3/8/07 #4

STATE OF FLORIDA
Jeb Bush, Governor

#2

07 MAR 26 AM 7:55
RECEIVED
CONSUMER SERVICES UNIT

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

#146

SUBMIT FORM TO:
Department of Health, Consumer Services Unit
4052 Bald Cypress Way, Bin C75
Tallahassee, Florida 32399-3275

I. OFFICE INFORMATION

RALPH GARRAMONE MD PA
Name of office

8660 COLLEGE PKWY SUITE 100
Street Address

FORT MYERS 33919 LEE
City / Zip Code / County

239-482-1900
Telephone

RALPH R. GARRAMONE MD
Name of Physician or Licensee Reporting

ME 75131 / 107
License Number & office registration number, if applicable

II. PATIENT INFORMATION

Age / Gender / Medicaid / Medicare

3.8.07
Date of Office Visit

POD #2 VISIT
Purpose of Office Visit

Diagnosis

518.4
ICD-9 Code for description of incident

III
Level of Surgery (II) or (III)

III. INCIDENT INFORMATION

3.8.07 2:30 PM
Incident Date and Time

Location of Incident:
☐ Operating Rm ☐ Recovery Rm
☒ Other OFFICE

Note: If the incident involved a death, was the medical examiner notified? ☐ Yes ☐ No
Was an autopsy performed? ☐ Yes ☐ No

A) Describe circumstances of the incident (narrative)

(use additional sheets as necessary for complete response)

SEE ATTACHED

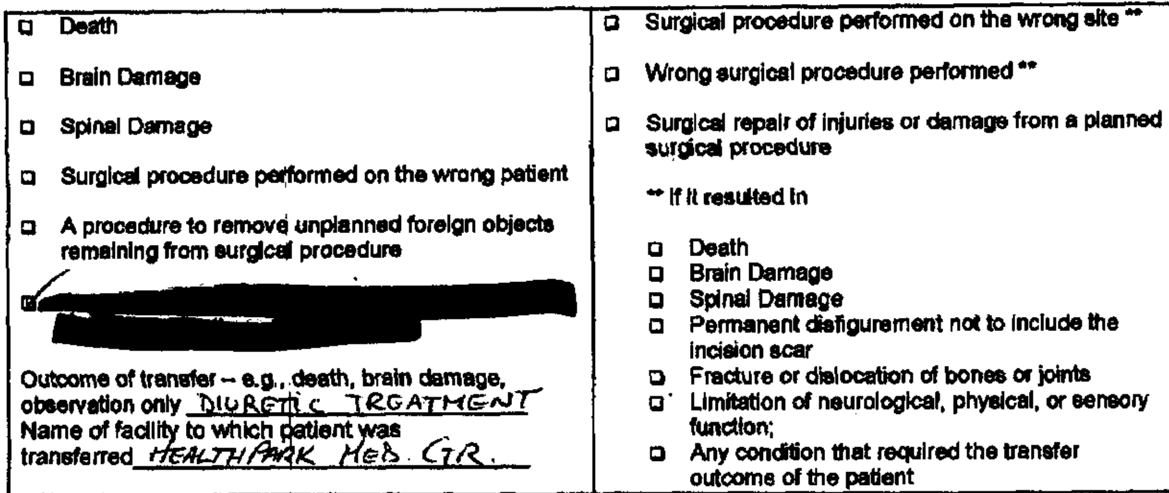
Form # DH-MQA1030- created 2-00; revised 3-24-03

B) ICD-9-CM Codes

V50.1 / 99214	E 878.9	518.4
Surgical, diagnostic, or treatment procedure being performed at time of incident (ICD-9 Codes 01-99.9)	Accident, event, circumstances, or specific agent that caused the injury or event. (ICD-9 E-Codes)	Resulting injury (ICD-9 Codes 800-999.9)

C) List any equipment used if directly involved in the incident (Use additional sheets as necessary for complete response)

D) Outcome of Incident (Please check)

