STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
LANSING

BUREAU OF HEALTH CARE SERVICES
HEALTH PROFESSIONS INVESTIGATION DIVISION

INVESTIGATION REPORT

51-134637
File No.
Reginald Sharpe, DO
Case Name

Danene Nunez — 3-4-15
Investigator/Initial — Date

3/4/2015
Manager Approval — Date

Investigation Director Approval — Date

Enforcement Director Approval — Date
(Only if case closure recommendation)

RECOMMENDATION

☐ Enforcement ☑ Expert Review ☐ Closure

☐ Returned Without Investigation ☐ Add'l Investigation Request ☐ Supplemental Report

ALLEGATION INFORMATION

[redacted] informed the State of Michigan Bureau of Health Care Services, of a report written on July 3, 2014, by Pam Lindsey, R.N., Surveyor for the Bureau of Health Care Facilities which indicates that the licensee performed a termination procedure without a nurse present.

INTERVIEWS CONDUCTED

Name	Connection to Allegation (C=complainant, W=witness, L=licensee, and relationship to the case)	Contact Information Phone number and/or e-mail address	Date Conducted (chronologically)
Pam Lindsey, RN	W-Health Care Facility Surveyor	(517) 897-2093	2-5-15
Jacob Kalo, MD	W-Owner of Women's Center of Southfield	[redacted]	2-9-15
Reginald Sharpe, MD	L	[redacted]	2-23-15
[redacted], RN	W-nurse employed at Women's Center of Southfiled	[redacted]	2-26-15

INVESTIGATOR ASSESSMENT

Pam Lindsey R.N., Surveyor, completed reports dated July 3 and November 24, 2014, regarding patient care issues identified during a survey of the Women's Care Center of Southfield located in Lathrup Village. Ms. Lindsey identified these patients to this Investigator as patient [redacted] and [redacted]. Ms. Lindsey informed that these issues as it pertains to Health Care Facilities were addressed with owner Jacob Kalo, M.D.

[redacted] presented herself to Women's Care Center of Southfield, Lathrup Village Clinic on [redacted], in which an ultrasound was performed which indicated that she was [redacted] gestation. The licensee stated that he spoke with the patient about the procedure which included risks and complications. The patient signed consent forms for treatment. Due to the later gestation of the fetus, the termination procedure is two day. One day to insert the Laminaria ([redacted]), and the next ([redacted]) for a "D&C," also known as dilation and curettage (scraping of the uterus).

The licensee informed that he does not recall the patient or the procedure. But upon review of the patient record he informed that there were no complications. The products of conception were verified; the patient was placed in recovery and then discharged the same day.

The licensee does not recall if a nurse was present during the procedure. This Investigator showed the licensee the signature of Nurse [redacted] who signed the medical record. The licensee does not recall Nurse [redacted].

Jacob Kalo, M.D., owns Women's Care Center of Southfield located in Lathrup Village. Dr. Kalo informed this Investigator, that after the procedure, he asked the R.N. who he hired, [redacted], R.N., to review the patient record of [redacted] from Dr. Sharpe. Ms. [redacted] signed the patient record. Ms. [redacted] did not denote the date in which she performed her review or the accurate date and time that she signed the record or that the signature was a late entry.

[redacted], R.N., informed that she decided to quit working for Dr. Kalo because she thought he asked her to do aspects of her job that were not ethical. Dr. Kalo asked her to review charts in which she was not present at termination procedures that were performed. Ms. [redacted] informed that she never worked with Reginald Sharpe, M.D. She does not recall patient [redacted]. She does not recall signing the chart of [redacted].

On [redacted], patient [redacted] presented herself for termination of pregnancy. On [redacted] an ultrasound indicated that she was approximately [redacted] gestation. The licensee showed the ultrasound or provided the option to review the ultrasound to the patient. This was a two day procedure which consisted of the Laminaria insertion on [redacted]. The patient received sedation for the insertion of the Laminaria which was injection of [redacted] therefore providing twilight sedation. However, the medication administration record indicates that the [redacted] was delivered via IV. The licensee acknowledged the error in the record indicating that the [redacted] was not administered via IV rather it was routed via injection. The licensee informed that on [redacted], he verbally counselled the patient informing her of the risk and complications of the procedure. [redacted] signed to appropriate consent forms for treatment.

[redacted] presented herself to the Lathrup Village location on [redacted], for the second step of the procedure which was the D&C. [redacted] was provided the sedation of [redacted] to relax and [redacted] for pain via injection. The licensee informed that this patient also had her vitals monitored via machine. However, he does not see the patient vital monitor strip sheet attached in the patient record.

The licensee explained that the procedure is performed with an ultrasound and he was able to see [redacted]. He uses forceps to remove the products of conception but due to [redacted] he was unable to remove it at the clinic and therefore around 9:50 am (the procedure started approximately 9:00am) EMS was called to transfer the patient to Botsford

Hospital for [redacted] EMS transported the patient from the facility to the hospital around 10:25 am.
The licensee stated that he contacted the ER physician informing that the patient was being transferred and the status. The licensee stated that at the time of transfer the patient was stable. The licensee spoke with the surgeon at approximately 12:23 pm who informed that the patient had not been taken to surgery yet because of the busy surgical schedule. The licensee stated that he was worried of [redacted] At 6:11 pm, he spoke with the hospital who indicated that surgery had begun. At 8:00 pm, he spoke with the surgeon who informed that the patient underwent [redacted].

The licensee feels that the [redacted] was due to the delay in surgical intervention at the hospital. The licensee does not deny that [redacted] was made. He explained that this [redacted] could have occurred because [redacted] or that because [redacted].

The licensee does not recall the name of the medical assistant that was present during the procedure and he does not recall if a nurse was present during the procedure. Review of the medical record does not indicate a nurse signature.

It is recommended that this allegation be sent to an expert for review to determine if there are Board Administrative Rule violations and/or Violations to the Michigan Public Health Code.

ADDITIONAL INFORMATION/CONTACTS

The licensee has had ten allegations (58166, 59116, 130421, 108712, 128090, 131166, 127808, 127641 and 114286) in which no action was taken. He has three allegations (135173, 128172 and 135562) which are currently open, and one allegation (98202) in which he received disciplinary action and is currently participating with the sanction.

The complainant, [redacted], was sent a letter informing of the authorization of the investigation. She was not interviewed due to past filings of allegations in which she could not provide any information and the current allegation in which only Health Facility letters were submitted. The complainant was not involved and could not provide any further information.

Patient [redacted] was contacted via telephone and did not respond to request for interview. [redacted] was not contacted due to information from Ms. Lindsey that [redacted] because of the incident.

ATTACHMENTS

#	Document Name	Provided By	Obtained By	# of Pages
1.	Letter of Allegation	[redacted]	Allegation Section	7

#	Document Name	Provided By	Obtained By	# of Pages
2.	Patient record of [redacted] from Women's Center of Southfield	James Burdick, attorney	Investigator	27
3.	Patient record of [redacted] from Women's Center of Southfield	James Burdick, attorney	Investigator	38
4.	November 24, 2014, Health Care Facility Letter	Pam Lindsey, RN	Investigator	4
5.	Patient record of [redacted] from Botsford Hospital	Pam Lindsey, RN	Investigator	10

POSSIBLE VIOLATIONS

333.16221 (a)
333.16221 (h)
R325.3840 (2)
R325.3847 (2) (h) (i)

QUESTIONS TO THE EXPERT

1. Does it appear that the licensee informed the patient(s) of what to expect and risks involved with the procedures? Did appropriate consent, counseling and discussion occur? Did the licensee appropriately document these actions in the patient record? Please explain.
2. Does it appear that a R.N. was present during the procedure(s)? If not, did the licensee practice below a minimal standard of care by not having an R.N. present during the procedure(s)? Please explain.
3. Does it appear that the licensee documented the correct medication, correct administration and correct route regarding the medications given to the patient(s)? If not, was this below a minimal standard of care?
4. Does it appear that the patient(s) were monitored (i.e. vitals) during the procedure? If not, was this below a minimal standard of care? Please explain.
5. Does it appear that the licensee [redacted] of patient [redacted]? Please explain.
6. Did the licensee recognize and treat [redacted] within a reasonable standard of care? Please explain.
7. Does it appear the licensee's conduct was a violation of general duty, consisting of negligence or failure to exercise due care, including negligent delegation to or supervision of employees or other individuals, whether or not injury resulted? Please explain.
8. Does it appear the licensee's conduct was a departure from, or failure to conform to, minimal standards of acceptable and prevailing practice for the profession, whether or not actual injury to an individual occurred? Please explain.
9. If during your review, you identify other issues or potential violations of the Michigan Public Health Code and/or Administrative Rules that have not been addressed, please include them in your written report.

