

***We are the regulator:** Our job is to check whether hospitals, care homes and care services are meeting essential standards.*

4 Ways Healthcare Limited

7 Marchmont Gate, Boundary Way, Hemel
Hempstead, HP2 7BF

Date of Inspection: 27 August 2013

Date of Publication:
September 2013

We inspected the following standards as part of a routine inspection. This is what we found:

Care and welfare of people who use services	✓	Met this standard
Cooperating with other providers	✓	Met this standard
Safeguarding people who use services from abuse	✓	Met this standard
Requirements relating to workers	✓	Met this standard
Complaints	✓	Met this standard

Details about this location

Registered Provider	4 Ways Healthcare Limited
Registered Manager	Miss Alison Lara Mackay
Overview of the service	4 Ways Healthcare Limited specialise in the remote analysis of diagnostic images. They do not carry out the procedure producing the image: this is usually done in an NHS or independent hospital or clinic, who subcontract the analysis phase to 4 Ways Healthcare Limited. They receive the images in digital format over a secure computer network, and return the diagnosis over the same network. 4 Ways Healthcare have no direct contact with patients.
Type of service	Diagnostic and/or screening service
Regulated activity	Diagnostic and screening procedures

Contents

When you read this report, you may find it useful to read the sections towards the back called 'About CQC inspections' and 'How we define our judgements'.

	Page
Summary of this inspection:	
Why we carried out this inspection	4
How we carried out this inspection	4
What people told us and what we found	4
More information about the provider	5
Our judgements for each standard inspected:	
Care and welfare of people who use services	6
Cooperating with other providers	8
Safeguarding people who use services from abuse	9
Requirements relating to workers	11
Complaints	12
About CQC Inspections	14
How we define our judgements	15
Glossary of terms we use in this report	17
Contact us	19

Summary of this inspection

Why we carried out this inspection

This was a routine inspection to check that essential standards of quality and safety referred to on the front page were being met. We sometimes describe this as a scheduled inspection.

This was an unannounced inspection.

How we carried out this inspection

We looked at the personal care or treatment records of people who use the service, carried out a visit on 27 August 2013, observed how people were being cared for and talked with staff. We reviewed information given to us by the provider.

We spoke with client organisations, namely, NHS hospitals and independent healthcare providers.

What people told us and what we found

The client organisations we spoke with were complimentary of the service provided. One NHS principal radiographer commented, "4 Ways provide a superb service and have an excellent audit process. The turnaround time is excellent for the one hour target, at least 90% are completed in 30 minutes. The manager and the staff are excellent and very efficient."

The Head of Diagnostics of a private organisation said, "4 Ways is open and transparent and easy to work with. The staff respond promptly and the reports are balanced and accurate. We are very pleased with them."

The provider is accredited by standards organisations, such as the Imaging Services Accreditation Scheme (ISAS) for radiological reporting, administered by the United Kingdom Accreditation Service(UKAS). The process and procedures conformed to the International Standards Organisation standard ISO 9001 and the use of information technology conformed to ISO 27001. These accreditations had ensured that best practice was followed, that the process and procedures were tightly controlled and externally validated and that standards were maintained at all times.

The clinical audit team routinely audited 10% of the CT and MRI scanned images and 2% of the plain film images to check that the correct diagnosis had been given. Prompt action had been taken to rectify any discrepancies.

We concluded that 4 Ways Healthcare Limited was compliant in all the five essential standards of quality and safety.

You can see our judgements on the front page of this report.

More information about the provider

Please see our website www.cqc.org.uk for more information, including our most recent judgements against the essential standards. You can contact us using the telephone number on the back of the report if you have additional questions.

There is a glossary at the back of this report which has definitions for words and phrases we use in the report.

Our judgements for each standard inspected

Care and welfare of people who use services

✓ Met this standard

People should get safe and appropriate care that meets their needs and supports their rights

Our judgement

The provider was meeting this standard.

Care and treatment was planned and delivered in a way that was intended to ensure people's safety and welfare.

Reasons for our judgement

We noted that information about the service was provided to prospective client organisations through the organisation's website and by responding to queries on the telephone. A leaflet detailing the fees was also available. This meant that organisations using the service were fully informed before they decided to use the service for their patients.

