

## Vital Healthcare Services Limited Vital Healthcare Services Limited

#### **Inspection report**

Sorrel Horse House 1 Sorrel Horse Mews, Grimwade Street Ipswich Suffolk IP4 1LN

Tel: 01473212089 Website: www.vitalhealthcare.co.uk

Ratings

#### Overall rating for this service

Date of inspection visit: 10 May 2017 12 May 2017 16 June 2017

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Requires Improvement

Is the service safe?	Requires Improvement
Is the service effective?	Requires Improvement
Is the service caring?	Good •
Is the service responsive?	Requires Improvement 🧶
Is the service well-led?	Requires Improvement 🧶

#### Summary of findings

#### **Overall summary**

We inspected the service on 10 and 12 May 2017. Notice was given so that the service staff could arrange for some people using the service to speak with us. This was the first inspection of this service at this location.

The service provides personal care and support for people living in their own homes. At the time of the inspection there were 23 people using the service.

There was a registered manager in post who was present during the days of our inspection. 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.

Many of the people using the service had complex needs requiring one to one staff support at all times. In order to provide the support to people their individuals risk assessment requires monitoring and updating in response to situations and peoples changing needs. Risks to people's health and wellbeing were not always assessed and documented in people's care plans. When risks had been identified staff had not always followed the actions as stated in the care plan, such as providing one to one care.

Medicines were not always managed safely. Staff had received training in the administration of medicines. However, they did not always administer medicines as prescribed in the medication administration record. Protocols for when to administer 'when required' (PRN) medicines were not in place for every person who used the service.

The staff had received training to safeguard people from harm and some staff were trained to provide therapies. The service is registered to provide nursing care, although the support people require is with their emotional and psychiatric needs. Sufficient numbers of staff were deployed by the service to meet the needs of people. There were recruitment procedures in place. Managers needed to make improvements to ensure that staff received appropriate support when providing 1:1 care.

Some staff informed us they had supervision, spot checks, appraisals and this support was appropriate for them. Whereas other staff said they did not have spot checks and found the group supervision ineffective as they wished to have one to one supervision.

Care plans were developed to guide staff about how best to support people, but were not always personalised and not always in place in sufficient detail when the person commenced using the service. People had access to healthcare services when they needed this and were supported with sufficient food and drinks of their choice.

Staff spoke positively about the care they provided, we saw caring practices of staff empathising and

understanding the needs of people using the service with complex needs. We also found some staff to be providing care in a dignified and respectful manner. However, we are also aware of occasions where staff had not supported people as well as they needed at that time.

People were not supported to have maximum choice and control of their lives and staff did not support them in the least restrictive way possible. The policies and systems in the service were not always clear regarding how to support people.

Best interests meetings had been held in collaboration with professionals involved in people's care and the service followed the legal requirements in accordance with the Mental Capacity Act (MCA) 2005. However the service had not always worked closely with other professionals and relatives for the full benefit of the people using the service.

Quality assurance systems were not robust enough and had not identified some of the concerns we found regarding medicines management and risk assessments being sufficiently detailed.

We found breaches of regulations in relation to safe care and treatment. You can see what action we asked the provider to take at the back of the full version of this report.

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

We always ask the following five questions of services.

Is the service safe?	Requires Improvement 😑
The service was not consistently safe.	
Staff had received medicines training; but medicines were not managed safely as people had not always been given their prescribed medicines and medicine records had not always been completed accurately.	
Risks assessments were in place, but staff had not always followed the care plan which had put people at risk of unsafe care.	
Staff had completed safeguarding training.	
There were safe recruitment processes in place.	
Is the service effective?	Requires Improvement 🗕
The service was not consistently effective.	
Staff supervision was not consistent and staff had not used their training to de-escalate situations.	
People's consent was sought and best interest's decisions were made in accordance with the Mental Capacity Act (MCA) 2005. People's capacity had not always been fully determined so that the support provided took full account of their needs.	
People accessed healthcare services to assess and monitor their healthcare needs and were supported with sufficient food and drink to meet their nutritional requirements.	
Is the service caring?	Good •
The service was caring.	
The wishes and thoughts of people using the service were sought.	
People were involved with making decisions	