DN nm
51134637investigationreport

WITNESS INTERVIEW –Pam Lindsey, RN

Address: Ottawa Building, 1st Floor
611 W. Ottawa Street
PO Box 30664
Lansing, MI 48909

Telephone #: (517) 897-2093

Professional #: 47-04-134404

Identified By: State ID

Interview Date: February 5, 2015

Location of Interview: Dunkin Donuts, Warren, MI

BACKGROUND

Pam Lindsey, RN, is a State of Michigan, LARA, Bureau of Health Care Services, Health Care Surveyor for the Health Facilities Division. She performed surveys of the Lathrup Village Clinic of Jacob Kalo, MD.

STATEMENT

Ms. Lindsey informed that she performed four surveys to the licensee's Women's Center of Southfield Clinic located at 28505 Southfield Road, Lathrup Village, MI. These surveys occurred on September 30, 2014, June 17, 2014, April 24, 2014, and December 2013. The facility was provided a letter shortly thereafter listing the areas of deficiency and request for correction.

Ms. Lindsey informed that the patient identified in the [redacted] survey is [redacted]. A copy of the survey is referred to as attachment #1 pages 2-3. Ms. Lindsey informed that upon entering the office she did not see a receptionist or any staff present at the counter. Ms. Lindsey telephoned the number of Dr. Kalo which was listed on the business card and was informed that the staff was in the back doing a procedure. Shortly thereafter, a medical assistant came to the desk and informed that the physician was Reginald Sharpe, DO, who was performing the termination and there was no nurse present on site. Ms. Lindsey informed that R325.3847 (h) requires the medical record to contain nurse's notes.

Ms. Lindsey informed that on [redacted] she viewed the patient record of [redacted] which did not contain a nurse signature. Ms. Lindsey did not make a photocopy of the record. Ms. Lindsey returned for survey on [redacted]. She made a

photocopy of [redacted] record. This time, a nurse signature was on the record. It appeared that the nurse, [redacted], signed the medical record. attachment #3 pages 19, 23, and 38. Ms. Lindsey spoke with Dr. Kalo about the signature of Ms. [redacted] appearing on the patient record. Dr. Kalo informed her that he hired Nurse [redacted] to review records of patient who had procedures and to sign that she reviewed the chart. Ms. Lindsey informed that it appeared that Dr. Kalo had the nurse sign the chart in which the chart is falsified. Furthermore, this patient was seen several weeks earlier at another office of Dr. Kalo in which Dr. Kalo referred the patient to the licensee. This period of time would have allowed Dr. Kalo and/or the licensee to request a nurse present for the procedure.

Ms. Lindsey informed that she reviewed the patient record of [redacted] when the Health Facilities received a complaint. A report regarding [redacted] is referred to as attachment #4. Ms. Lindsey informed that on [redacted], [redacted] went to Women's Center of Southfield located in Lathrup Village for part of 2nd trimester abortion that was to be completed by the licensee. Ms. Lindsey stated that upon review of the medical record there were discrepancies which consisted of failure to document patient counseling by physician, documentation regarding medication administered and monitoring of the patient (vitals) failed to address the right route, dosage or monitoring, as well as no nurse present for the procedure.

[redacted] was transported to the hospital for [redacted]. The patient experienced [redacted] Ms. Lindsey spoke with the surgeon at the hospital who informed that the patient was [redacted] at the time of surgery. The [redacted]. The surgeon noted [redacted]. An [redacted] was performed as well as [redacted]. Ms. Lindsey informed that the facility failed to have a transfer log with follow up, lacked documentation regarding the incident, failure to monitor. It was believed that the licensee performed a 2nd trimester procedure at the center without an RN on site and no staff with the patient in the PACU.

Ms. Lindsey informed that she has spoken to [redacted] about the treatment. [redacted] because of the incident. [redacted] told Ms. Lindsey that she [redacted] due to the situation. Ms. Lindsey feels that the physician notes about the post treatment documented by the licensee are false.

Ms. Lindsey asked that this Investigator not contact [redacted] regarding the situation.

Ms. Lindsey provided this Investigator with partial patient record of [redacted] from Beaumont Hospital. Refer to attachment #5.

DN cc
51134637pamlindsey

Case: Reginald Sharpe, DO
File #51-134637

WITNESS INTERVIEW –Jacob Kalo, MD

Address: 28477 Hoover Rd.
Warren, MI 48093/license address

[redacted]

Telephone #: [redacted]

Professional #: 43-01-040053

Identified By: Michigan Professional License Number

Interview Date: February 9, 2015

Location of Interview: Women's Center of Southfield, 28505 Southfield Rd., Lathrup Village, MI 48076

Also Present: James Burdick, attorney

BACKGROUND

Dr. Kalo practices Obstetrics/Gynecology. He was educated at Tel Aviv University. He has been licensed with the State of Michigan since 1978. He has staff privileges at DMC Sinai-Grace Hospital, Hutzel and Harper Hospitals as well as St. John Hospital. His Lathrup Village clinic has been closed for patient care since October 2014. His current office locations are West Bloomfield, Sterling Heights, Warren and Detroit (8 Mile location). He is the only practitioner currently working at the facilities. He is Board Certified in Obstetrics/Gynecology.

Attorney Burdick provided this Investigator with the medical record of patients [redacted] and [redacted]. Refer to attachments #2 and 3.

STATEMENT

Dr. Kalo informed that Reginald Sharpe, DO was a contract employee who performed pregnancy terminations up to 24 weeks gestation. Dr. Kalo terminated the employment agreement with Dr. Sharpe in August 2014, because of the perforations Dr. Sharpe had with his patient care. Dr. Sharpe was employed since December 2012.

Dr. Kalo informed that he examined patient [redacted] on [redacted] regarding termination of pregnancy. Dr. Kalo does not perform terminations on patients who are [redacted] such as [redacted]. Dr. Kalo referred the patient to Dr. Sharpe.

Dr. Kalo informed that he was not present during the termination procedure for patient [redacted] performed by Dr. Kalo on [redacted] (record indicates that the termination was performed on [redacted] and the ultrasound and laminaria was performed on [redacted] He explained that on [redacted], he was present at the Lathrup Village office but he was not in the procedure room. Dr. Kalo received a phone call from [redacted]. Dr. Kalo left the facility to go to [redacted]. While enroute, he received a phone call from his office staff indicating that Pam Lindsey, Health Care Surveyor, was there for another survey. He asked to have Ms. Lindsey wait for him, to which she refused, therefore Dr. Kalo stated that he returned to the facility and by the time he got there, Ms. Lindsey had left.

