INVESTIGATION REPORT

Facility: PLANNED PARENTHOOD LEAG MA CN
470 PLEASANT STREET
WORCESTER, MA, 01609

Reference # 08-1090

Date Received: 08/28/2008

Date Investigated: 09/03/2008

A. INVESTIGATORY STEPS:

1. PERSONS INTERVIEWED

Executive Director
Medical Director
Nurse Practitioner #2
Patient #1
Vice President of Clinical Ops.
Nurse Practitioner #1
Risk Manager
Physician #1

2. RECORDS REVIEWED

Hospital Record
Personnel Files
Policies/Procedures
Policies/Procedures
On Call Progress Notes
Policies/Procedures
Clinical Records
Policies/Procedures
Patient Comment Card
Ultrasound Dating
Policies/Procedures

3. PHYSICAL EVIDENCE REVIEWED

Patient Care Equipment
Physical Plant
Medical Supplies

B. ISSUES FOR INVESTIGATION

1. SYNOPSIS: It was alleged that the Clinic did not appropriately test and treat Client #1, during her follow-up appointment after a to confirm that the that the Clinic Nurse Practitioner(NP) informed Client #1 that her had been and she did not require any additional care; and that alleged approximately two weeks later, Client #1 began to and required at a hospital to

The validity of the allegation was unable to be determined because: the Clinic followed their policy and procedure regarding follow up care for a and instructed Client #1 to return to the Clinic if she had any concerns or problems, interview indicated that Client #1 was told that her was complete and then two weeks later started to Interview

indicated Client #1 did not call the Clinic when she began to and chose to obtain treatment at a hospital where she required treatment for .

2. ISSUES: 1. Quality of Care/Treatment-Oth

C. ISSUE # 1

Quality of Care/Treatment-Oth

BRIEF EXPLANATION OF FINDINGS

It was alleged that the Clinic failed to provide appropriates testing and care when Client #1 had her follow-up appointment after a . It was alleged that the Clinic Nurse Practitioner (NP) informed Client #1 that her had been and that Client #1 did not require any additional care, however, approximately two weeks later, Client #1 began to and required at a hospital to .

State regulations require that each clinic shall maintain administrative records that include written policies and procedures designed to safeguard the health and safety of patients and staff.

The Clinic record indicated that Client #1 was seen at the Clinic on 6/ /08 for service intake. The Service Intake form, dated 6/ /08, indicated that Client #1's first day of 5/ /08. The intake form indicated that a medical history was completed and signed by Client #1.

A Request for Medical Services and Acknowledgement of Receipt of Notice of Health Information Privacy Practices, dated 6/ /08, indicated that Client #1 signed the document acknowledging she received information about the test(s), treatment(s), procedure(s), and method(s) to be provided, including benefits, risks, possible problems/complications, and alternative choices. The notice indicated that Client #1 signed that she should ask questions about anything she did not understand and a clinician was available to answer her questions. The notice indicated that no guarantee had been given to her as to the results that may be obtained from any services rendered. The notice signed by Client #1 was witnessed by NP #1 on 6/ /08.

Nurse Practitioner(NP) #1 was interviewed by telephone at 12:30 A.M. on 9/22/08. NP #1 said she first saw Client #1 on 6/ /08 when she did an to confirm that Client #1 had . NP #1 said the Clinic did not use the ,

) because the test would only confirm which was essential in establishing prior to a . NP #1 said after she confirmed that Client #1 had , then Client #1 was seen by the Clinic Assistant who reviewed all of Client #1's options.

An Examination Report, dated 6/ /08, indicated that based upon her , Client #1 was . The report indicated that the . The report indicated that by , Client #1 was . The report indicated that NP #1 performed the examination.

The clinical record contained a document entitled Client Information for Informed Consent regarding and indicated that Client #1 signed the document on 6/ /08. The consent indicated that a clinic assistant witnessed Client #1 receive the information, that Client #1 said she read the information, understood it, and had an opportunity to ask questions.

