STATE OF MICHIGAN
RICK SNYDER
GOVERNOR
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF HEALTH CARE SERVICES
MIKE ZIMMER
ACTING DIRECTOR

November 24, 2014

Women's Center of Southfield (636949)
C/O Pam DiMaggio
28505 Southfield Road
Lathrup Village, MI 48076

COMPLAINT INVESTIGATION

Participants

Facility:
RN1, Hospital A
RN2, Hospital A
Physician1, Hospital A
Physician2, Hospital A
Physician3, Hospital A
Michelle Doyle, Medical Assistant, Women's Center of Southfield *(Survey 4/24/14)
Pam DiMaggio, Office Manager, Women's Center of Southfield *(Survey 4/24/14)
State Agency:
Pam Lindsey, RN, Health Care Surveyor
Andrew Schefke, Health Care Surveyor

GENERAL INFORMATION

The Complaint Investigation was conducted on Women's Center of Southfield.

On October 13, 2014 the department received via email the initial complaint. (It was noted this complainant had been identified previously as part of a patient sample during the 4/24/14 post annual follow up survey conducted at Women's Health Center of Southfield)

On October 17, 2014 surveyor #1 met with complainant to complete the intake. The provision of care began at Women's Center of Southfield where the complainant was having a 2nd trimester abortion and ended with an emergent transfer to Hospital A for a surgical repair of a perforated uterus.

On October 20, 2014 both surveyors went to Hospital A to interview staff and review medical records related to the complaint. The survey started with a brief opening conference with the RN2. Clinical record review was completed. Four Hospital A staff members were interviewed.

Physician3 interviewed stated they didn't recall anything related to the care of the complainant.

Four (4) of six (6) complaint allegations were substantiated or partially substantiated while the remaining two (2) allegations could not be confirmed by medical record review or interview.

Complaint Allegations

1. It was alleged Dr. Sharpe and Dr. Kalo failed to inform the patient of what to expect, and risks involved when having a 2nd trimester abortion. Was told it was a simple procedure. (Partially Substantiated)
2. It was alleged the morning of the procedure the patient and husband arrived and patient received no counseling, or discussion of informed consent (Substantiated)
3. It was alleged patient was given 2 pills in a cup before the procedure and no IV medication, and was ignored when asked what the medications were.
4. It was alleged no RN was present and no vital signs were taken during the procedure (Substantiated)
5. It was alleged that at the point in the procedure when patient felt an intense burning pain blood started spraying everywhere and staff left room to get swifter mop to clean up blood and doctor changed cover gown before calling 911.
6. It was alleged staff put patient in diaper and had EMS take her out the back winding steps instead of straight out the front to ambulance (partially substantiated)

Bureau Investigation Findings

On 2/28/14 complainant went to Women's Center of Southfield for second part of 2nd trimester abortion procedure by Dr. Sharpe. Review of the medical record revealed the following:

- Informed consent forms signed by patient but no documentation of counseling having been provided. Complainant alleged that they did not sign any consent forms. Note that the patient signature on the consent forms appears to be consistent with the patient signature elsewhere in the medical record.
- No physician documentation in progress notes regarding discussion of procedure with patient.
- No documentation found regarding pills except listing them on the Anesthesia record.
- Progress notes by medical assistant (AC) found in medical record indicate procedure started approximately 9AM. Operative Procedure notes signed by medical assistant state 10cc of 1% Xylocaine local anesthesia to cervix, estimated blood loss 50cc & tissue obtained sent to pathology.
- Anesthesia record states anesthesia given by Dr. Sharpe. No mention of IV having been started. States drugs given as Diazepam 5mg/1ml, Promethazine 25mg/1ml, and Demerol 100mg/1ml, with sedation listed as sleep. No documentation was found for time, or route for drugs given. Spo2 monitoring was checked off, but no Spo2 documentation was found

on the Anesthesia or O.R. record.

- No documentation of vital signs (BP, Pulse or Respirations) was found on the OR record. No evidence of patient monitoring was found. The chart contained no documentation for observations related to patient's color or condition during procedure.
- No registered nurse was present in the facility on day of procedure. In the progress notes by medical assistant AC it states Community EMS was dialed at approximately 930-945AM, put MA on hold, so they dialed 911. States EMS arrived at 1000 AM.

EMS report indicates arrival at Women's Health Center @ 1009 AM. Found complainant on treatment table with adult diaper on. Blood was noted on treatment floor. EMS notes state IV had been started and 800 ML of Lactated Ringers had been given prior to our arrival. Report states Dr. Sharpe stated that he believed the upper portion of the fetus head is still attached. Patient transferred by stretcher to Hospital A. No mention of how patient exited the building.

During a phone interview on 10/20/14 with Physician1, who was the complainant's surgeon at Hospital A, stated that the patient appeared pasty white, tachycardic and hypotensive, but hemodynamically stable at the time of surgery. He described the uterine perforation to be 6mm, and retained fetal cranium within the abdominal cavity. He also mentioned the patient had a significant hemoperitoneum. Physician 1 stated he was contacted by Dr. Sharpe and he told him the procedure he performed and updated him on the patient's condition.

The operative report from 2/28/14 lists procedures performed as 1) Exploratory laparotomy with extraction of retained fetal parts, 2) Repair of uterine perforation, and 3) Evacuation of hemoperitoneum. The report states "the patient was noted to have a hemoperitoneum with over 1000cc of blood."

On a follow up post annual survey conducted at Women's Center at Southfield on 4/24/14, the complainant was discussed as part of a sample of patients selected by surveyors. One issue identified was the facility failed to have a transfer log with follow up. This patient's chart was reviewed at that time and discussed with participants* as indicated on current participant list. Lack of documentation, failure to monitor, necessity of provision of care by an RN, and establishing a quality program to review and prevent cases like this was all discussed. To date no such program has been established. In addition on 6/17/14 Dr. Sharpe was found doing a 2nd trimester procedure at the center without an RN on site and no staff with patient in PACU.

COMPLAINT SUMMARY

Four (4) of six (6) complaint allegations were substantiated or partially substantiated while the remaining two (2) allegations could not be confirmed by medical record review or interview. Please note that any enforcement actions due to these survey findings will be sent under a separate cover.

Pam Lindsey

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