Dr. Kalo informed that he spoke with Ms. Lindsey at a later date regarding the pregnancy termination of [redacted]. Dr. Kalo confirmed that he was not in the procedure room, he left the facility, and no other licensed person, other than Dr. Sharpe was at the facility. Dr. Kalo informed this Investigator, that after the procedure, he asked the RN who he hired, [redacted], RN, to review the patient record of [redacted] from Dr. Sharpe. Ms. [redacted] signed the patient record. Ms. [redacted] did not denote the date in which she performed her review or the accurate date and time that she signed the record or that the signature was a late entry. Refer to attachment #3 pages 19, 23 and 38.

AS cc
51134637jacobkalo

Case: Reginald Sharpe, DO
File #51-134637

LICENSEE INTERVIEW

Address: 15801 W. McNichols
Detroit, MI 48235

Telephone #: [redacted]

Professional #: 51-01-010839

Identified By: Previous Meeting

Interview Date: February 23, 2015

Location of Interview: Cadillac Building, Detroit

Also Present: Michael Sharpe, attorney

BACKGROUND

The licensee specializes in Obstetrics and Gynecology. He has been licensed with the State of Michigan since 1989. He is currently working for Summit Medical Clinics.

The licensee has retained the legal representation of Michael Sharpe ([redacted]/mjsharpe2003@yahoo.com).

STATEMENT

The licensee began working for Jacob Kalo, MD who owns Women's Center of Southfield located in Lathrup Village in June 2013 until approximately February 2014. The licensee did not have a written contract for employment with Dr. Kalo. The licensee performed pregnancy terminations at Dr. Kalo's clinics.

The licensee informed that he performed the termination for patient [redacted] occurring on [redacted]. This was a two day procedure in which [redacted] presented herself to the Lathrup Village Clinic on [redacted] in which an ultrasound was performed which indicated that she was [redacted] gestation. The licensee stated that on [redacted], he provided the ultrasound or provided the patient the opportunity to view the ultrasound to confirm pregnancy. He spoke with the patient about the procedure which included risks and complications. The patient signed consent forms for treatment. [redacted] to begin the procedure. Due to the [redacted] gestation of the fetus, the termination procedure is two day. One day to insert the Laminaria which is used to expand the cervix, the mouth of the uterus, before certain medical procedures. They place a layer of laminaria directly inside the cervix, the "neck" of the uterus. This layer of laminaria is sometimes called a "tent." The purpose of the

tent is to enlarge the cervix before "D&C," also known as dilation and curettage (scraping of the uterus). Laminaria tents are also used in pregnant women to "ripen" (expand) the cervix to make labor and delivery easier, and also to cause abortions during the first three months of pregnancy.

The patient presented herself on [redacted] to the Lathrup Village Clinic for the second step of the procedure which is the D&C. [redacted] was under twilight sedation which was [redacted] to relax and [redacted] for pain. The licensee informed that this was administered via injection. The patient vitals at the time of injection were BP [redacted], Pulse [redacted] temp [redacted] The licensee informed that the facility is equipped with a machine that monitors vitals. The patient is connected to the machine that at random times takes vitals during the D&C procedure. This strip of vitals is a piece of paper and is generally placed in the patient's medical record. Refer to attachment #3 page 36. The patient's vitals were hand noted also by the medical assistant during the procedure. Refer to attachment #3 page 23.

The licensee informed that he does not recall the patient or the procedure. But upon review of the patient record (refer to attachment #3) he informed that there were no complications. The products of conception were verified; the patient was placed in recovery and then discharged the same day.

The licensee does not recall if a nurse was present during the procedure. This Investigator showed the licensee the signature of Nurse [redacted] who signed the medical record. Refer to attachment #3 pages 19, 23 and 38. The licensee does not recall Nurse [redacted]. The licensee informed that he knew there was a change of the law indicating that a nurse needed to be present but he does not know when this law changed or became in effect. He explained that it was the responsibility of Dr. Kalo to provide a nurse at the facility. The licensee informed that at his current employer, Summit, there is always a nurse present during procedures.

The licensee stated that he recalls Dr. Kalo present at the facility but not present in the room during the procedure.

The licensee informed that Dr. Kalo did not contact him post procedure regarding any changes that were made to the patient record of [redacted]. The licensee is not the keeper of the record and it remains at Dr. Kalo's office.

The licensee informed that he recalled the treatment provided to patient [redacted] because she was transferred to the hospital from the facility. On [redacted] presented herself for termination of pregnancy. The licensee performed an ultrasound which indicated that she was approximately [redacted] gestation. The licensee showed the ultrasound or provided the option to review the ultrasound to the patient. Refer to attachment #2, page 3. [redacted] signed the consent acknowledging the ultrasound and the approximate weeks of gestation. Refer to attachment #2 page 4.

This was a two day procedure which consisted of the Laminaria insertion on [redacted]. The patient received sedation for the insertion of the Laminaria which was injection of [redacted] therefore providing twilight sedation. However, the medication administration record indicates that the [redacted] was delivered via IV. The licensee acknowledged the error in the record indicating that the [redacted] was not administered via IV rather it was routed via injection. Refer to attachment #2 page 13.

The licensee informed that on [redacted], he verbally counselled the patient informing her of the risk and complications of the procedure. [redacted] signed to appropriate consent forms for treatment.

[redacted] presented herself to the Lathrup Village location on [redacted], for the second step of the procedure which was the D&C. [redacted] was provided the sedation of [redacted] to relax and [redacted] for pain via injection. Vitals pre procedure was BP [redacted], Pulse was [redacted] and temp was [redacted]. The licensee informed that this patient also had her vitals monitored via machine. However, he does not see the patient vital monitor strip sheet attached in the patient record. The licensee stated that the patient was monitored yet the sheet does not appear in her record. Refer to attachment #2.

The licensee informed that the procedure was going pretty well. He viewed the [redacted]. He viewed the [redacted]. The licensee explained that the procedure is performed with an ultrasound and he was able to see the [redacted]. He uses [redacted] but due to [redacted] at the clinic and therefore around 9:50am (the procedure started approximately 9:00am) EMS was called to transfer the patient to Botsford Hospital for [redacted] EMS transported the patient from the facility to the hospital around 10:25am. Refer to attachment #2 page 9. The licensee informed that the patient was transferred via stretcher to the ambulance through a door that leads from the facility procedure area to the main entrance of the building. The patient is not transferred out through the facility waiting room. The licensee denied that the patient was transferred out of the building through a back door.

The licensee stated that he contacted the ER physician informing that the patient was being transferred and the status. The licensee stated that at the time of transfer the patient was stable. The licensee spoke with the surgeon at approximately 12:23pm who informed that the patient had not been taken to surgery yet because of the busy surgical schedule. The licensee stated that he was worried of [redacted]. At 6:11pm, he spoke with the hospital who indicated that surgery had begun. At 8:00pm, he spoke with the surgeon who informed that the patient underwent [redacted]. Refer to attachment #2 page 24.

The licensee explained that the patient was [redacted] There was [redacted] that would be associated with the procedure however he feels that the [redacted] was due to the delay in surgical intervention at the hospital. The licensee does not deny that during the extraction procedure [redacted]. He explained that this [redacted] could have occurred because [redacted] or that because the [redacted].

The licensee does not recall the name of the medical assistant that was present during the procedure and he does not recall if a nurse was present during the procedure. Review of the medical record does not indicate a nurse signature. Refer to attachment #2.

The licensee stated that he spoke with the patient when she was done with surgery. The patient was grateful that the situation was recognized so quickly and treatment was provided quickly. Refer to attachment #2 page 24. The licensee informed that on the progress notes where he indicated all his contact with various hospital personnel or the patient, he spoke with these people.

The licensee stated that the situation with [redacted] was complication that was explained that possibly could occur. He felt that he recognized the situation and took proper steps to provide care.

The licensee added that he had provided numerous terminations to patient that did not have complications and he has provided a safe service to those seeking this procedure.

The licensee stated that he never spoke with an inspector with the State of Michigan about these two patient care situations.