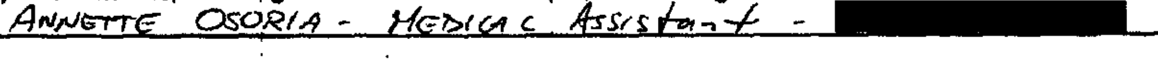


☐ Death	☐ Surgical procedure performed on the wrong site **
☐ Brain Damage	☐ Wrong surgical procedure performed **
☐ Spinal Damage	☐ Surgical repair of injuries or damage from a planned surgical procedure
☐ Surgical procedure performed on the wrong patient	** If it resulted in
☐ A procedure to remove unplanned foreign objects remaining from surgical procedure	☐ Death ☐ Brain Damage ☐ Spinal Damage ☐ Permanent disfigurement not to include the incision scar
☑ [redacted]	☐ Fracture or dislocation of bones or joints ☐ Limitation of neurological, physical, or sensory function; ☐ Any condition that required the transfer outcome of the patient
Outcome of transfer – e.g., death, brain damage, observation only DIURETIC TREATMENT Name of facility to which patient was transferred HEALTHPARK MED. CTR.	

E) List all persons, including license numbers if licensed, locating information, and the capacity in which they were directly involved with this incident.

RALPH GARRAMONE MD - ME 75131 - SURGEON

F) List witnesses, including license numbers if licensed, and locating information if not listed above



ANNETTE OSORIA - MEDICAL ASSISTANT - [redacted]

IV. ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response)

SEE ATTACHED

B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

SEE ATTACHED

V. Ralph R. Garramone MD — ME 75131

SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT — **LICENSE NUMBER**

3-19-2007 — 745 AM

DATE REPORT COMPLETED — **TIME REPORT COMPLETED**

Form # DH-MQA1030- created 2-00; revised 3-24-03

Dr. Ralph Garramone March 19, 2007

Circumstances of the Incident

is a year old lb who presented on March 7, 2007 to my JCAHO accredited office surgical facility for a breast lift, abdominoplasty, and limited liposuction of the lateral chest and hips under general anesthesia. history was significant for hypertension under control, hypothyroidism and hypercholesterolemia for which was taking Norvasc, Hyzaar, Synthroid and Lipitor. was also taking Paxil, Activella (HRT) and ASA daily, which stopped prior to surgery. was a one pack per day smoker for many years and had been warned by internist to quit due to medical history and a family history of heart disease. internist evaluated prior to surgery and felt was an acceptable candidate, provided quit smoking, which did three weeks prior to the procedure. He also advised to lose weight prior to surgery which did (35 lbs.) by attending the gym several times a week. preoperative EKG showed minor T wave changes, which when compared to previous EKG, demonstrated improvement as per internist. The patient had been NPO since 9pm the night before surgery.

The patient entered the OR at 8 am. The procedure started at 8:25 am and ended at 1:17pm and was discharged from the office at 3pm. During the procedure received 1800 ml of normal saline IV. received the remaining 200 ml IV in the recovery room for a total of 2000 ml. 500 ml of tumescent anesthetic fluid was administered subcutaneously and total liposuction aspirate was 725 ml. experienced no complications intraoperatively. Vital signs in the OR ranged from 110 to 140 systolic BP over 60 to 80 diastolic BP, pulse in the 70's, and oxygen saturation 100%. Upon admission to recovery room, was noted to have an oxygen saturation of 93% on 2 LPM of oxygen. LMA was removed by was breathing well and was put on oxygen via nasal cannula. Within 30 minutes, saturation rose to 95%. After 45 minutes in recovery room developed bilateral expiratory wheezes which resolved after treatment with two puffs of an albuterol inhaler. After 90 minutes in recovery room, oxygen saturation was 95% on room air and the patient was discharged. When I called to check status the evening of surgery, informed me that was sleeping comfortably and that there were no problems.

General anesthesia

The patient was seen in my office on postoperative day one. In light of respiratory history in the recovery room, I auscultated lungs and noted that had rales at the bases. ich only rose to 85% with the administration of oxygen and eventually to 88% on room air. was transferred to the hospital ER for evaluation and was worked up for pulmonary embolism, which was negative. EKG, cardiac specific enzymes, and echocardiogram (to evaluate wall motion) were also normal, however, was treated successfully with diuretics and released four days later (stay was extended due to a resultant electrolyte imbalance from the diuretics). has been seen since in my office and in internist's office and is doing well both medically and surgically.