The clinical record contained a document entitled Client Information for Informed Consent Supplement to Patient Agreement Form. The information indicated that was a medication used to provide . The information indicated that research studies had shown that alternative treatment plans were as safe and effective as the Federal Drug Administration (FDA) treatment plan, and women found them highly acceptable alternatives to the FDA regimen. The form indicated that Client #1 initialed the Alternative Treatment Plan: plan. The information indicated that Client #1 agreed that she was not more than and her medication would be taken on Day 1. The form indicated that Client #1 would be given . to take home with her on Day 1. The form indicated that this eliminated the need for Client #1 to return to the Clinic, just to . The form indicated that on Day two or three (24 to 48 hours after the), Client #1 agreed to take . The form indicated that Client #1 would place between her cheek and gum then hold the tablets there for 30 minutes. The form indicated that after 30 minutes, Client #1 would swallow any remaining fragments. The form indicated that Client #1 understood that she would need to have a follow-up appointment at the Clinic to make sure that was complete. The form indicated that the follow-up appointment at the Clinic would be within one to two weeks of her first visit.

The Client Information for Informed Consent Supplement to Patient Agreement Form indicated that Client #1 understood

that the method she chose was studied and found to be as safe and effective as the method approved by the FDA and understood that was recommended to in the unlikely event that failed. The form indicated that Client #1's provider answered all of her questions about the alternative options of taking .. The form indicated Client #1 chose the method that was the best choice for her and indicated her choice by checking one of the boxes (and by signing the form she consented to the treatment indicated). The form was signed by Client #1 and dated 6/ '08. The form was witnessed by one of the clinic assistants.

A Patient Agreement Form for indicated that Client #1 had read the attached medication guide, discussed the information with her provider, that all of her questions were answered, and that her provider provided information regarding what to do if she developed or needed emergency care due to treatment.

The Patient Agreement Form for indicated that Client #1 knew that in some cases treatment would not work and understood that if continued after treatment with , Client #1 would talk with her provider about her choices which may include a . The form indicated that she understood that if the ', or if she needed a , her provider would do the procedure or refer Client #1 to another provider who would. The form indicated that Client #1 had the name, address and phone number of her provider and knew that she could call the provider if she had any questions or concerns. The form indicated that Client #1 decided to take the and would follow her providers advice about when to take each and what to do in an emergency. The form indicated that Client #1 would contact her provider right away if she had ,. The form indicated that Client #1 would take her Medication Guide with her when she visited an emergency room or a provider who did not give her so they would understand that she was and would return to the providers office in two/three days to see if her and if not her provider would give her . The form indicated that Client #1 would return to the provider's office about 14 days after beginning treatment to be sure that and that she was well. The form was signed by Client #1 on 6/ /08 and witnessed by a clinic assistant.

A Request for Surgery of Special Procedure, dated 6/ /08, indicated that Client #1 requested that a person authorized by the Clinic provide

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was witnessed by a clinic assistant.

A Department of Public Health (DPH) Consent Form, dated 6/ /08, included information regarding . The information indicated that after you take the , it may take a few days, or sometimes up to a few weeks, before they work. When the medicines work you would probably have Other commonly reported side effects include feeling sick to your stomach (nausea), vomiting, and diarrhea. The form initiated that it was important for the client to have access to a telephone and to transportation in case there was need for . The form indicated the Client must see her health care provider for a follow-up exam to be sure that this . The form indicated if the did not work to , she must agree to have a .

The DPH consent form indicated that problems with were rare but problems could include or . The form indicated that follow-up care was extremely important to be sure the .

The DPH consent form indicated that Client #1 authorized the Clinic to perform . Client #1 signed the form and dated the form on 6/ /08. The form was witnessed by the clinic assistant.

The Information Session Report, dated 6/ /08, indicated that Client #1 received information regarding risks and benefits of both , including aftercare information. The report was signed by the clinic assistant.

NP #1 said again, on 6/ /08 she saw Client #1 after Client #1 was given all the information regarding methods and Client #1 had given consent to have a . NP #1 said she reviewed the information Client #1 had received to make sure that Client #1 understood her choice to have .