DN cc
51134637reginaldsharpe

Case: Reginald Sharpe, DO
File #51-134637

WITNESS INTERVIEW - [redacted], RN

Address: [redacted]

Telephone #: [redacted]

Professional #: [redacted]

Identified By: Telephone Number

Interview Date: February 26, 2015

Location of Interview: Telephone

BACKGROUND

Ms. [redacted] was identified by Jacob Kalo, MD, as the nurse who reviewed the patient record of [redacted] Refer to attachment #2 pages 19, 23 and 38.

STATEMENT

Ms. [redacted] explained that she worked for Jacob Kalo, MD at the Lathrup Village office for a few days. She cannot recall the days in which she worked. She thinks that she was only at the Lathrup Village office on one day in [redacted] however, she does not recall the specific date.

Ms. [redacted] informed that she decided to quit working for Dr. Kalo because she thought he asked her to do aspects of her job that were not ethical. Dr. Kalo asked her to review charts in which she was not present at termination procedures that were performed. Ms. [redacted] informed that she never worked with Reginald Sharpe, MD. She does not recall patient [redacted]. She does not recall signing the chart of [redacted].

Ms. [redacted] informed this Investigator that she would review her calendar to determine if she worked for Dr. Kalo on [redacted]. She informed that she would contact this Investigator with the information.

NOTE:

On February 26, 2015, Ms. [redacted] contacted this Investigator with a question as to whether or not she was under investigation or if she would be in "trouble" regarding signing a chart that she was not present for the termination procedure. This Investigator informed Ms. [redacted] that currently there are cases pertaining

on Drs. Kalo and Sharpe that are under investigation and that the Boards of Medicine, Osteopathy and Nursing will review the information.

On February 26, 2015, this Investigator emailed Ms. [redacted] a redacted sheet of [redacted] record asking to confirm her signature. As of date, Ms. [redacted] has failed to provide this Investigator the information as to whether or not it is her signature. Ms. [redacted] has failed to respond to further request for information regarding the signature in the record of [redacted] .

DN cc
[redacted]

Expert Report

Case Name: Reginald Sharpe, DO

File #51-14-134637

Questions

1. **Does it appear that the licensee informed the patient(s) of what to expect and risks involved with the procedures? Did appropriate consent, counseling and discussion occur? Did the licensee appropriately document these actions in the patient record? Please explain.**

   Response: The content of the consent itself is unknown. The form used is a generic form that would be the same for an early (D&C) abortion and a second trimester (D&E) abortion. The consent specifies D&C which would suggest inadequacy of documentation. However, the procedure also states (termination of pregnancy" which is vague enough to include however the procedure for the given gestational age was to be performed. The consent form does include the estimated gestational age of the pregnancy which implies the patient was informed about the planned procedure for that gestational age. I cannot state from the documentation or testimony that the patient was not informed of the planned procedure and risks. Accordingly, since the patient signed this form, I can only assume that appropriate consent, counseling and discussion did occur.

2. **Does it appear that a R.N. was present during the procedure(s)? If note, did the licensee practice below a minimal standard of care by not having a R.N. present during the procedure(s)? Please explain.**

   Response: The records and the testimony all indicate that a nurse was not present for the procedure. Per rule R325.3840(2), this is against the medical code. From a standard of care standpoint, some other licensed professional should be present in the facility with conscious sedation being administered. Medical standard of care would not denote that person be a R.N. (a L.V.N. would be medically acceptable) but the Michigan law appears to indicate this person must be a R.N. Accordingly, this act is not below the medical standard of care but does violate Michigan legal code. However, for [redacted] and [redacted] procedures, sleep/heavy sedation was documented for which another physician or nurse anesthetist should have been present from a medical standard of care. Even a registered nurse would not be within medical standard of care.

Because Michigan legal code R325.3840(2) stipulates a nurse must be present for the procedure to occur and Dr. Sharpe performed the procedure without a nurse present, that is Dr. Sharpe's issue in relation to the law. Dr. Sharpe stated that Dr. Kalo, as owner of the clinic, has the responsibility to provide the nurse. However, if one is not present, Dr. Sharpe as an independently licensed professional makes his own decisions about whether or not to proceed without a nurse. If Dr. Sharpe had indicated that the urgency of the situation required he proceed even without a nurse, that would be sound medical judgment. However, the interview of Dr. Sharpe did not indicate that he felt this was the reason to proceed without a nurse.

The record for [redacted] is highly suspicious for fraud as the location for RN signature is crossed out and "MS" written in. A signature from [redacted] RN, dated 6/16/14 is then signed below for the operative report and signed below without a date for the recovery room summary. Given that the testimony of Drs. Kalo and Sharpe indicate that no nurse was present, this signature is fraud. Ms. [redacted] is a licensed clinician and this act of fraud would be on her part whether or not pressure was applied by the physicians.

3. **Does it appear that the licensee documented the correct medication, correct administration and correct route regarding the medications given to the patient(s)? If not, was this below a minimal standard of care?**

Response: Per Dr. Sharpe's testimony, [redacted] received twilight sedation with [redacted] injection for laminaria placement. Dr. Sharpe indicated that the medical record was in error with documentation that the [redacted] injection was IV. Dr. Sharpe also added that [redacted] received [redacted] and [redacted] injection for the procedure. Dr. Sharpe did not state if this injection was IM or IV. The medical record indicates that she received [redacted] and [redacted] for sleep for the procedure itself the following day. These medications would have been administered IV.

Per Dr. Sharpe's testimony, [redacted] received twilight sedation with [redacted] and [redacted] per injection. Dr. Sharpe did not state if this injection was IM or IV. The medical record indicates [redacted] received IV [redacted] for laminaria placement. The medical record indicates that she received [redacted] and [redacted] for sleep/heavy sedation for the procedure itself the following day. These medications would have been administered IV.

The documentation is very sloppy and below accepted standard of care from a quality standpoint. The dose written in the record is likely not written in the record by the physician and provides the concentration of the solution used, not the actual dose. The medical record should document clearly the dose, time of administration and the route.

4. **Dos it appear that the patient(s) were monitored (i.e. vitals) during the procedure? If not, was this below a minimal standard of care? Please explain.**

   Response: There is no documentation in the records I received of appropriate monitoring for either patient. The physician testified that an automatic machine documents vital signs but the patient's oxygenation status also need to be documented for conscious sedation at a regular interval of at least every 10 minutes. For heavy sedation/sleep, constant monitoring by a physician or nurse anesthetist including vital signs, oxygenation status and level of consciousness would be required by the American Academy of Anesthesiologists (http://anesthesiology.pubs.asahq.org/article.aspx?articleid=1944958). Even the American Academy of Dentists requires another qualified dentist or qualified anesthesia healthcare provider for provision of this level of anesthesia for dental procedures (https://www.ada.org/~/media/ADA/About%20the%20ADA/Files/anesthesia_use_guidelines.ashx). Accordingly, all deep sedation provided to both patients in this review were below the minimal standard of care.

5. **Does it appear that the licensee [redacted] of patient [redacted]? Please explain.**

   Response: Yes, the licensee [redacted] of [redacted].

6. **Did the licensee recognize and treat [redacted] within a reasonable standard of care? Please explain.**

   Response: Yes, the licensee recognized and treated the patient appropriately for the [redacted] I agree with the testimony of the licensee that the hospital that received the transfer did not assess the risk and status of the patient and provide the patient with surgery to treat the patient's medical condition within a reasonable period of time. No records from the hospital are included. However, as a physician who has treated many such patients on referral from outside clinics as well as patients of my own, urgency in going to the OR is the appropriate standard of care.

7. **Does it appear that the licensee's conduct was a violation of general duty, consisting of negligence or failure to exercise due care, including negligent delegation to or supervision of employees or other individuals, whether or not injury results? Please explain.**

   Response: All of the care provided related to provision of sedation was negligent and below standard of care. Other individuals in the facility were involved with this care and the licensee did not set the appropriate standard for acceptable care related to sedation.