We noted that client organisations were able to terminate the service at any time without giving notice and without any penalty and there was no connection charge. It was not even mandatory to use dedicated computer hardware. This provided further evidence that the client organisations were satisfied with the service, because otherwise they would have terminated the arrangement.

During our inspection, we spoke with a number of the client organisations, comprised of mainly NHS hospitals and independent healthcare organisations. They were all complimentary of the service provided. When the contract was negotiated, a protocol was also agreed specifying exactly how the work would be carried out, so that 4 Ways Healthcare Limited would integrate seamlessly into the client's routine processes.

During our inspection, we were shown the electronic medical records system. A member of the training staff showed us a sample of the patient records, and explained the procedures and processes from the time of referral to the completion of all the tasks. The staff walked us through the referral process, beginning with the referral form from the client organisation. Staff checked and verified that all the images sent for diagnostic reporting belonged to the right patient. For example, they matched the patient's name and hospital reference number with those on each scanned image. This was to guard against another patient's images being wrongly stored with the patient's details at the client organisation. These multiple checks were done before the case was assigned to the radiologist for analysis. This ensured that the radiologist received the correct patient referral and radiological images for diagnostic reporting and screening. The diagnostic reports enabled the patient's own consultant or doctor to provide safe and appropriate care and treatment.

Staff showed us the secured steps the radiologist had to follow to gain access to the computer system before they were able to carry out their analysis. The radiologist had access to the images only whilst they were analysing them. The finalised report was dispatched to the client organisation by means of the secure computer network. This meant that all parties adhered to the Data Protection Act 1998.

On the day of the inspection, we spoke with one of the consultant radiologists who was also the medical director of 4 Ways Healthcare Ltd. We were told that all the contracted radiologists were consultants who also worked in NHS and independent hospitals. They worked from home using a secure computer system and used voice recognition technology to produce the electronic reports. We were told that all the radiologists had received training on accessing the computer and the use of the voice recognition system. New recruits had competency assessments on at least 15 cases before they were given a caseload to report on. This had assured quality analysis and mitigated the risk of errors in the diagnosis of images, to ensure that patients received appropriate care and treatment.

The manager stated that the staff were required to follow the provider's policy and the protocols agreed with the client organisations. The members of staff we spoke with confirmed that they had received induction training on the provider's policy and procedures, the Data Protection Act 1998 and other relevant topics to enhance their knowledge in the roles they had to perform.

We were told that the provider held a weekly audit meeting to discuss any detected errors made by the radiologists in the analysis of the images. Relevant lessons had been learnt. There was a protocol for dealing with under-performance. If a radiologist's performance was found to have deviated from the organisation's 'standard prescription' the disciplinary procedure was initiated. This had ensured that patients were safeguarded from incompetent staff.

We noted that the turnaround time for the reports was 24 or 48 hours, depending on the client's needs. A faster service was provided for urgent cases: full body polytrauma cases were reported in 1 hour, and stroke cases were reported in 30 minutes.

The company is accredited in radiological reporting by ISAS through UKAS. The procedures and process used in the business conformed to ISO 9001. The use of information technology conformed to ISO 27001 and IG SoC. The training and professional development of staff was validated by the CPD Accreditation Service. These accreditations had ensured that best practice was followed and that the procedures and process were tightly controlled.

These measures had ensured that people received appropriate care and treatment.

People should get safe and coordinated care when they move between different services

Our judgement

The provider was meeting this standard.

People's health, safety and welfare was protected when more than one provider was involved in their care and treatment, or when they moved between different services. This was because the provider worked in co-operation with others.

Reasons for our judgement

The nature of the work undertaken meant that 4 Ways Healthcare Limited worked closely with the client organisations, which were mainly NHS Hospitals, to achieve quality radiology reports to a high standard. This had ensured that patients received appropriate care and treatment.

During our inspection, we received evidence which demonstrated that the provider had maintained its quality assurance practices to a high standard, substantiated by the yearly accreditation renewal by the various accreditation organisations such as ISAS and ISO.

The provider gave practical support to client organisations in NHS Trust Hospitals in terms of managing the increased volume of emergency and trauma cases. The time from receiving the images to the finished radiology reports had been within the agreed limits.

This meant that the Trusts' radiology services were more manageable, especially since the service was available 24 hours a day, 7 days a week, with access to a pool of specialist radiologists. The feedback from client organisations such as from the principal radiologists in NHS hospitals and private independent healthcare had all been complimentary about the service provided.

