Arolygiaeth Gofal Iechyd Cymru
Healthcare Inspectorate Wales

DRIVING IMPROVEMENT THROUGH INDEPENDENT AND OBJECTIVE REVIEW

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Inspection 2009/2010

Healthcare Inspectorate Wales
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Inspection Date:	Inspection Manager and Reviewers:
23 November & 11 December 2009	P Price A Astles

Introduction

Independent healthcare providers in Wales must be registered with the Healthcare Inspectorate Wales (HIW). HIW acts as the regulator of healthcare services in Wales on behalf of the Welsh Ministers who, by virtue of the Government of Wales Act 2006, are designated as the registration authority.

To register, they need to demonstrate compliance with the Care Standards Act 2000 and associated regulations. The HIW tests providers' compliance by assessing each registered establishment and agency against a set of *National Minimum Standards,* which were published by the Welsh Assembly Government and set out the minimum standards for different types of independent health services. Further information about the standards and regulations can be found on our website at: **www.hiw.org.uk**.

Readers must be aware that this report is intended to reflect the findings of the inspection episode. Readers should not conclude that the circumstances of the service will be the same at all times.

Background and main findings

An announced inspection was undertaken to the Albany Medical Centre, Pontypridd on the 23 November 2009 by a HIW pharmacist reviewer and on the 11 December 2009 by an Inspection Manager. The clinic was first registered on the 29 December 2008 and is registered to provide weight management and reduction advice and treatment provided by medical practitioners to patients who are eighteen years or over.

Prior to the inspection visits the registered provider submitted a completed pre-inspection questionnaire. The inspections focused upon the analysis of a range of documentation, discussion with the registered provider, examination of patient records and consideration of the ordering, storage, use and disposal of medicines. A tour of the premises was also undertaken.

In respect of the inspection findings the registered person had in place:

- A range of policies and procedures, staff had signed to state that they were aware and understood the policies.
- Comprehensive information for patients including a patient guide.
- A system of obtaining patient views was available and viewed.
- Staff employment files were available. Confirmation that the practitioners were registered with an appropriate professional body, references, training records and an enhanced Criminal Record Bureau check were available.
- A protection of vulnerable adult's policy was in place. Staff had undertaken training in this area.

- A confidentiality policy/procedure was available. Staff had signed to state they were aware of this policy.
- There was a procedure for clinical audit.
- There was a current British National Formulary available. An obesity resource pack was present.

However, it was noted that no staff fire training and fire drills had been undertaken.

In respect of the other inspection findings the main focus of the visit was the ordering, storage, use and disposal of medicines. In relation to this area the following issues were noticed:

1. A written procedure was present review date 1/4/11 which was accessible to staff. There was a statement in the policy about error recording. No error reporting system was in place,
2. A treatment protocol was present, but this was not referenced to the National Institute of Clinical Excellence (NICE) and there was no evidence of adherence to NICE guidance. Copies of obesity management guidelines to be made available for patients. eg NICE
3. There were records of medicines issued to individual patients. The doctor signed the records to patients, but not the stock book. It was stated that the doctor checked the stock books, and as such the doctor should sign these to take responsibility for the balances.
4. Medicines were kept in a locked metal cabinet inside a second locked metal cabinet. The outside cabinet was a significant size (wardrobe-sized) and did not appear to be fixed to a wall. The large door appeared to have one central lock. In addition, the small cupboard was not big enough to store medicines in an organised fashion.
   It was not evidenced that the cabinet meets the safe custody requirements for diethylpropion.
5. No DOOP kits were present. The clinic was not clear about disposal of stock waste medicines. The policy stated that the manager would arrange a third party disposal contract but this was not in place.
6. The policy states that MHRA alerts will be received, but they are not received by the clinic.
7. It was stated that no prescribing outside the product license takes place, but this had not been audited. There was no policy regarding unlicensed use.
8. Temperature of storage area was not evidenced. A thermometer for the rooms where medicines were kept was required.
9. In relation to patients being given information regarding the medications that were prescribed for them, there was some limited information for clients on the registration form. The doctor stated that he discussed medicines with clients. However, no patient information leaflets were provided to patients with their medicines.
10. Batch numbers were present on the stock sheets, but were not recorded for each patient.

It must be noted that a number of actions had been taken with regard to outcomes from the pharmacist reviewer visit. These have been noted above.

The Inspection Manager would like to thank the manager and staff for there time and co-operation during the inspection visit.

Achievements and compliance

The clinic was first registered in December 2008, therefore there was no previous inspection report for this establishment.

Registration Types

This registration is granted according the type of service provided. This report is for the following type of service

Description
Independent Clinic

Conditions of registration

This registration is subject to the following conditions. Each condition is inspected for compliance. The judgement is described as Compliant, Not Compliant or Insufficient Assurance.