8. **Does it appear the licensee's conduct was a departure from, or failure to conform to, minimal standards of acceptable and prevailing practice for the profession, whether or not actual injury to an individual occurred? Please explain.**

   Response: The D&E procedures were appropriate and [redacted] is an accepted complication. Risk of [redacted] is decreased by appropriate [redacted]. Standard of care was not achieved for provision of sedation for both patients. The pictures of the patient being loaded into the ambulance ([redacted]) did not show any concerns to me. I listened to the audio recording of the 911 call from the clinic and information/urgency was supplied correctly during the call.

9. **If during your review, you identify other issues or potential violations of the Michigan Public Health Code and/or Administrative Rules that have not been addressed, please include them in your written report.**

   Response: No other issues were identified.

[redacted]

1/3/16
date

LARA/HPD-200 (1/13) Michi[illegible]epartment of Licensing and Regulation Attachment

Bureau of Health Care Services
Health Professions Division
P.O. Box 30454
Lansing, MI 48909-9897
(517) 373-9196

Office Use Only
Rec'd: RECEIVED
AUG 28 2014
Department of Licensing & Regulatory Affairs
Bureau of Health Care Services
Enforcement Section - Allegation Unit

ALLEGATION FORM

Authority: Public Act 368 of 1978, as amended
Completion: Voluntary Penalty: None

I wish to complain against the individual named below. **I understand that this agency and the Licensing Board DO NOT assist citizens seeking reimbursement or resolution of billing and fee disputes.**

INSTRUCTIONS: Print legibly or type information. Complete all sections of this form. Sign at the bottom. Return the white copy to the address above. Please complete a separate form for each practitioner you are filing an allegation against. **Please be advised that this agency DOES NOT investigate anonymous allegations.**

Information About You	
Your Name	[redacted]
Street Address	[redacted]
City	[redacted]
State / Zip Code / Country	[redacted] / [redacted] / USA
Patient's Name	N A
Patient's Date of Birth (MM/DD/YYYY)	N A
Patient's Last 4 Digits of Their Social Security Number	N A
Your Telephone Numbers With Area Code	Cell: [redacted] Home: [redacted] Work:

Allegation Being Filed Against	
Practitioner's First and Last Name	Reginald D. Sharpe
Street Address	15801 W. McNichols
City	Detroit
State / Zip Code	Mich / 48235
Practitioner's Telephone Number	
Treatment/Incident Date	N/A

Amend file # 51-13-128172

Check the profession for which you are lodging an allegation about:

- ☐ Acupuncture
- ☐ Allopathic Physician (MD)
- ☐ Athletic Trainer
- ☐ Audiologist
- ☐ Chiropractor
- ☐ Counselor
- ☐ Dentistry
- ☐ Dietitian or Nutritionist
- ☐ Marriage & Family Therapist
- ☐ Massage Therapist
- ☐ Nurse (RN or LPN)
- ☐ Nursing Home Administrator
- ☐ Nurse Aide (CNA)
- ☐ Occupational Therapist
- ☐ Optometrist
- ☒ Osteopathic Physician (DO)
- ☐ Pharmacist
- ☐ Physical Therapist
- ☐ Physician's Assistant
- ☐ Podiatrist
- ☐ Psychologist
- ☐ Respiratory Therapist
- ☐ Sanitarian
- ☐ Social Worker
- ☐ Speech/Language Pathologist
- ☐ Veterinarian

Is there civil actions pending?	Is there a police report?	May we release your name and this information to the practitioner?	Will you testify at an Administrative Hearing if necessary?
☐ Yes ☐ No ?	☐ Yes ☒ No	☐ Yes ☒ No	☒ Yes ☐ No

Please provide details of your specific concerns related to the treatment rendered. Attach additional sheets if necessary.

I would like to amend my complaint on Reginald D. Sharpe. Re: [redacted] (Attachment #1) did a second tri-mester abortion without registered nurse – Rule R325.3340(2). Please see the attached report written by Pam Lindsey of LARA/State Licensing Section dated July 3, 2014

Your Signature: [redacted] Date: 8-25-2014

The Department of Licensing and Regulatory Affairs will not discriminate against any individual or group because of race, sex, religion, age, national origin, color, marital status, disability or political beliefs. If you need assistance with reading, writing, hearing, etc., under the Americans with Disabilities Act, you may make your needs known to this agency.

STATE OF MICHIGAN
RICK SNYDER
GOVERNOR

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF HEALTH CARE SERVICES

STEVE ARWOOD
DIRECTOR

July 3, 2014

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

SUBJECT: Second Annual Follow-Up State Licensure Survey Findings for Above-Referenced Agency

Dear Pam DiMaggio:

A second annual follow-up state licensure survey was attempted on June 17, 2014 at Women's Center of Southfield located at 28505 E. Southfield Rd., Lathrup Village, MI 48076.

Upon entering the facility the surveyor found an unstaffed reception desk. After multiple attempts to call out to personnel with no response the surveyor placed a call to the phone number listed on Dr. Kalo's business card that was found on the counter. The respondent stated that the staff were in the back doing a procedure. Shortly after the call a medical assistant came to the desk and confirmed that they had just finished a procedure. When the surveyor asked if a Registered Nurse was in the facility she stated no, only two medical assistants and the physician, Dr. Sharpe.

The surveyor accompanied by the medical assistant went into the PACU to find the patient unattended. In the next room Dr. Sharpe was on the phone and the second medical assistant was working with the specimen and instrumentation used during the procedure. When the surveyor inquired regarding when the patient had been scheduled for the procedure, it was discovered that the patient had been seen at another clinic of Dr. Kalo's several weeks earlier, and then put on the schedule for the Lathrup Village clinic. This should have allowed adequate time to arrange for a registered nurse to be on site for provision of care as required by Rule R325.3840 (2). (During the previous survey on April 29, 2014 the facility provided paperwork for a Registered Nurse that had been hired by the facility, and was supposed to be working on the days when procedures were scheduled.)

The absence of nursing care prevents the facility from achieving compliance with Rule R325.3847 (h) which requires the medical record to contain nurse's notes that include vital signs pre & post operatively, color, appearance & other relative observations. Surveyor examined the patient's medical record and found no such documentation.