Analysis and Corrective/Proactive Action

As soon as possible after the event, I met with the anesthetist and contacted the patient's internist to discuss this incident to help determine why it may have happened and what could be done to help prevent it in the future. The facility healthcare risk manager was notified to ensure compliance with state reporting requirements.

Medication interactions/side effects were examined and rejected as a contributing factor to this occurrence. The patient did not receive any Narcan, from which pulmonary edema is a known side effect. As airway obstruction due to biting of a laryngeal mask tube may result in negative pressure pulmonary edema, this potential scenario was discussed with the anesthetist and recovery room RN who both described a very smooth removal of the LMA at the appropriate depth of anesthesia without any biting of the tube, coughing, or larygospasm/obstructive breathing. It was felt by the patient's internist that, although the echocardiogram was normal, ███ myocardial compliance may be borderline and the fluids administered during surgery, while not excessive, may have challenged ██ cardiac reserve, resulting in the pulmonary edema.

I have never had a similar adverse patient occurrence in the nine years that I have been in practice. In the future, in light of this event, I will be more selective with regard to the candidacy of patients with significant cardiac risk factors for multiple procedures under anesthesia in my office. In addition, patients with a similar history will receive more conservative IV fluid administration during the intra- and immediate postoperative period.

3/24/07 (#5)

STATE OF FLORIDA
Jeb Bush, Governor

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

#147

SUBMIT FORM TO:
Department of Health, Consumer Services Unit
4052 Bald Cypress Way, Bin C75
Tallahassee, Florida 32399-3275

I. OFFICE INFORMATION

INST OF COSMOPLASTIC SURGERY
Name of office

TAMPA FL 33609
City Zip Code County

CHRISTINA B PAYLAN
Name of Physician or Licensee Reporting

3226 W. KENNEDY BLVD
Patient's address for Physician or Licensee Reporting

3226 W. Kennedy Blvd.
Street Address

813-877-8183
Telephone

ME 82839 / OSR 539
License Number & office registration number, if applicable

II. PATIENT INFORMATION

Patient Identification Number

Diagnosis

Age 3/24/07 Gender Medicaid Medicare

Date of Office Visit

Purpose of Office Visit

ICD-9 Code for description of incident

Level of Surgery (II) or (III)

III. INCIDENT INFORMATION

3/24/07 14:00
Incident Date and Time

Location of Incident:
☒ Operating Rm ☐ Recovery Rm
☐ Other________

Note: If the incident involved a death, was the medical examiner notified? ☐ Yes ☐ No N/A
Was an autopsy performed? ☐ Yes ☐ No

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete response)

See Attached Sheet
Pt transferred for Observation purposes only
No complications in outcome

Form # DH-MQA1030- created 2-00; revised 3-24-03

This is a ▇ yo ▇ who was admitted to the surgical center for excision of redundant skin under the right underarm on the lateral chest wall. The total length of procedure was 3.5 hours. There were no intraoperative complications. Patient's vital signs remained stable throughout the procedure. BP 104/50 RR 12 HR 112 and T 98.4. At the conclusion of the procedure, patient was not as arousable as ▇ had been in the previously procedures that ▇ had undergone with me. I listened to ▇ lungs and felt that there may be some decreased breath sounds on the left. I suspected either a lung collapse or possibly a pneumothorax. Paramedics were calle▇ by paramedics and transferred to Tampa General Hospital.

Prior to paramedics leaving, I called Tampa General ER and spoke to Dr. Kelly in the ER at TGH and relayed to her the summary of care, reasons for her transfer and patient's current status.

In the ER, patient underwent CXR and CT scan of the chest and brain all of which were negative for any findings. ▇ was admitted and weaned from the ventilator and extubated without any complications. ▇ was discharged from the hospital without any adverse outcome.

In follow u▇ resumed all of ▇ prior activities upo▇ rom the hospital.