People should be protected from abuse and staff should respect their human rights

Our judgement

The provider was meeting this standard.

People who use the service were protected from the risk of abuse, because the provider had taken reasonable steps to identify the possibility of abuse and prevent abuse from happening.

Reasons for our judgement

The nature of the work undertaken meant that staff had no direct contact with patients. However, all staff had access to the Hertfordshire County Council safeguarding procedures and the whistle-blowing policy so that they knew who to report a safeguarding incident to, apart from the provider. This demonstrated that staff had been prepared to respond appropriately and effectively in the event of a safeguarding incident. We were told that additional training on safeguarding issues would be arranged for staff later this year.

During our inspection, the manager stated that all the radiologists were consultants employed either in an NHS hospital or in an independent hospital. They would raise awareness of any safeguarding concerns with the appropriate NHS provider and the relevant local authority. As the provider is based in Hertfordshire, the manager would also notify Hertfordshire County Council (HCC) in accordance with the HCC safeguarding procedures.

We were told that the provider had a weekly audit meeting to discuss any detected discrepancies in reporting made by radiologists in their analysis of the images. There had been regular internal audits by the Clinical Audit team. They routinely audited 10 per cent of the CT and MRI scanned images and 2 per cent of the plain film images to check that the correct diagnosis had been given.

The provider was accredited under ISO 27001:2005 (Information Security Management) and was accredited by ISAS as a teleradiology service. This meant that the provider's policies and procedures for service delivery and clinical quality assurance were consistently of a high standard. The cases of misdiagnosis were analysed statistically and presented in a report. This showed a mean rate of misdiagnosis of 0.19%. Patients had therefore been safeguarded against wrong diagnosis and treatment.

There was a policy of taking disciplinary action against any radiologist who was under-performing.

These measures had mitigated the risk associated with wrong diagnosis and patients had therefore been safeguarded against being given wrong treatment. Since the provider's

registration with CQC, no cases had been reported of a patient suffering harm due to a misdiagnosis by one of the provider's radiologists.

Requirements relating to workers

✓ Met this standard

People should be cared for by staff who are properly qualified and able to do their job

Our judgement

The provider was meeting this standard.

The provider employed suitably qualified, skilled and experienced staff. There were effective recruitment and selection processes in place.

Reasons for our judgement

During our inspection, we observed the administrative, IT and operations staff engaged in their work. The members of staff we spoke with were clear about their role and were professional in their approach. They were aware of the security involved and the stringent checks they had to make before allocating the cases to the radiologists.

We checked some staff recruitment documents, and found them to be satisfactory. We noted that the recruitment process was in accordance with the organisation's policy and procedures. The application form was detailed and gave the applicant's employment history and the outcome of the interview. Two written references, including one from the previous employer, had been followed up in each case.

We saw evidence of the qualifications of the doctors and radiologists, and the training certificates for courses they had attended. We were told that all the radiologists' staff files had been reviewed recently to ensure they had renewed their registration with their respective professional bodies, such as the General Medical Council and the Royal College of Radiologists, and that they held a valid indemnity insurance certificate.

We spoke with two new administrative staff. They told us that they had been given an induction period and on-going training. Topics covered had included security procedures, fire safety, health and safety, and the Data Protection Act 1998. New staff had undergone enhanced Disclosure and Barring Service (DBS) checks. Whilst waiting for DBS clearance, they had shadowed and been supervised by experienced staff.

All these measures had ensured that the staff employed were skilled and competent, and had the requisite experience to do their job.

Complaints

✓ Met this standard

People should have their complaints listened to and acted on properly

Our judgement

The provider was meeting this standard.

There was an effective complaints system available and comments and complaints people made were responded to appropriately.

Reasons for our judgement

The provider categorised all discrepancies in radiological reporting using the Department of Health 5 Point Scale for radiological errors. Category 1 is the most serious while Category 5 represents no discrepancy in the findings; but, on the contrary, it provides a means to offer praise or encouragement for exceptional work. Category 4 refers to a disagreement with the style and/or presentation of the report, including failure to describe features which would, however, have no effect on the patient's treatment. Category 3 indicates that the clinical significance of the discrepancy is debatable or the likelihood of harm is low, or there has been a failure to follow agreed escalation procedures. Category 2 refers to a definite omission or misinterpretation of a finding with a strong likelihood of moderate resulting morbidity but not a threat to life. Category 1 signifies there is a definite omission or misinterpretation with unequivocal potential for serious morbidity or threat to life. The Internal Audit Process and the Discrepancy Process follow the same policy guidelines when dealing with categories 4 to 1. This showed that the occurrence of errors and their consequences for the patient concerned were taken extremely seriously, and were reported on in an open and transparent way.