NP #1 said she then administered to Client #1 and reviewed the instructions regarding care and follow up required and detailed in the booklet . NP #1 said she gave Client #1 a copy of the instruction booklet and made an appointment for Client #1 to return to the Clinic on 7/ /08.

The Service Medical report, dated

6/ /08, indicated that Client #1 received by mouth and was given to be taken in a single dose on Day two or day three . The report indicated that Client #1 was instructed to take 30 minutes after administration of the for any , and by mouth for seven days. The report indicated that Client #1 was given a follow-up appointment for 7/ /08. The report was signed by NP #1 as the treating clinician.

NP #1 said Client #1 did not keep her 7/ /08 appointment. NP #1 said Client #1 came to the Clinic on 7, /08 and was seen for her follow-up appointment. NP #1 said she did and interviewed Client #1 to determine if the . NP #1 said Client #1 told her that she had self administered on 6/ '08 as instructed and that she had . NP #1 said Client #1 told her that she was at the present time, had no NP #1 said she documented on the Medical Report, dated 7/ 1/08, that the showed an and that there was no , no and no . NP#1 said she dispensed a one month supply of to Client #1 before Client #1 left the Clinic.

NP #1 said the was easier to read on the than the picture produced by the . NP #1 said that when the and . NP #1 said the seen in Client #1's on 7/ 08 was less than . NP #1 said Client #1's looked normal and it was good that Client #1 was . NP #1 said she had no concern that Client #1 had on 7/ /08. NP #1 said she would have told Client #1 that she might expect a little more nd told her to call if she had any questions. NP #1 said she gave Client #1 a pamphlet on the she dispensed to Client #1 but there was no additional pamphlet regarding Client #1's that she would have given Client #1. NP #1 said the pamphlet Client #1 received on 6/ /08 entitled contained all the information Client #1 needed and was intended to provide information for Client #1's

NP #1 said following a a client could continue to have for four to six weeks but generally it would be less time for a woman that was using a . NP #1

said the pamphlet indicated that a client was to call if she developed

or had any other symptoms that were severe or persistant. NP #1 said the Clinic staff is experienced in care and would prefer their clients to call them if they experienced any problems because they would know best how to handle the problem or to which hospital to refer the client.

NP #1 said an could continue to remain positive for up to eight weeks after so would not have been useful information on Client #1's follow-up appointment on 7/ /08. NP #1 said the was the standard measure the Clinic clinicians used to determine that . NP #1 said Client #1 did not call the Clinic after her 7/ /08 appointment to inform them that she was experiencing any problems. NP #1 said there was no indication on 7/ /08 that Client #1 would have any further problems or that . NP #1 said complications rarely occur and it is hard to predict when a problem would develop.

The progress note, dated 7/ '08, indicated that Client #1 did not show for her follow-up appointment.

The progress note, dated 7/ /08, indicated the chart was reviewed on 7/ /08 by a clinic assistant.

A Medical Report, dated 7/ /08, indicated that Client #1 was seen for a follow-up Visit. The report indicated the visit occurred on day 25. The report indicated that Client #1 had received on 6/ /08. The report indicated that Client #1 told NP #1 that and that she experienced . The report indicated that Client #1 stated she was

The Medical Report, dated 7/ /08 contained report. The indicated that and no physical exam was indicated. The report indicated that there was no no evidence of and no evidence of . The report indicated that a month supply was dispensed along with a fact sheet, and FDA insert. The report was signed by NP #1.

Client #1 was interviewed by telephone at 12:30 P.M. on 9/3/08. Client #1 said she was told at the time of her follow-up appointment that everything was fine that the worked and she was .. Client #1 said she was given a fact sheet at the time of her first visit but not anything further regarding her at her follow-up visit. Client #1 said she was given at her follow-up visit that made her sick so she stopped using it. Client #1 said two weeks after her follow-up Clinic visit she started . Client #1 said she did not call the Clinic, but instead went to the closest hospital because . Client #1 said she had to have an was told that she

The Hospital History and Physical (H&P) Examination form, dated 7/ /08, indicated that Client #1 presented with , which started earlier in the day. The H&P indicated that Client #1 reported she had given in two separate doses (on 6/ 08 and 6/ /08) and then had a poor experience with which was discontinued, followed by then again by . The H&P indicated evealed a complex consistent with

The 7/ /08 H&P indicated Client #1 was . The H&P indicated that Client #1's were stable and her were stable. The H&P indicated that Client #1 had an and a was deferred to the operating room. The H&P indicated that Client #1 gave consent for

The Report, dated 7/ /08, indicated that Client #1's diagnosis was . The diagnosis was and with a pending report.