B) ICD-9-CM Codes

Surgical Excision of Excess Skin	None	None
Surgical, diagnostic, or treatment procedure being performed at time of incident (ICD-9 Codes 01-99.9)	Accident, event, circumstances, or specific agent that caused the injury or event. (ICD-9 E-Codes)	Resulting injury (ICD-9 Codes 800-999.9)

(R) [illegible]

C) List any equipment used if directly involved in the incident
(Use additional sheets as necessary for complete response)

D) Outcome of Incident (Please check)

☐ Death	☐ Surgical procedure performed on the wrong site **
☐ Brain Damage	☐ Wrong surgical procedure performed **
☐ Spinal Damage	☐ Surgical repair of injuries or damage from a planned surgical procedure
☐ Surgical procedure performed on the wrong patient	** if it resulted in
☐ A *procedure* to *remove* unplanned *foreign* objects remaining from surgical procedure	☐ Death ☐ Brain Damage
X Any condition that required the transfer outcome of the patient to a licensed hospital	☐ Spinal Damage ☐ Permanent disfigurement not to include the incision scar
Outcome of transfer – e.g., death, brain damage, observation only ______ Name of facility to which patient was transferred Tampa General Hospital	☐ Fracture or dislocation of bones or joints ☐ Limitation of neurological, physical, or sensory function; ☐ Any condition that required the transfer outcome of the patient

E) List all persons, including license numbers if licensed, locating information, and the capacity in which they were directly involved with this incident.

Claudia [illegible], RN 9185755 Exp: 4/30/05

F) List witnesses, including license numbers if licensed, and locating information if not listed above

[illegible] / [illegible]

IV. ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response)

Patient recommended for follow up 24hr sleep study

B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

Sleep Study to discern sleep Obstructive apnea

V. [signature] ME32839

SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT **LICENSE NUMBER**

5/26/07 2pm

DATE REPORT COMPLETED **TIME REPORT COMPLETED**

Form # DH-MQA1030- created 2-00; revised 3-24-03

STATE OF FLORIDA
Jeb Bush, Governor

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

SUBMIT FORM TO:
Agency for Health Care Administration,
Consumer Services Unit, Post Office Box 14000,
Tallahassee, Florida 32317-4000

I. OFFICE INFORMATION

Southeastern Urological Center
Name of office

2000 Centre Pointe Blvd
Street Address

Tallahassee 32308 Leon
City / Zip Code / County

850-309-0400
Telephone

Joseph L Camps MD
Name of Physician or Licensee Reporting

ME 0057214
License Number & office registration number, if applicable

Same as above
Patient's address for Physician or Licensee Reporting

II. PATIENT INFORMATION

Age 3-29-07 Gender Medicare Medicaid

Purpose of Office Visit

Diagnosis

ICD-9 Code for description of incident
NA

Level of Surgery (II) or (III)

CONSUMER SERVICES UNIT 07 ... -9 PM 2:44

III. INCIDENT INFORMATION

3/29/07 @ 11:00 Am
Incident Date and Time

Location of Incident:
☐ Operating Rm ☐ Recovery Rm
☑ Other physician's office

Note: If the incident involved a death, was the medical examiner notified? ☐ Yes ☐ No
Was an autopsy performed? ☐ Yes ☐ No

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete response)

Patient arrived for catheter removal post operatively. Patient complained of swelling in left lower leg. Doppler ultrasound obtained and diagnosis of deep vein thrombosis made. Patient is transferred to hospital for admission and treatment via ambulance.

Form # DH-MQA 1030- created 2-00; revised 9-6-01

B) ICD-9-CM Codes

NA	NA	
Surgical, diagnostic, or treatment procedure being performed at time of incident (ICD-9 Codes 01-99.9)	Accident, event circumstances, or specific agent that caused the injury or event. (ICD-9 E-Codes)	Resulting injury (ICD-9 Codes 800-999.9)

C) List any equipment used if directly involved in the incident
(Use additional sheets as necessary for complete response)

NA

D) Outcome of Incident (Please check)

- ☐ Death
- ☐ Brain Damage
- ☐ Spinal Damage
- ☐ Surgical procedure performed on the wrong patient
- ☐ A procedure to remove unplanned foreign objects remaining from surgical procedure
- ☒ Any condition that required the transfer outcome of the patient to a licensed hospital