People's privacy and dignity were respected.	
Is the service responsive?	Requires Improvement 😑
The service was not always responsive.	
Staff had acted in a reactive rather than a proactive way.	
Care plans were not in place when a person began to use the service	
There was a complaints policy and procedure but the actions taken as a result of complaints had not fully addressed the situation	
Is the service well-led?	Requires Improvement 😑
<b>Is the service well-led?</b> The service was not always well-led.	Requires Improvement 🗕
	Requires Improvement
The service was not always well-led. Quality monitoring systems were not fully effective in recognising medicines had not been recorded as being administered and	Requires Improvement



# Vital Healthcare Services Limited

**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 was planned to check 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.

This was an announced inspection which took place on 10 and 12 May 2017. The service was given 48 hours' notice. This was so that arrangements could be made so that people using the service had the opportunity to speak with us if they wished.

Before the inspection, we looked at the information we held about the service including any notifications they had sent to us and information from the local authority. Before the inspection, the provider completed a Provider Information Return (PIR). This is a form that asks the provider to give some key information about the service, what the service does well and improvements they plan to make.

The inspection team was made up of two inspectors. We visited three people using the service in their own home and two people using the service came to speak with us in the service office. We spoke with one relative and looked at five care plans. We spoke with the registered manager and six members of staff. We spoke with other professionals supporting people using the service after the announced visit. We looked at three staff files and other service documents. The manager sent us some further documents after the inspection visits.

#### Is the service safe?

#### Our findings

Medicines were not always administered in line with the instructions of the prescriber. Records demonstrated that a person in the care of the service missed taking three medicines at the prescribed time on one occasion. The person had a plan in place about increasing independence with their medicines. However, the action staff should have taken in the event that the person did not take their medicines was not documented. An assessment of the person's ability with regard to taking their medicines had not been fully explored. Therefore it was not clear whether or not the person had the capacity to understand the risks involved with not taking their prescribed medicines. Despite the person not taking their medicines the staff did not take that appropriate action at that time to protect the person from harm. The staff member had not sought the advice of a senior member of staff or spoken with the person's GP.

In one person's medication administration record (MAR), there were four gaps where medicines had not been signed for. This was for two medicines that had not been signed for on 30 April 2017 at 9pm. Also one medicine had not been signed as given on 7 May 2017 at 6pm and 9pm. There was no medicine audit that had identified this issue of the MAR not being signed.

Another person had six medicines prescribed on a PRN basis. That means to be given as needed. However, there was no PRN protocol in place to advise the staff when and why the medicine should be administered.

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

One person told us how their medicines were stored in a locked cupboard. They explained to us how the staff ordered the medicines for them and how the staff collected them with them as part of a shopping trip. They had no concerns about their medicines as staff familiar to them supported them and they were confident those staff knew about their medicines. Another person told us that they were aware of their medicines and staff had explained their potential side-effects and benefits to them.

The service is responsible for having procedures in place regarding protecting people from harm. This must include effective risk assessments clearly stating the measures to be taken to reduce the risk of harm to the person. For example one person had been assessed as being a risk to themselves and requiring one to one support and sometimes two carers had been assigned to provide support to them at anyone time. This person had acquired medicines with which they attempted to harm themselves despite having staff assigned to them at all times to support them with their needs.

On another occasion a member of staff when providing one to one support to a person who had been assessed as requiring one to one support at all times had left the person alone. The risk assessment was clear that the person was not to be left alone and required one to one support. A serious incident resulted from the person being left on their own. Although no harm occurred to the person on that occasion the impact could have been severe.

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

We found there was a lack of checking that new staff understood the care plan and risk assessments. A new member of staff although introduced by a senior member of staff to the person they were supporting had not had a detailed explanation about what was required for them to support the person safely. They had not been told by senior staff why a person required two staff to support them when going out. This meant the risk of harm to the person because staff had not been fully informed about the needs of the person.

