicines in particular.

The registered manager told us they had been working as the clinical lead in recent weeks and leading the nursing team. This gave them an in-depth knowledge of the people who used the service and the issues that affected them. However, this had also affected their ability to maintain an effective oversight of the wider service. We acknowledge that the new clinical leads and the newly appointed deputy should assist with this in the near future.

Having received so many negative comments about how long people had to wait for their call bells to be

answered, we asked whether there was any audit of the times people waited. The call bell system was able to display and then print out how long each call bell had taken to be answered but the registered manager did not know how to organise this. They have given us an assurance that this is now in place and should be a useful tool in monitoring staff response times in future.

The registered manager and the regional manager told us that, according to the dependency tool used, the service was technically overstaffed. They told us that strategies were in place to try to ensure people's needs were met by staff who knew them well. We found that, although this was the intention, the reality was different with staff, residents and relatives all telling us that staffing was a problem. Our own observations were that there were several occasions when people who used the service were left unsupervised and it was difficult to locate a member of staff. This meant that we questioned the robustness of the dependency tool used at the service and the monitoring of staffing levels.

We found that recording systems needed further improvement to ensure that each person's care needs were met. There were several occasions when staff were unable to find the information we asked for. This was because information was stored in different places. Some staff were unfamiliar with recording systems and old information, which should have been archived, remained in files. This was confusing for staff. We observed one agency nurse working from an out of date care plan which should have been archived. This placed the person at risk of receiving inappropriate care and support. Some excellent recording systems were in place, such as the falls booklet. However, the lack of clear structure within the recording systems alongside many new and agency staff, increased the risk of care not meeting people's individual needs.

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

The registered manager, and the more senior managers at Caring Homes Healthcare Group, demonstrated a willingness to engage with CQC and drive forward the improvements that are required. They accepted our feedback and contacted us straight after the inspection to share an initial action plan they had drawn up to begin addressing some of the concerns we identified.

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
Accommodation for persons who require nursing or personal care Treatment of disease, disorder or injury	Regulation 12 HSCA RA Regulations 2014 Safe care and treatment The provider failed to ensure the safe management of medicines. They also failed to ensure risks were fully assessed and actions taken to reduce these risks. Regulation 12 (2) (a) (b) and (g).

Regulated activity	Regulation
Accommodation for persons who require nursing or personal care Treatment of disease, disorder or injury	Regulation 17 HSCA RA Regulations 2014 Good governance The provider failed to ensure that there were effective systems in place to assess, monitor and improve the quality and safety of the service. Regulation 17 (2) (a).

Regulated activity	Regulation
Accommodation for persons who require nursing or personal care Treatment of disease, disorder or injury	Regulation 18 HSCA RA Regulations 2014 Staffing The provider failed to ensure that there were enough competent, skilled and experienced staff. Regulation 18 (1).