Outcome of transfer – e.g., death, brain damage, observation only admit to hospital
Name of facility to which patient was transferred TMH

- ☐ Surgical procedure performed on the wrong site **
- ☐ Wrong surgical procedure performed **
- ☐ Surgical repair of injuries or damage from a planned surgical procedure

** if it resulted in

- ☐ Death
- ☐ Brain Damage
- ☐ Spinal Damage
- ☐ Permanent disfigurement not to include the incision scar
- ☐ Fracture or dislocation of bones or joints
- ☐ Limitation of neurological, physical, or sensory function;
- ☐ Any condition that required the transfer outcome of the patient

E) List all persons, including license numbers if licensed, locating information, and the capacity in which they were directly involved with this incident.

Joseph L Camps MD	ME 0057214	Ordered transfer + admission Physician of record
Patricia Clark MA	no license	assisting in patient care
Shelley Keever RN	RN 2737062	Charge nurse assisting with transport

F) List witnesses, including license numbers if licensed, and locating information if not listed above

IV. ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response)

Patient arrived for routine post op visit, symptoms assessed and acted upon requiring transfer to acute care for admission and continued care.

B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

none needed – appropriate transfer – If patient had called us with the complaint of leg swelling earlier [redacted] would have been assessed and hospitalized at that time

V. [signature] RN — RN 915912
SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT — LICENSE NUMBER

9-4-07 — 2000
DATE REPORT COMPLETED — TIME REPORT COMPLETED

Form # DH-MQA1030- created 2-00; revised 9-6-01

STATE OF FLORIDA
Jeb Bush, Governor

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

SUBMIT FORM TO:
Department of Health, Consumer Services Unit
4052 Bald Cypress Way, Bin C75
Tallahassee, Florida 32399-3275

RECEIVED CONSUMER SERVICES UNIT
07 APR -3 AM 10:11

I. OFFICE INFORMATION

MEDERO MEDICAL
Name of office

4806 N. OBT
Street Address

ORLANDO 32810 OR
City Zip Code County

407-206-3326
Telephone

EUGENE GERNIER PAC / NAGY SHANAWANY MD
Name of Physician or Licensee Reporting

(License Number & office registration number, if applicable

See below
Patient's address for Physician or Licensee Reporting

II. PATIENT INFORMATION

Age Gender Medicaid Medicare

3/23/07
Date of Office Visit

Purpose of Office Visit

ICD-9 Code for description of incident

Diagnosis

Level of Surgery (II) or (III)

III. INCIDENT INFORMATION

3/23/07 @ 12:35 PM
Incident Date and Time

Location of Incident
☐ Operating Rm ☐ Recovery Rm
☐ Other OFFICE

Note: If the incident involved a death, was the medical examiner notified? ☐ Yes ☐ No
Was an autopsy performed? ☐ Yes ☐ No

A) Describe circumstances of the incident (narrative) Low Back Spasm
(use additional sheets as necessary for complete response)

y/o for follow up LBS c/o severe pain in the BACK 9-10/10. Pt found laying on the Bed with ... lumbar pain can't Move due to severe pain. I Eugene Gernier told the MA to Administered ICE TX to Relieved spasm, but patient was complaining of More pain & I told the MA to administered 60mg Toradol (IM), but, by the time I look At the chart & Realized that patient is allergic to ASA, Motrin, Benadryl, PCN, it was too late the shot was already given. I went to the Room & observed the patient @ that time no reaction

Form # DH-MQA1030- created 2-00; revised 3-24-03

8 patient wanted to leave █ was told █ need to be
observed, due the fact A Medication that █ is allergic
to was accidentally administered. Then few minutes
later █ started having urticaria & swelling @
the face. c̄ ∅ SOB ∅ chest pain. █ was trans-
ported to the Trauma where █ received
125mg Solumedrol x 1 (I.M), 0,3 m epi SubQ, O_2
Nasal Cannulae @ 2 liter. & was put on the Monitor.
Pt was doing well c̄ the swelling & urticaria
under control Normal HEENT & CardioVascular
Exam & Lung Exams, but After Pt took █
cell phone & took picture of the face █ Star-
ted to be agitated, Breathing fast, upset, c̄
Hyperventilated █ Pt was told to calm
down take Deep Breath. All was done c̄
communication c̄ Dr. Shannawhay... c Dr grant