Staff were in attendance during a time of difficulty experienced by two people being supported by the staff who did not respond to de-escalate the situation. This meant that risks had not been identified and supporting plans to keep the people safe and guiding the staff were not comprehensive.

The staff we spoke with told us there were sufficient staff employed to support people using the service. One member of staff told us, "The rota is worked out well in advance and I am consulted to do extra shifts and help out." A person who used the service told us, "I do have the same people working with me for the vast majority of the time."

Rotas were written to include the times people received their care visits. Some people required 24 hour support and some people required more than one member of staff to be with them at all times. There were no missed calls and no gaps identified in any of the rotas. This meant that staff had been assigned to support each person using the service as identified by their support plan.

However, staff raised concerns with us about not having allocated breaks during their shifts, which were usually eight hours long. This meant that some staff were supporting people with highly complex needs without a work break.

One member of staff told us, "I have worked up to 65 hours per week, this is because some staff are not reliable and I try to help out." We saw from the rota this was an exception as many staff worked 48 and 42 hours per week.

Staff we spoke with understood the types of abuse people could experience and explained that if the service failed to act on a safeguarding matter they would raise their concerns with external organisations. One member of staff told us, "If you see anything you report it, I would tell a manager or report."

Safe recruitment checks had been carried out on potential employees before they began work. Staff files contained information that included two references, identification, and checks with the Disclosure and Barring Service (DBS). The DBS checks assist employers in making safer recruitment decisions by ensuring that prospective staff members are not barred from working with people who require support.

Some staff were studying psychology and related subjects and hence considered working for the service on a part-time basis very helpful to them and provided an insight to the needs of the people. There studies were discussed at interview along with set questions to determine that they were suitable to be employed to support the people using the service. We saw that staff had a job contract and job description.

#### Is the service effective?

#### Our findings

Staff received training some of which was delivered by the senior staff who were accredited trainers, and there were training facilities at the offices of the service. Records showed that staff had received training in subjects such as food hygiene, first aid, infection control and these training records were up to date.

Training was provided for staff in positive behaviour support (PBS) and physical intervention at induction and then on a yearly basis. The trainers providing this training also undertook refresher training yearly. We saw records that informed us the training was up to date of the internal trainers.

A member of staff informed us the PBS training is over two days. They had completed one day of the training but not the second as yet and they were working with a person where they may have been required to use the PBS. This meant that the training was not effective as the training should be completed prior to the staff member working with the people using the service.

A person and their relative informed us how the person had not been effectively supported during a difficult time of conflict with another person using the service. The PBS training commenced with de-escalating but the training on this occasion had not been used or was not effective. This was a contributing factor to the person leaving the support of the service. This meant the staff had not used the skills from the training to effectively support the people using the service.

Other members of staff explained to us they had received an induction before they commenced work and received the appropriate training in order to carry out their roles effectively. One member of staff told us, "We have lots of training. It gives you what you need to know. It has helped me a lot, training has boosted my confidence." Another member of staff told us they had training in the care of a person with epilepsy. We saw the training information was consistent with information in the persons care plan.

Training was provided for the staff and some staff spoke positively about this and were confident how to use the information. However other staff were not. A member of staff we spoke with had attended training about caring, but they could not recall the content of the training. For the people using the service to have effective support, the staff require effective training which they put into practice.

We were aware from the training matrix staff were provided with training so that they could be part of the on-call team. We asked one member of staff what training they had received so that they could effectively be part of the on-call team. They could not recall having had any training but did say, "I think it is because I have been with the company for a long time."

A person with highly complex needs was being supported by a member of staff who although had completed their induction training had only been with the service for three weeks. To care and support people to express their views, positive caring relationships need time to be developed. The new member of staff was providing one to one care already. We did not consider that they had sufficient time as yet to get to know the person and to have provided care on their own to a person with such highly complex needs. They

had been introduced to the person and had completed a shadow shift with another member of staff to support the person. The impact is that the new member of staff had not had sufficient time to build up a supportive relationship with the person, when they were being required to provide one to one support for them.