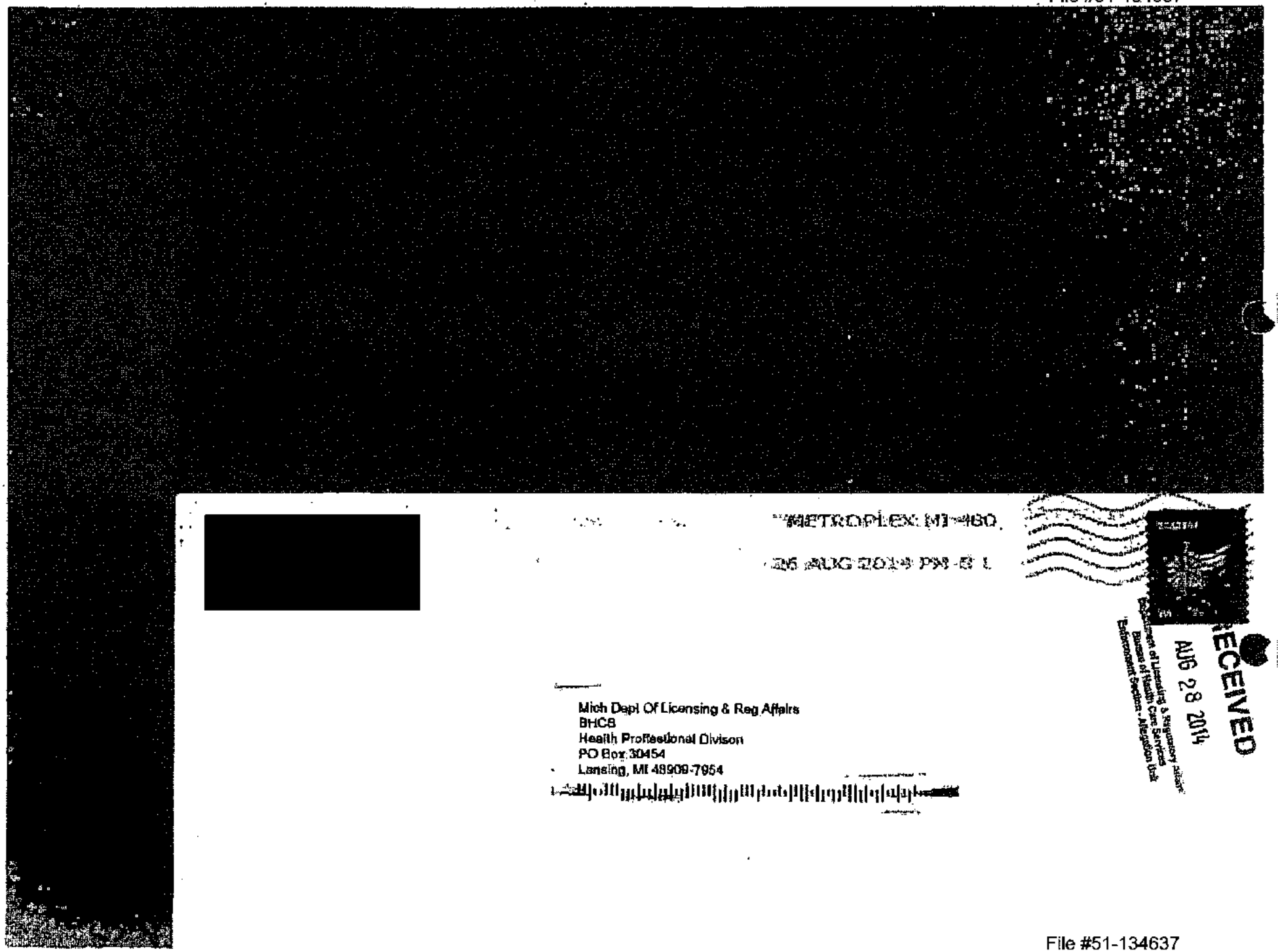
R325.3842 remained out of compliance as the narcotics log could not be documented correctly with only one licensed health professional within the building.

The surveyor was unable to assess whether corrections had been made to Rule R325.3836 because Dr. Kalo and the office manager were not at the facility.

After completion the third facility survey since December 2013, the facility still remains out of compliance with state licensing rules: R325.3836, R325.3840, R325.3842, and R325.3847. Please refer to survey letters dated January 8, 2014 and April 29, 2014. Your facility license renewal has been placed on hold. If the facility does not take immediate action to correct the deficiencies, the department may take additional action against the license. Feel free to contact Jay Calewarts at calewartsj@michigan.gov or by phone at (517) 241-2640 if you have any questions.

Pam Lindsey

Pam Lindsey, RN, BSN, Surveyor
Licensing and Regulatory Affairs
State Licensing Section
LindseyP@michigan.gov
(P): 517-897-2093
(F): 517-241-3354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RECEIVED
AUG 28 2014
Department of Licensing & Regulatory Affairs
Bureau of Health Care Services
Enforcement Section - Allegation Unit
Mich Dept Of Licensing & Reg Affairs
BHCS
Health Professional Divison
PO Box 30454
Lansing, MI 48909-7954

Daneen Nunez (Investigator)
Cadillac Place
State of Mich/ Department of Licensing & Reg. Affairs
3028 W. Grand Boulevard
11 th Floor, Suite 400
Detroit, MI 48202

August 25, 2014

Dear Ms Nunez,

Enclosed is a copy of the most recent FSOF survey for the Women's Center in Southfield. (aka Lathrup Village.)

Reginald D. Sharpe, whom you are investigating, is mentioned in the survey. I believe based upon the notes of Pam Lindsey, RN, BSN, Surveyor, Sharpe is again in violation of the Michigan medical code.

He did an abortion, probably late term, (I base this on the circumstances surrounding this termination and Pam Lindsey's notes) without benefit of an RN.

Yes, I know this facility belongs to Jacob Kalo. But, Sharpe was the only licensed medical professional in charge. He was the only one with authority. Sharpe should know through his own experience, his own mishaps, that there needs to be an RN there when he does these procedures. It's state law.

Pam Lindsey looked at the patient records and found no documentation for vital sign, pre & post op care, color, appearance and other relative observations.

I thank you for looking at this. I hope it helps your investigation.

Sincerely [redacted]

[redacted]

STATE OF MICHIGAN

RICK SNYDER
GOVERNOR

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF HEALTH CARE SERVICES

STEVE ARWOOD
DIRECTOR

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Pam Lindsey

Pam Lindsey, RN, BSN, Surveyor
Licensing and Regulatory Affairs
State Licensing Section
LindseyP@michigan.gov
(P): 517-897-2093
(F): 517-241-3354

FINANCIAL AGREEMENT

Patient Name: _____ **Birthdate:** _____ **SS#** _____

Are you covered by any type of medical insurance?

(If you are covered under more than one plan, you must provided us with information for **all** plans)

NO___ YES____, If yes what plans? _____

Standard fees for services are posted at Womancare. I understand that these are the charges established for services by Womancare and these charges will be submitted to my insurance company.

REDUCED FEE/GRANT PROGRAM REQUEST

I understand that some patients may qualify for a grant for any of the following reasons: Limited or no health insurance, unemployed or under-employed, student status single parent, and/or financial need not stated. Grant amounts are scheduled by Womancare and are not negotiable. They are considered upon individual request and are awarded at the discretion of Womancare.

I request a reduction in my fees, because I believe I qualify for a grant. I agree to pay for my services on the day they are rendered.

I understand that my grant will be rescinded, if, at any time in the future, it is determined that I have medical insurance that covers Womancare services, I submit a claim for reimbursement or request that information be sent to my insurance company for reimbursement.

Patient Initials: _____ Parent/Guardian Initials: _____

DEDUCTIBLE / COPAY / COINSURANCE INFORMATION

Insurance companies offer many different types of health coverage. Most of the plans require the patient to pay deductible, copay and/or co-insurance charges. The amount of your copay, coinsurance and deductible depends on your individual insurance plan. Your insurance company will deduct the amount of your copay, coinsurance and deductible from the total amount paid to us. If you have any questions about your plan, call your insurance company. Below is an explanation of these charges:

DEDUCTIBLE

Most insurance plans require a patient to pay an annual deductible. The patient must pay their health care provider/s for services totaling the deductible amount *before* the insurance company will begin to pay. Your insurance company will not pay any charges until you have met your *current yearly deductible*.

COPAY/COINSURANCE

Many insurance plans require the patient to pay a percentage of their health care costs, this amount is your coinsurance and is payable to the health care provider. If a service is not covered by the insurance plan, by law, the patient is usually responsible for the full amount. You may also have a set amount you pay at each visit, this amount is your copay.

PLEASE NOTE

Womancare staff will check your insurance coverage. When we call, we are told that the information given is not a guarantee of benefits and the information provided may not be current. The billing staff will charge you according to the information quoted by your insurance company. When we receive payment, if your insurance company has determined you owe additional charges, *as required by law*, you will be billed. If we determine you have overpaid, a refund will be given.

I agree to pay for all charges not covered by insurance on the day of service. This includes facility fees, copays, coinsurances and deductibles.

I have read & understand the above information. I agree to pay Womancare as stated above.