B) ICD-9-CM Codes

Surgical, diagnostic, or treatment procedure being performed at time of incident (ICD-9 Codes 01-99.9)	Accident, event circumstances, or specific agent that caused the injury or event (ICD-9 E-Codes)	Resulting injury (ICD-9 Codes 800-999.9)

C) List any equipment used if directly involved in the incident
(Use additional sheets as necessary for complete response)

D) Outcome of Incident (Please check)

- ☐ Death N/A
- ☐ Brain Damage N/A
- ☐ Spinal Damage N/A
- ☐ Surgical procedure performed on the wrong patient N/A
- ☐ A procedure to remove unplanned foreign objects remaining from surgical procedure N/A
- ☐ Any condition that required the transfer outcome of the patient to a licensed hospital

Outcome of transfer – e.g., death, brain damage, observation only ______
Name of facility to which patient was transferred Florida Hospital South

- ☐ Surgical procedure performed on the wrong site ** N/A
- ☐ Wrong surgical procedure performed ** N/A
- ☐ Surgical repair of injuries or damage from a planned surgical procedure N/A

** If it resulted in

- ☐ Death N/A
- ☐ Brain Damage N/A
- ☐ Spinal Damage N/A
- ☐ Permanent disfigurement not to include the incision scar N/A
- ☐ Fracture or dislocation of bones or joints N/A
- ☐ Limitation of neurological, physical, or sensory function; N/A
- ☑ Any condition that required the transfer outcome of the patient Allergic reaction (chest pain tightness)

E) List all persons, including license numbers if licensed, locating information, and the capacity in which they were directly involved with this incident.

F) List witnesses, including license numbers if licensed, and locating information if not listed above

IV. ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response)

Administer Solumedrol IM 125mg x 2 & Epi SubQ 0.3mg O2 2 Liter. Monitor on AKG O2 Sat (100%) ē Dr Nagy [illegible]

B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

As Mention above & Pt responded, but Transferred to Hospital due to complaints of chest tightness or Chest pain

V. [signature] FL 910315
SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT — LICENSE NUMBER

DATE REPORT COMPLETED — TIME REPORT COMPLETED

Form # DH-MQA1030- created 2-00; revised 3-24-03

STATE OF FLORIDA
Jeb Bush, Governor

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

SUBMIT FORM TO:
Department of Health, Consumer Services Unit
4052 Bald Cypress Way, Bin C75
Tallahassee, Florida 32399-3275

I. OFFICE INFORMATION

Back Center - Brevard Orthopaedic
Name of office

315 E NASA BLVD
Street Address

Melbourne NJ 32901 Brevard
City Zip Code County

321 - 723 7716
Telephone

Dr Lily Voegel
Name of Physician or Licensee Reporting

ME 85032
License Number & office registration number, if applicable

Same
Patient's address for Physician or Licensee Reporting

II. PATIENT INFORMATION

Age 3-21-07 Gender Medicaid Medicare

Date of Office Visit

Patient Identification Number 724

Purpose of Office Visit

Diagnosis

ICD-9 Code for description of incident

Level of Surgery (II) or (III)

III. INCIDENT INFORMATION

3/21/07 15-30
Incident Date and Time

Location of Incident:
☐ Operating Rm ☑ Recovery Rm
☐ Other________

RECEIVED
CONSUMER SERVICES UNIT
07 MAR 28 PM 2:36

Note: If the incident involved a death, was the medical examiner notified? ☐ Yes ☐ No
Was an autopsy performed? ☐ Yes ☑ No

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete response)

Pt had nerve block injection done - Was recovered + was getting dressed on the stretcher as instructed. Pt stated [redacted] tried to stand to complete dressing + [redacted] to floor onto buttock. [redacted] was assisted to chair. Dr Voegel informed + checked pt. Pt stated [redacted] has intermittent weakness of legs @ times. X-ray suggested to pt + family - declined for today. Pt able to walk to car using [redacted] cane. Pt asked to call immediately if change +/or increase symptoms.