In conclusion we found mixed information from the staff about the training they had received. Some were content while others had not completed training in pbs, could not recall the content of a training session and had been asked to take on additional responsibilities without having received training. This meant that the senior staff of the service had not consulted effectively with the staff to check that they had completed and understood the content of the training provided.

There were a number of different supervision supports being provided by the senior staff of the service, these included spot checks, group supervision, clinical supervision and management supervision. A member of staff told us, "Supervision was last month, we talked about things that you do at work using scenarios." Another staff member told us, "Clinical supervision looks into the role as a support worker. Group supervisions are good as they build the team and is a forum to share experiences. Also develops the team we learn from each other."

However, some staff told us that they had never had a spot check on their practice. Another staff member informed us they did not feel confident to discuss issues in group supervision and they wished to have one to one supervision as well as, or instead of, group supervisions. One person told us they could not raise issues in group supervision which they wished to be kept as confidential. For the service to be fully effective staff need to feel confident in the supervision process and procedure.

All staff we spoke with told us that they had a yearly appraisal. Appraisals were used to plan opportunities for staff to develop their skills in the forthcoming year.

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.

Other than on one occasion, there was evidence to show that the service staff had applied the MCA appropriately to determine people's capacity and had sought advice appropriately from relatives and other professionals. Capacity assessments must be completed in order that the staff can be clear upon the support the person requires.

Staff we spoke with were aware of the need to gain the person's consent before providing care and support. Staff had received MCA training which had given them the knowledge that people may have capacity in some day to day decisions but lack capacity in others with regard to more complex issues such as finance. Best interests meetings had been held in consultation with people and health professionals about specific decisions relating to their overall care.

People we spoke with told us they were supported with their nutrition and were involved in meal planning and shopping. One person told us, "I can do some of the cooking and the staff help me with the rest." They also explained that they usually had the same staff supporting them and they had got to know each other well. We asked a member of staff how they supported someone not able to speak with regard to foods and

drinks they liked. They informed us that little was known about the person before using the service. Therefore they had introduced foods and drinks encouraging them to taste different foods. Those they did not like were recorded to build up the information and increase choices of foods available.

People had access to healthcare services when this was required. We saw that future appointments had been recorded for dentist and doctor appointments. One person told us, "I go to the dentist once a year, I do not mind they are nice." Records showed that visits to GP's and other health professionals were recorded and information added to the care plan to inform staff how to support the person.

## Our findings

Staff spoke positively about their roles and explained the reasons why they enjoyed the support they delivered to people in their respective homes. One member of staff told us, "I enjoy the job because of the people, seeing them improve and develop."

We saw that some positive caring relationships had developed between staff and people they were supporting. Some staff had supported the same people regularly, had got to know them well. They understood their preferences and interests, and how best to communicate with them to meet their needs. One member of staff explained that people used their body language, such as their facial expressions, to indicate if they preferred the choices that were made available to them

One person told us, "I think the staff care about me, they listen to me." They explained that they considered their care mattered to the staff, their care plan was discussed with them and was person-centred. This was because it took account of their preferences and focussed upon the support the staff provided in respect of their needs.

Another person told us how the staff had encouraged their interest to have pets of their own and had supported them to purchase and care for their pets. The person told us how much they enjoyed looking after their pets and the comfort they brought to them. This meant that the service staff had listened to the persons views and supported to enhance the quality of their life.

A person explained to us that they knew their care plan because a member of staff read it to them. They told us they had spoken about their life history, what was important to them and events that had upset them. They considered that as information had been recorded, staff knew why at times of anniversaries they became upset. They considered staff were respectful to them because they took this into account when supporting them at difficult times.

One person told us, "I would rate it eight out of ten, pretty good, I like having my own flat and most staff are good and knowledgeable and I get on well with them. Those I do not get on with or like is because they are not experienced." The person further explained to us, "Good staff know in difficult times how to distract me and support me, for example I like playing board games that always helps."