Condition number	Condition of Registration	Judgement
1.	The. The registered person must not provide medical or psychiatric services of any kind nor any “listed services” as defined by section 2(7) of the Care Standards Act 2000 other than weight management /reduction advice and treatment provided by medical practitioners to patients who are eighteen years old or over.	Compliant
2.	Advice and treatment must only be provided by registered medical practitioners.	Compliant
3.	Patients must be aged eighteen years old or over.	Compliant
4.	Overnight accommodation must not be provided to patients.	Compliant

Assessments

The Healthcare Inspectorate Wales carries out on site inspections to make assessments of standards. If we identify areas where the provider is not meeting the minimum standards or complying with regulations or we do not have sufficient evidence that the required level of performance is being achieved, the registered person is advised of this through this inspection report. There may also be occasions when more serious or urgent failures are identified and the registered person may additionally have been informed by letter of the findings and action to be taken but those issues will also be reflected in this inspection report. The Healthcare Inspectorate Wales makes a judgment about the frequency and need to inspect the establishment based on information received from and about the provider, since the last inspection was carried out. Before undertaking an inspection, the Healthcare Inspectorate Wales will consider the information it has about a registered person. This might include: A self assessment against the standards, the previous inspection report findings and any action plan submitted, provider visits reports, the Statement of Purpose for the establishment or agency and any complaints or concerning information about the registered person and services.

In assessing each standard we use four outcome statements:

Standard met	No shortfalls: achieving the required levels of performance
Standard almost met	Minor shortfalls: no major deficiencies and required levels of performance seem achievable without extensive extra activity
Standard not met	Major shortfalls: significant action is needed to achieve the required levels of performance
Standard not inspected	This is either because the standard was not applicable, or because, following an assessment of the information received from and about the establishment or agency, no risks were identified and therefore it was decided that there was no need for the standard to be further checked at this inspection

Assessments and Requirements

The assessments are grouped under the following headings and each standard shows its reference number.

- Core standards
- Service specific standards

Standards Abbreviations:

C = Core standards
A = Acute standards
MH = Mental health standards
H = Hospice standards
MC = Maternity standards
TP = Termination of pregnancy standards
P = Prescribed techniques and technology standards
PD = Private doctors' standards

If the registered person has not fully met any of the standards below, at the end of the report, we have set out our findings and what action the registered person must undertake to comply with the specific regulation. Failure to comply with a regulation may be an offence. Readers must be aware that the report is intended to reflect the findings of the inspector at the particular inspection episode. Readers should not conclude that the circumstances of the service will be the same at all times; sometimes services improve and conversely sometimes they deteriorate.

Core standards

Number	Standard Topic	Assessment
C1	Patients receive clear and accurate information about their treatment	Standard almost met
C2	The treatment and care provided are patient – centred	Standard met
C3	Treatment provided to patients is in line with relevant clinical guidelines	Standard almost met
C4	Patient are assured that monitoring of the quality of treatment and care takes place	Standard almost met
C5	The terminal care and death of patients is handled appropriately and sensitively	Standard not inspected
C6	Patients views are obtained by the establishment and used to inform the provision of treatment and care and prospective patients	Standard met
C7	Appropriate policies and procedures are in place to help ensure the quality of treatment and services	Standard almost met
C8	Patients are assured that the establishment or agency is run by a fit person/organisation and that there is a clear line of accountability for the delivery of services	Standard met
C9	Patients receive care from appropriately recruited, trained and qualified staff	Standard met
C10	Patients receive care from appropriately registered nurses who have the relevant skills knowledge and expertise to deliver patient care safely and effectively	Standard not inspected
C11	Patients receive treatment from appropriately recruited, trained and qualified practitioners	Standard met
C12	Patients are treated by healthcare professionals who comply with their professional codes of practice	Standard met
C13	Patients and personnel are not infected with blood borne viruses	Standard met

Number	Standard Topic	Assessment
C14	Children receiving treatment are protected effectively from abuse	Standard not inspected
C15	Adults receiving care are protected effectively from abuse	Standard met
C16	Patients have access to an effective complaints process	Standard met
C17	Patients receive appropriate information about how to make a complaint	Standard met
C18	Staff and personnel have a duty to express concerns about questionable or poor practice	Standard met
C19	Patients receive treatment in premises that are safe and appropriate for that treatment. Where children are admitted or attend for treatment, it is to a child friendly environment	Standard met
C20	Patients receive treatment using equipment and supplies that are safe and in good condition	Standard met
C21	Patients receive appropriate catering services	Standard not inspected
C22	Patients, staff and anyone visiting the registered premises are assured that all risks connected with the establishment, treatment and services are identified, assessed and managed appropriately	Standard almost met
C23	The appropriate health and safety measures are in place	Standard not inspected
C24	Measures are in place to ensure the safe management and secure handling of medicines	Standard not met
C25	Medicines, dressings and medical gases are handled in a safe and secure manner	Standard almost met
C26	Controlled drugs are stored, administered and destroyed appropriately	Standard not met
C27	The risk of patients, staff and visitors acquiring a hospital acquired infection is minimised	Standard met
C28	Patients are not treated with contaminated medical devices	Standard not inspected
C29	Patients are resuscitated appropriately and effectively	Standard not inspected
C30	Contracts ensure that patients receive goods and services of the appropriate quality	Standard met
C31	Records are created, maintained and stored to standards which meet legal and regulatory compliance and professional practice recommendations	Standard met
C32	Patients are assured of appropriately competed health records	Standard met
C33	Patients are assured that all information is managed within the regulated body to ensure patient confidentiality	Standard met