We were told that there had been discrepancies regarding the contents of radiologists' imaging reports. Discrepancies might have been highlighted as a result of the work of the Independent Clinical Audit team or as a result of complaints raised by the client organisation. The complaints could be raised because the report was incorrect or because the images had been reviewed elsewhere and an alternative interpretation had been provided.

The manager confirmed that all complaints had been addressed promptly and had been responded to within 15 days from the time the issues had first been raised. All remedial actions had been taken and completed in a timely manner. This had avoided further escalation of the complaint. This also meant that patients had not been unduly affected in receiving appropriate care and treatment.

Client organisations we spoke with were complimentary about the strict auditing process and the prompt remedial action taken by the provider. This had mitigated and reduced the number of errors and therefore reduced the number of complaints that would otherwise have been made. We were told that the percentage of errors made by radiologists had been minimal. For example, the percentage of cases leading to complaints about

discrepancies reported in July 2013 was 0.18% compared to May 2013 which was 0.23%. The complaints raised were mainly in category 2 (6), 3 (16) and 4 (10) There were none for category 1.

We saw statistical evidence in the latest audit reports. The documents submitted for this inspection showed that the provider was thorough and open and transparent in dealing with the concerns raised.

About CQC inspections

We are the regulator of health and social care in England.

All providers of regulated health and social care services have a legal responsibility to make sure they are meeting essential standards of quality and safety. These are the standards everyone should be able to expect when they receive care.

The essential standards are described in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 and the Care Quality Commission (Registration) Regulations 2009. We regulate against these standards, which we sometimes describe as "government standards".

We carry out unannounced inspections of all care homes, acute hospitals and domiciliary care services in England at least once a year to judge whether or not the essential standards are being met. We carry out inspections of other services less often. All of our inspections are unannounced unless there is a good reason to let the provider know we are coming.

There are 16 essential standards that relate most directly to the quality and safety of care and these are grouped into five key areas. When we inspect we could check all or part of any of the 16 standards at any time depending on the individual circumstances of the service. Because of this we often check different standards at different times.

When we inspect, we always visit and we do things like observe how people are cared for, and we talk to people who use the service, to their carers and to staff. We also review information we have gathered about the provider, check the service's records and check whether the right systems and processes are in place.

We focus on whether or not the provider is meeting the standards and we are guided by whether people are experiencing the outcomes they should be able to expect when the standards are being met. By outcomes we mean the impact care has on the health, safety and welfare of people who use the service, and the experience they have whilst receiving it.

Our inspectors judge if any action is required by the provider of the service to improve the standard of care being provided. Where providers are non-compliant with the regulations, we take enforcement action against them. If we require a service to take action, or if we take enforcement action, we re-inspect it before its next routine inspection was due. This could mean we re-inspect a service several times in one year. We also might decide to re-inspect a service if new concerns emerge about it before the next routine inspection.

In between inspections we continually monitor information we have about providers. The information comes from the public, the provider, other organisations, and from care workers.

You can tell us about your experience of this provider on our website.

How we define our judgements

The following pages show our findings and regulatory judgement for each essential standard or part of the standard that we inspected. Our judgements are based on the ongoing review and analysis of the information gathered by CQC about this provider and the evidence collected during this inspection.

We reach one of the following judgements for each essential standard inspected.

✓ Met this standard This means that the standard was being met in that the provider was compliant with the regulation. If we find that standards were met, we take no regulatory action but we may make comments that may be useful to the provider and to the public about minor improvements that could be made.

✗ Action needed This means that the standard was not being met in that the provider was non-compliant with the regulation. We may have set a compliance action requiring the provider to produce a report setting out how and by when changes will be made to make sure they comply with the standard. We monitor the implementation of action plans in these reports and, if necessary, take further action. We may have identified a breach of a regulation which is more serious, and we will make sure action is taken. We will report on this when it is complete.