Staff described how they respected people's privacy and dignity by supporting people with care in the least intrusive way. To ensure their dignity they explained they covered certain areas of their body when providing personal care and made sure the curtains were drawn and doors were closed so their privacy was maintained. Staff explained how they planned trips out which included taking sufficient resources including changes of clothes if they were so required.

#### Is the service responsive?

## Our findings

We understood from a professional supporting a person that approximately nine visits were planned with the staff to assess the person's individual needs. Only two went ahead and therefore an accurate assessment of how the staff would respond to support the person to meet their assessed needs was not completed. Relatives and other professionals had not been invited to all of the planned meetings. The service began to support the person without a full assessment having been completed to identify all of the person's needs.

Concerns were raised by professionals and relatives that an inconclusive assessment had been carried out. The assessment had not identified the full personal care and support the person required. This meant the person's support needs had not been accurately recorded and the support plan was not sufficiently detailed for them for the person to understand and the staff to provide support.

A professional well known to the person visited them shortly after they began to use the service. The professional explained to the staff the difficulties the person was experiencing was because the staff were expecting the person to carry out many household tasks independently. The person required more support from the staff at this time to support them to develop their independence skills. This was despite the staff knowing the person had always lived in the family home and most tasks were carried out by a relative. Hence the person required positive motivation and support to increase their independence and develop their skills. This meant that the person's needs had not been accurately assessed and hence the plan to support them was not sufficiently robust and detailed for the staff to support them.

One person's care plan was not up to date. This was because entries into the daily notes had not always been taken account of in the care plan. For staff to effectively communicate with the person and each other and truly listen and reflect their needs, the care plan needs to be accurate. We raised with a senior member of staff and they assured us they would resolve the situation later that day, after they had provided care to the person. We were aware that the care plan had been updated in the past after events had occurred. However the impact of this inconsistency means that information was not always being accurately communicated.

The manager had put arrangements in place so that all people using the service had a keyworker. The intention was that people would receive personalised care which was responsive to their assessed needs. The role of the keyworker is to provide one to one meetings and support to build a rapport with the person to understand their needs and aspirations. One person told us that they had built up a supportive relationship with the keyworker who they could discuss issues and difficulties with.

The manager explained they were aware of the complex needs of many people using the service. The culture of the organisation was to provide therapy for people as identified from an assessment and support in line with their needs. Then to provide from assessments therapies for people using the service some with highly complex needs and requiring long term support. We saw that this was indeed the case in some instances. However we also saw that some assessments and support plans were not up sufficiently detailed. This

meant that the support received by some people was inconsistent.

One person told us, "Despite many difficulties, I feel I am getting better." Another person told us, I have a care plan and I have therapy, for this I have to keep a diary and record my feeling and important events, we then discuss them in therapy and try to link them together." This meant that the benefits of the therapy had been explained to the person and staff were working with them upon assessed identified needs.

People told us that staff did discuss their care with them and respected their views. A senior member of staff explained to us. "There are a number of shops, parks and other places we visit, I ask the person where they want to go and why?" They explained the person sometimes want to go to a shop near a park and combine the two, other times they wanted to come back straight back after shopping. This is an example of how the staff were supporting a person to make choices of what they did during the day.

The service had a complaints policy and procedure and the complaints that had been raised had been recorded as required by the procedure. Staff told us that they were aware of the complaints procedure and would advise people if they could not resolve the situation they would encourage them to make a complaint. A person told us, "I know who to complain to and I know the manager to speak with if needed." One member of staff told us, "I would encourage anyone to talk with the manager and they will always try to sort things out."

However we were informed by a relative that the service had not worked fully with them and their relative to resolve the concerns they had raised about the support provided by the service staff. The manager upon becoming aware of our inspection had informed the relative of our inspection and arranged for us to meet with them.

#### Is the service well-led?

## Our findings

The management of the service must ensure there is good governance in operation so that systems and processes are established and working effectively. We saw that a range of audits were carried out this included medicines, reviewing support plans including risk assessments, staff supervision and the effectiveness of the induction programme for new staff. These audits were ineffective in identifying some issue we found at the inspection. When issues with people's care being provided by this service were identified, we found that the actions had not always been effective in keeping people safe.