Number	Standard Topic	Assessment
C34	Any research conducted in the establishment/agency is carried out with appropriate consent and authorisation from any patients involved, in line with published guidance on the conduct of research projects	Standard not inspected

Service specific standards - these are specific to the type of establishment inspected

Number	Private Doctors	Assessment
PD1	Arrangements for the provision of treatment	Standard met
PD2	Management of patients	Standard met
PD3	Minor surgery	Standard not inspected
PD4	Midwifery and ante natal care	Standard not inspected
PD5	Prescribing	Standard almost met
PD6	Pathology services	Standard not inspected
PD7	Contacting practitioners and Out of Hours services	Standard met
PD8	Information to GP's	Standard met

Schedules of information

The schedules of information set out the details of what information the registered person must provided, retain or record, in relation to specific records.

Schedule	Detail	Assessment
1	Information to be included in the Statement of Purpose	Met
2	Information required in respect of persons seeking to carry on, manage or work at an establishment	Met
3 (Part I)	Period for which medical records must be retained	Met
3 (Part II)	Record to be maintained for inspection	Met
4 (Part I)	Details to be recorded in respect of patients receiving obstetric services	Not applicable
4 (Part II)	Details to be recorded in respect of a child born at an independent hospital	Not applicable

Requirements

The requirements below address any non-compliance with The Private and Voluntary Health Care (Wales) Regulations 2002 that were found as a result of assessing the standards shown in the left column and other information which we have received from and about the provider. Requirements are the responsibility of the 'registered person' who, as set out in the legislation, may be either the registered provider or registered manager for the establishment or agency. The Healthcare Inspectorate Wales will request the registered person to provide an 'action plan' confirming how they intend to put right the required actions and will, if necessary, take enforcement action to ensure compliance with the regulation shown.

Standard	Regulation	Requirement	Time scale
C3	14 (1) (b)	**Findings** There was no evidence of documentation to support that the general principles with the National Service Frameworks and National Institute of Clinical Excellence were applied where appropriate. **Action Required** The registered person is required to reflect published research evidence and guidance issued by the appropriate professional and expert bodies where appropriate.	Within 2 months of receipt of this report.
C22, C24, C25 C26 & PD5	14 (5)	**Findings** The findings are detailed within the background and main findings section of the report numbered 1 – 9. **Action Required** 1. Create a process for recording and learning from near miss errors. This is to be implemented by clinic personnel. 2. Reference NICE guidance in prescribing policies, and justify deviation from NICE where appropriate. 3. Ensure that doctor signs stock books when the balances of medication are checked. 4. Ensure that controlled drugs are stored in a cabinet that meets the requirements of the Misuse of Drugs (Safe Custody) Regulations 1973	Within 28 day of receipt of this rep report. (Stated and confirmed by manager as completed March 2010) Within 28 day of receipt of this report. Within 28 day of receipt of this rep report. (Stated and confirmed by manager as completed March 2010) Within 14 day of receipt of this rep report.

Standard	Regulation	Requirement	Time scale
		5. Manager to put in place a legal process for disposal of stock medicines waste.	Within 28 day of receipt of this rep report. (Stated and confirmed by manager as completed March 2010)
		6. Arrange to receive medicine alerts from the MHRA	Within 28 day of receipt of this report. (Stated and confirmed by manager as completed March 2010)
		7. Audit prescribing activity against the product licenses.	Within 28 day of receipt of this report.
		8. Create a policy for unlicensed medicines use that includes information for patients .	Within 28 day of receipt of this rep report.
		9. Ensure that the batch number and expiry date of medicines issued to each patient can be tracked clearly.	Within 28 day of receipt of this rep report. (Stated and confirmed by manager as completed March 2010)
		10. Fit a thermometer in the area where medicines are kept and record the temperature.	Within 28 day of receipt of this rep report. (Stated and confirmed by manager as completed March 2010)

Recommendations

Recommendations may relate to aspects of the standards or to national guidance. They are for registered persons to consider but they are not generally enforced.

Standard	Recommendation
C2	Patient information leaflets should be provided to patients with their medicine. Stated and confirmed by manager that the following action has been undertaken. Patients are given the manufacturers information leaflets and we have printed on our registration forms further information on the unlicensed status and side effects of the medication, we will look at incorporating this information into our patient information leaflets. March 2010.
C2	Ensure that copies of obesity management guidelines such as NICE are available.
C22	Ensure hazard notices regarding medicines are received and acted upon.
C 32	All appropriate data must be carried over from current sheet to new sheet.