Patient Signature _____ Date _____

Parent/Guardian Signature_____ _____ Date _____

Witnessed _____ Date _____

Misoprostol (Cytotec),a prostaglandin medication- Guidelines

Patients who are between 14-24 weeks gestation. or at the discretion of the physician, may be required to have Misoprostol to aid in the cervical dilation process. Misoprostol is given to dilate and soften the cervix. The patient may require the use of laminaria OR Misoprostol only to prepare the cervix for the abortion, or the patient may need BOTH laminaria and Misoprostol .

Although Misoprostol is widely used for abortion services, the FDA does not approve it for this purpose. It is approved for the treatment of stomach ulcers. Using Misoprostol to aid in the dilation of the cervix is considered an "off-label" use. The off-label use of this product is legal and widely accepted as a standard of medical care, including abortion care. Patients are to be informed of the off-label use of Misoprostol .

Patients are to be informed of the possible side effects of Misoprostol , which include: birth defects (no assurances can be given about the outcome of the pregnancy if the abortion is not completed), uterine cramping and/or contractions, vaginal bleeding, nausea, vomiting, diarrhea, fever and chills. In very rare cases, tearing of the cervix or rupture of the uterus may occur, which may require additional surgery and/or hospitalization to repair and/or remove the uterus.

Patients will be screened for contraindications to Misoprostol , which include: C-section, inflammatory bowel disease (such as colitis and Crohns disease), dehydration, any medical condition that required the patient to take blood thinners (such as aspirin, Coumadin (warfarin) or Heparin and any allergic reaction to any prostoglandins. Misoprostol will be given in the absence of contraindications.

It is possible that the Misoprostol MAY NOT sufficiently dilate the cervical opening to safely remove the pregnancy. If this occurs, the physician may insert laminaria or give more Misoprostol to continue dilating the cervical opening. The physician will either have the patient return later in the day for the surgery to be completed or have the patient return the following day.

The physician will decide how the Misoprostol is to be administered (vaginally, rectally, buccally, orally) along with dosage and wait time.

WomanCare of Southfiel
28505 Southfield Rd
Lathrup Village, MI 4807

Laminaria Information Sheet

The insertion of Laminaria is the beginning of the abortion procedure. Laminaria is a thin piece of special material that is inserted into your cervical canal through your vagina. Once inserted, the laminaria absorbs your natural body fluids. This causes the cervix to slowly and safely expand (dilate). The Laminaria will be removed prior to beginning the surgical abortion procedure. Some women may require Laminaria insertion a second time over a two day period.

INSTRUCTIONS

1) The laminaria may cause severe cramping and/or pressure in your lower back or abdomen. Do not be alarmed, this means the Laminaria is working to slowly open the cervix. You can take Tylenol or any ibuprophen product such as Advil or Motrin for the discomfort.
   DO NOT TAKE ANYTHING CONTAINING ASPRIN.
2) If you are bleeding, remember this is not uncommon. Do not be alarmed. However, if you bleed through full size large maxi pad in one hour or less, or if you have a high fever (100 degrees or more) **CALL US IMMEDIATELY!!**

OFFICE NUMBER # 248-569-7010
AFTER HOURS # 1-800-899-9858

3) DO NOT pull out the gauze packing from your vagina.
4) If the laminaria or gauze sponges come out of your vagina during the night, do not be alarmed, but contact the office to let us know. It is important.
5) Once the laminaria is inserted you can not have anything enter your vagina. NO tub baths, douches, swimming, tampons or sexual intercourse. You MAY use the shower.
6) You will be given a medication to help prevent infection. Take this medication according to the directions printed on the bottle.
7) **NO FOOD AFTER MIDNIGHT!** You may drink clear fluids only until after the abortion procedure is completed.
8) You may be in the office up to 3 hours for this appointment however your driver must stay in the office for your entire appointment. **DO NOT** bring any children with you to this appointment.
9) If you are taking any medications, be sure to tell the doctor or office staff what medication you are taking. The doctor will decide if you should continue taking it once the laminaria have been inserted.

REMEMBER, YOU MUST RETURN TO OUR OFFICE AT _____

IF YOU ARE GOING TO BE LATE, OR ARE HAVING PROBLEMS KEEPING THE GIVEN APPOINTMENT TIME CONTACT US AT ONCE. EVERYTHING WE DO IS TIMED AND COORDINATED TO PROVIDE YOU WITH THE SAFEST CARE, PLEASE HELP US TO HELP YOU.

Take Home

Pt prescriptions, Given on first day

JACOB KALO, M.D., F.A.C.O.G.
GYNECOLOGY & OBSTETRICS

28505 SOUTHFIELD ROAD
LATHRUP VILLAGE, MI 48076-2715 (248) 569-7010

11474 15 MILE ROAD
STERLING HEIGHTS, MI 48312 (586) 979-2190

NAME _____ DOB _____

ADDRESS _____ DATE _____

TAMPER-RESISTANT FEATURES INCLUDE: SAFETY-BLUE ERASE-RESISTANT BACKGROUND, "ILLEGAL" PANTOGRAPH AND REFILL INDICATOR

℞

MOTRIN 800mg
1 Tab TID #15

METHERGINE 0.2 MG
1 TAB TID #12

AMPICILLIN 500mg
QID #24

J. Kalo MD

Refill: NR 1 2 3 4 5

(Signature)

Another brand of generically equivalent product, identical in dosage, form and content of active ingredients, may be dispensed unless box is initialed D.A.W. _____

3FOB0488345

Pt prescriptions attached
info given on day 1

TAKE Home

Woman Care of Southfield
28505 Southfield Rd
Lathrup Village, MI 48076

AFTERCARE INFORMATION

If you have any questions or concerns about your procedure or your recovery, please do not hesitate to call us. Our phones are answered 24 hours a days, seven days a week. If you are calling after hours, please our toll free number at 1-800-899-9858.

DISCHARGE MEDICATIONS

Upon discharge, you will be given a prescription for 3 different medications. YOU MUST START TAKING THESE MEDICATIONS TODAY AND CONTINUE TAKING THEM UNTIL COMPLETELY FINISHED.

AN ANTIBOTIC: Take as directed by the pharmacist. This medication is used to prevent infection

METHERGINE: Take as directed by the pharmacist. This medication is taken to contract your uterus and minimize the bleeding

PAIN RELIEVER: Take as directed by the pharmacist. This medication is optional and is used to relieve your cramping and discomfort

POST OPERATIVE RESTRICTIONS

Your post-operative examination is in two weeks, observe all restrictions to avoid Complications.

- DO NOT return to work for the next two weeks
- DO NOT lift, push or pull anything over 10lbs
- DO NOT engage in strenuous activity
- DO NOT do any extended walking or standing
- DO NOT immerse the lower half of your body in water
- DO NOT swim, douche, or bath (showers are permitted)
- DO NOT have sexual intercourse
- DO NOT use tampons or feminine sprays. Sanitary pads only.
- DO NOT drink alcoholic beverages for 24 hours
- DO NOT take aspirin or aspirin containing drugs

Return to the clinic in 14 days for your post-op exam unless you were instructed by the doctor to come sooner. The purpose of this exam is to determine that you've healed, recovered normally and you can return to unrestricted activity. If you have come a long distance be sure to see your own doctor for your post-op exam.

If you decide to see your own physician, emergency room doctor or any other doctor for complications following the procedure make sure that either you or the doctor contact our clinic immediately. The doctor's decision on how to treat you adequately is strongly related to the medical information from us.

Please feel free to come to the clinic anytime you feel abnormal symptoms related to the surgical procedure or if you are late on your period.

ECTOPIC PREGNANCY/TUBAL PREGNANCY

Very rarely you may also be pregnant outside the uterus or pregnant in two different sites. This pregnancy has to be terminated by abdominal surgery. Call us immediately if you experience dizziness, fainting, strong lower abdominal pain, shoulder pains or back pains.