The report indicated that a bi-manual examination revealed . The report indicated that was performed and complete was felt to be accomplished.

The laboratory report indicated that sample included . A final diagnosis was

Physician #1 was interviewed by telephone at 4:00 P.M. on 9/19/08. Physician #1 said he was the on call on 7/ /08 when he was called by the hospital emergency room physician. Physician #1 said he saw

Client #1 in the emergency room for related to . Physician #1 said he performed the on Client #1 on 7/ /08 and his bi-manual examination of Client #1 in the operating room revealed . Physician #1 said on 7/ /08 he performed on Client #1. Physician #1 said Client #1 had no complications from the procedure.

The Clinic Director was interviewed in person throughout the day on 9/03/08. The Clinic Director said the Clinic had no information that Client #1 had any problems after her follow-up Clinic visit on 7/ /08. The Clinic Director said if the Clinic knew of any problem there would have been a full review of the chart, as per their policy and procedures related to complications and emergency protocols for

The Medical Director was interviewed by telephone at 1:22 P.M. on 9/3/08. The Medical Director said she had not reviewed Client #1's chart but would do so.

The Medical Director was interviewed by telephone at 2:00 P.M. on 9/23/08. The Medical Director said she reviewed Client #1's medical record and agreed that was within normal limits and that fact, in combination with Client #1's report of at the time of her follow-up appointment on 7/ /08, would strongly indicate that Client #1's had been successful. The Medical Director said the is not 100% accurate and the most common complications after a would be and . The Medical Director said the complications were more likely to occur within two weeks following the which was why they had the clients seen for a follow up appointment two weeks after the . The Medical Director said complications were less likely to occur after the two week period of time.

The validity of the allegation was unable to be determined because:

1. The clinical record indicated that Client #1 was provided information regarding the medications she was given to . The record indicated that Client #1 received printed information regarding her and instructions to call the Clinic if she had any problems or concerns.

2. The clinical record and interview with NP #1 indicated that Client #1 returned to the Clinic for a follow-up visit on 7/ /08 and had an that indicated Client #1 had an There was no evidence that Client #1 was informed that complications could occur after her follow up appointment on 7/ /08

3. Interview with NP #1 indicated that could continue to remain positive for up to eight weeks . so an test would not have been useful information on Client #1's follow-up appointment on 7/ /08. NP #1 said the was the standard measure the Clinic clinicians used to determine that the had been completed.

4. Interview with NP #1 indicated that there was no indication that Client #1 would have any complications following ..

5. NP #1 said she did not review the pamphlet with Client #1 on her follow-up visit on 7/ /08 but did tell Client #1 to call if she had any questions.

6. NP #1 said the was not 100% reliable in confirming the was complete.

7. Client #1 said she was told on 7/ 08, at the time of her follow-up appointment, that everything was fine, that the worked and she was nt. Interview indicated that Client #1 left the Clinic on 7/ /08 thinking that the had been and there was no problems that would take place. Client #1 said she was given a fact sheet at the time of her first visit but nothing further regarding her at her follow up visit.

8. Record review indicated that Client #1 signed a DPH consent form that indicated that problems with were rare but problems could include

9. The hospital record indicated that Client #1 presented herself at the emergency room 13 days after her Clinic follow-up appointment with complaints of .

10. The hospital record indicated that Client #1 had on 7/ /08 and the laboratory report indicated the final diagnosis was .

11. The Client #1 said on 7/27/08 she began to and did not even think to call the Clinic, rather went to the closest hospital for care.

VALIDITY: Unable to determine

D. RECOMMENDATIONS/COMMENTS