For example, we noted serious concerns with the management of medicines. There was a lack of clarity and leadership to determine the person's capacity regarding the amount of support they required with their medicine. As a result the person had not received their prescribed medicine. The audits of medicine records had failed to identify gaps in people's administration records for both regular and PRN medicines. This meant the systems in place to monitor the quality and safety of the service were not effective.

Records in relation to the care and support of people were not sufficiently detailed. One person had received support from the service without an accurate record having been established of their personal needs. This meant that the staff did not have the clarity to know how to support them

The service provides support to people with highly complex needs. After serious incidents the records and risk assessments had not been reviewed thoroughly to guide the staff and keep people safe. We found that a person had attempted to harm themselves while being supported by the service with one to one support. Later while receiving one to one support a member of staff left the person on their own. This is poor care and people when assessed as needing one to one support at all times must have that support so that their complex needs are met.

People using the service have high complexities of need. Although the service staff had undertaken reviews of care and risk on a planned basis of six months not all reviews of care were arranged as quickly and frequently as required for people using the service in response to events on all occasions. Not all of the staff involved with the support were fully aware of the person new care needs after events happened. This meant that the support provided had not been planned to take account of and changed in the light of events in the person's life.

The manager explained lessons for them and senior staff had been learned in particular keeping people informed from a situation regarding the assessment and arranging support for a person. However the learning from this was not shared with the full staff team.

The systems and processes operated by the service was to provide therapy for people as identified from an assessment and support in line with their needs.

These examples are all breaches of Regulation 17 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. This is because the systems and processes operated by the service to ensure

that the service was safe, effective, responsive and well-led were not sufficiently robust.

The service had a registered manager. They explained to us how they had built a senior management team and developed a therapy team to provide support to the people. We saw that a number of therapies including dialectic behaviour therapy were provided to support people. Dialectic behaviour therapy is a recognised therapy by the medical professional to support people experiencing emotional difficulties.

The manager was aware of their duty to keep people safe. This had included when proven they dismissed a member of staff for inappropriate conduct. The manger had also put policies and procedure into place which included a whistle-blowing policy and staff told us that they had received information about how to use it.

There were examples of good leadership. A member of staff told us, "I feel supported by the management team, the training is good and you are alerted to what you need to do on the rota." They further explained you can approach the managers and they understand the times you can work and have tried their best to accommodate. However, we also saw that further development to lead and support staff was required.to ensure that training was effective and staff felt confident with the types of supervision being used. The management had not identified that staff group supervision meant that some staff could not explain difficulties which related to other members of staff in that format.

We spoke with the manager about the on-call system and were informed that the senior staff took it in turns to be on-call and hence a 24 hour cover was provided. They wished to support staff at all times and hence why they wished to be consulted about the need for PRN medicines being required. The manager also was aware that many people using the service had complex needs and hence the need for support and advice to be available for the staff and in turn to support the people.

We saw that the employee satisfaction survey carried out in May and June 2016 on the whole was positive, usually scoring over 75% satisfaction of the questions asked. Work life balance was the poorest score and the manager intended looking further into situation and looked to staff for suggestions of how this could be improved. They had noted that staff requested a faster response to annual leave requests which we understood from talking with members of staff had improved.

High quality care can only be provided by staff that are well supported. Records and staff rota's did not demonstrate there were plans in place for staff to have allocated breaks. Further work was needed to ensure that staff received appropriate support to carry out their role effectively.

#### 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 12 HSCA RA Regulations 2014 Safe care and treatment
	Regulation 12 Care and treatment must be provided in a safe way for service users (a) assessing the risk to the health and safety of services users of receiving the care or treatment (b) doing all that is reasonably practicable to mitigate any such risks
Regulated activity	Regulation
Personal care	Regulation 17 HSCA RA Regulations 2014 Good governance
	Regulation 17 Good governance must be established and operated effectively (a) to ensure compliance with the requirements to assess, monitor and improve the quality and safety of the services provided in the carrying on of the regulated activity (b) assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk which arise from the carrying on of the regulated activity.