BLEEDING

The bleeding you are now experiencing is not a menstrual flow. It is due to the procedure. However, you may experience intermittent menstrual like cramps, bleeding and passing of soft blood clots during the next 1-2 week healing process.

If you experience no bleeding at all that is completely normal also. During the healing process you may experience a sudden rush of blood and soak a pad thoroughly, this often occurs when a patient has been over active. If you continue to soak your pad completely and must put on a new pad every hour for the next 2-3 hours go to the ER or call the emergency number of the clinic immediately.

YOUR NEXT PERIOD

Expect your next period in 4 weeks after the termination of pregnancy. It may be heavier and last longer.

IN CASE OF EMERGENCY

OFFICE: (248) 569-7010/TOLL FREE: 1-800-899-9858

YOUR POST-EXAM IS _____ AT _____

Office Visit / Exam: Free
Hormone test: $25

Take Home

Which birth control method is right for me?

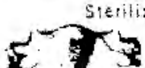
There are many birth control options available today, and the choices can seem confusing. This list can help you decide which method would best fit your lifestyle.

HORMONAL CONTRACEPTIVES

Hormonal contraceptives [illegible]

NONHORMONAL CONTRACEPTIVES

Nonhormonal contraceptives prevent pregnancy by providing a barrier against sperm or by interfering with sperm movement or by creating an "unfriendly" environment for sperm. These methods do not use hormones, so they do not interfere with your natural reproductive cycle.

	HOW EFFECTIVE IS THIS METHOD?	HOW MANY OPTIONS ARE AVAILABLE?	HOW OFTEN DO I NEED TO USE IT?	ARE THERE INTERRUPTIONS WITH THIS METHOD?	HOW QUICKLY CAN I GET PREGNANT IF I STOP USING IT?	DO I NEED TO SEE MY HEALTH CARE PROFESSIONAL TO START?	DO I NEED A PRESCRIPTION?	DOES THIS PROTECT AGAINST HIV AND STDs?	THIS METHOD INTERESTS ME. I WOULD LIKE MORE INFORMATION
HORMONAL CONTRACEPTIVES									
The Patch	99% effective	There is only 1 contraceptive patch	The Patch is applied once a week for 3 weeks. During week 4 no patch is used	There are no interruptions with this method	Once stopped, it may take a few cycles before you can become pregnant	You need to learn how to apply the Patch correctly	Yes	No	☐ YES, I'd like to talk to my health care professional about this method
Oral Contraceptive (The Pill) 	99% effective	There are a variety of pills available in different doses	You should take your pill every day at about the same time each day	There are no interruptions with this method	Once stopped, it may take a few cycles before you can become pregnant	You may need instruction on the correct way to [illegible]	Yes	No	☐ YES, I'd like to talk to my health care professional about this method
Contraceptive Injections	99% effective	There are 2 options currently available: a monthly injection and an injection that is given every 3 months	Is injected at medical office monthly or every 3 months	There are no interruptions with this method	Ovulation may be delayed up to a year	A health care professional administers the injection	Yes	No	☐ YES, I'd like to talk to my health care professional about this method
Progestin-Releasing Intrauterine Device (IUD)	99% effective	There is 1 hormone-releasing IUD currently available	The suggested length of use is 5 years or less	There are no interruptions with this method	Once removed, fertility can return within a year	Your health care professional inserts and removes the IUD	Yes	No	☐ YES, I'd like to talk to my health care professional about this method
Vaginal Ring	99% effective	There is only 1 vaginal ring	Each month, the vaginal ring is inserted into the vagina and left in place for 3 weeks. During week 4 you do not wear the ring	There are no interruptions with this method	Once stopped, it may take a few cycles before you can become pregnant	You need to learn how to insert and remove the vaginal ring	Yes	No	☐ YES, I'd like to talk to my health care professional about this method
NONHORMONAL CONTRACEPTIVES									
Male Condom	97% effective	There are a variety of styles, sizes, colors, materials and textures	A new one must be used every time you have sex	Must be applied when the penis is erect. May cause a slight interruption before sex	Without this device, there is no protection against pregnancy	Tell your health care professional that you plan to use condoms	No	Yes	☐ YES, I'd like to talk to my health care professional about this method
Female Condom	95% effective	There is 1 female condom currently available	A new one must be used every time you have sex	A female condom can be inserted up to 8 hours before sex	Without this device, there is no protection against pregnancy	Tell your health care professional that you plan to use a female condom	No	Unless the female condom slips out of place or is torn, it should provide protection against STD exposure comparable with that of male condoms	☐ YES, I'd like to talk to my health care professional about this method
Intrauterine Device (IUD)	99% effective	There is 1 copper-T IUD currently available	Once inserted in the uterus, it can be left in place for up to 10 years	There are no interruptions with this method	Once removed, fertility can return within about 1 month	Your health care professional inserts and removes the IUD	Yes	No	☐ YES, I'd like to talk to my health care professional about this method
Spermicides	94% effective — use with a vaginal barrier increases effectiveness	There are a variety of spermicides available in foams, jellies, creams, and vaginal suppositories	Must be used every time you have sex	Must be inserted no more than 1 hour before sex	Without this device, there is no protection against pregnancy	Tell your health care professional. You may be advised to use an additional contraceptive method	No	No	☐ YES, I'd like to talk to my health care professional about this method
VAGINAL BARRIERS Diaphragm 	94% effective	There are a variety of sizes available	Must be used every time you have sex (and fresh spermicide must be applied each time)	The diaphragm can be inserted 6 to 8 hours before sex	Without this device, there is no protection against pregnancy	You need to be fitted and must learn how to use the diaphragm	Yes	Diaphragms do not protect against HIV (AIDS). There is a mild reduction in the risk of some STDs	☐ YES, I'd like to talk to my health care professional about this method
Cervical Cap 	84% effective in women who have had a child (91% in those who have not)	There are a variety of sizes available	Must be used every time you have sex (and spermicide must be applied when inserted)	The cervical cap provides continuous protection for up to 48 hours	Without this device, there is no protection against pregnancy	You need to be fitted and must learn how to use the cervical cap	Yes	No	☐ YES, I'd like to talk to my health care professional about this method
PERMANENT METHODS Surgical Sterilization 	Greater than 99% effective	For women, there is a tubal ligation (having your tubes "tied"); for men, there is a vasectomy	These procedures are permanent and irreversible	There are no interruptions with this method	You will no longer be able to get pregnant	These surgical procedures are performed by a health care professional	Physician recommended	No	☐ YES, I'd like to talk to my health care professional about this method

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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
[redacted], Medical Assistant, Women's Center of Southfield *(Survey 4/24/14)
[redacted], 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 [redacted] 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 [redacted].

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 [redacted] 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 [redacted] and staff left room to get swifter mop to clean up [redacted] and doctor changed cover gown before calling 911.
6. It was alleged staff [redacted] and had EMS take her out the back winding steps instead of straight out the front to ambulance (partially substantiated)

Bureau Investigation Findings

On [redacted] 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 [redacted] sent to pathology.
- Anesthesia record states anesthesia given by Dr. Sharpe. No mention of IV having been started. States drugs given as [redacted] 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 [redacted]. [redacted] was noted on treatment floor. EMS notes state IV had been started and [redacted] had been given prior to our arrival. Report states Dr. Sharpe stated that he believed the [redacted]. 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 [redacted] at the time of surgery. He described the [redacted]. He also mentioned the patient had a [redacted]. 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 [redacted] lists procedures performed as [redacted]. The report states "the patient was noted to have [redacted]."

On a follow up post annual survey conducted at Women's Center at Southfield on [redacted], 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 [redacted] 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

Pam Lindsey, RN, BSN, Surveyor
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