✗ Enforcement action taken If the breach of the regulation was more serious, or there have been several or continual breaches, we have a range of actions we take using the criminal and/or civil procedures in the Health and Social Care Act 2008 and relevant regulations. These enforcement powers include issuing a warning notice; restricting or suspending the services a provider can offer, or the number of people it can care for; issuing fines and formal cautions; in extreme cases, cancelling a provider or managers registration or prosecuting a manager or provider. These enforcement powers are set out in law and mean that we can take swift, targeted action where services are failing people.

How we define our judgements (continued)

Where we find non-compliance with a regulation (or part of a regulation), we state which part of the regulation has been breached. Only where there is non compliance with one or more of Regulations 9-24 of the Regulated Activity Regulations, will our report include a judgement about the level of impact on people who use the service (and others, if appropriate to the regulation). This could be a minor, moderate or major impact.

Minor impact - people who use the service experienced poor care that had an impact on their health, safety or welfare or there was a risk of this happening. The impact was not significant and the matter could be managed or resolved quickly.

Moderate impact - people who use the service experienced poor care that had a significant effect on their health, safety or welfare or there was a risk of this happening. The matter may need to be resolved quickly.

Major impact - people who use the service experienced poor care that had a serious current or long term impact on their health, safety and welfare, or there was a risk of this happening. The matter needs to be resolved quickly

We decide the most appropriate action to take to ensure that the necessary changes are made. We always follow up to check whether action has been taken to meet the standards.

Glossary of terms we use in this report

Essential standard

The essential standards of quality and safety are described in our *Guidance about compliance: Essential standards of quality and safety*. They consist of a significant number of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 and the Care Quality Commission (Registration) Regulations 2009. These regulations describe the essential standards of quality and safety that people who use health and adult social care services have a right to expect. A full list of the standards can be found within the *Guidance about compliance*. The 16 essential standards are:

Respecting and involving people who use services - Outcome 1 (Regulation 17)

Consent to care and treatment - Outcome 2 (Regulation 18)

Care and welfare of people who use services - Outcome 4 (Regulation 9)

Meeting Nutritional Needs - Outcome 5 (Regulation 14)

Cooperating with other providers - Outcome 6 (Regulation 24)

Safeguarding people who use services from abuse - Outcome 7 (Regulation 11)

Cleanliness and infection control - Outcome 8 (Regulation 12)

Management of medicines - Outcome 9 (Regulation 13)

Safety and suitability of premises - Outcome 10 (Regulation 15)

Safety, availability and suitability of equipment - Outcome 11 (Regulation 16)

Requirements relating to workers - Outcome 12 (Regulation 21)

Staffing - Outcome 13 (Regulation 22)

Supporting Staff - Outcome 14 (Regulation 23)

Assessing and monitoring the quality of service provision - Outcome 16 (Regulation 10)

Complaints - Outcome 17 (Regulation 19)

Records - Outcome 21 (Regulation 20)

Regulated activity

These are prescribed activities related to care and treatment that require registration with CQC. These are set out in legislation, and reflect the services provided.

Glossary of terms we use in this report (continued)

(Registered) Provider

There are several legal terms relating to the providers of services. These include registered person, service provider and registered manager. The term 'provider' means anyone with a legal responsibility for ensuring that the requirements of the law are carried out. On our website we often refer to providers as a 'service'.

Regulations

We regulate against the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 and the Care Quality Commission (Registration) Regulations 2009.

Responsive inspection

This is carried out at any time in relation to identified concerns.

Routine inspection

This is planned and could occur at any time. We sometimes describe this as a scheduled inspection.

Themed inspection

This is targeted to look at specific standards, sectors or types of care.

Contact us

Phone: 03000 616161

Email: enquiries@ccq.org.uk

Write to us
at: Care Quality Commission
Citygate
Gallowgate
Newcastle upon Tyne
NE1 4PA

Website: www.cqc.org.uk

Copyright Copyright © (2011) Care Quality Commission (CQC). This publication may be reproduced in whole or in part, free of charge, in any format or medium provided that it is not used for commercial gain. This consent is subject to the material being reproduced accurately and on proviso that it is not used in a derogatory manner or misleading context. The material should be acknowledged as CQC copyright, with the title and date of publication of the document specified.