Form # DH-MQA1030- created 2-00; revised 3-24-03

B) ICD-9-CM Codes

724.2 E24.6		
Surgical, diagnostic, or treatment procedure being performed at time of incident **(ICD-9 Codes 01-99.9)**	Accident, event, circumstances, or specific agent that caused the injury or event. **(ICD-9 E-Codes)**	Resulting injury **(ICD-9 Codes 800-999.9)**

C) List any equipment used if directly involved in the incident
(Use additional sheets as necessary for complete response)

D) Outcome of Incident (Please check)

☐ Death	☐ Surgical procedure performed on the wrong site **
☐ Brain Damage	☐ Wrong surgical procedure performed **
☐ Spinal Damage	☐ Surgical repair of injuries or damage from a planned surgical procedure
☐ Surgical procedure performed on the wrong patient	** if it resulted in
☐ A procedure to remove unplanned foreign objects *remaining from surgical procedure*	☐ Death ☐ Brain Damage ☐ Spinal Damage ☐ Permanent disfigurement not to include the incision scar
☐ *Any condition that required the transfer outcome of* the patient to a licensed hospital	☐ Fracture or dislocation of bones or joints ☐ Limitation of neurological, physical, or sensory function; ☐ Any condition that required the transfer outcome of the patient
Outcome of transfer – e.g., death, brain damage, *observation only* ________ Name of facility to which patient was transferred [redacted] [redacted] discharged to home	

E) List all persons, including license numbers if licensed, locating information, and the capacity in which they were directly involved with this incident.

Dr L Voegel – ME 85032 / 315 E Nasa Blvd
Maureen Vorylenski RN 2069822 / Melbourne FL 32901

F) List witnesses, including license numbers if licensed, and locating information if not listed above

IV. ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response)

Pt did not follow instructions to dress on the stretcher. [redacted] had weakness of legs @ times but did not bring cane in with [redacted]

B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

Continue to give instructions on dressing self procedure while on stretcher)

V.

[signature] — **SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT**

ME 85032 — **LICENSE NUMBER**

3/21/07 — **DATE REPORT COMPLETED**

16:40 — **TIME REPORT COMPLETED**

Form # DH-MQA1030- created 2-00; revised 3-24-03

addendum: 3/23/07 11:50 AM Pt went to ER evening of 3/21/07. X rays done – no fractures. Pt doing well today with pain relief.

STATE OF FLORIDA
Jeb Bush, Governor

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

SUBMIT FORM TO:
Agency for Health Care Administration,
Consumer Services Unit, Post Office Box 14000,
Tallahassee, Florida 32317-4000

RECEIVED CONSUMER SERVICES UNIT 07 MAR 27 AM 9:41

X

I. OFFICE INFORMATION

Southeastern Urological Center
Name of office

2000 Centre Pointe Blvd
Street Address

Tallahassee 32308 Leon
City Zip Code County

850-309-0400
Telephone

Rebecca Hankins-Ivey
Name of Physician or Licensee Reporting

1947932
License Number & office registration number, if applicable

Same as above
Patient's address for Physician or Licensee Reporting

II. PATIENT INFORMATION

Patient Identification Number

Age Gender Medicaid Medicare

3-21-07
Date of Office Visit

assessment of infected penile prosthesis
Purpose of Office Visit

Diagnosis

NA
ICD-9 Code for description of Incident

N/A
Level of Surgery (II) or (III)

III. INCIDENT INFORMATION

3/21/07 @ 9:30 Am
Incident Date and Time

Location of Incident:
☐ Operating Rm ☐ Recovery Rm
☒ Other

Note: If the incident involved a death, was the medical examiner notified? ☐ Yes ☐ No
Was an autopsy performed? ☐ Yes ☐ No

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete responses)

Patient presented to office for assesment of infected penile prosthesis. Complained of irregular heart beat, left sided [redacted] and tightness, and nausea. Given nitroglycerine aspirin and oxygen. EMS called and patient transported to TMH for continued care.

Form # DH-MQA1030- created 2-00; revised 9-6-01

B) ICD-9-CM Codes

NA	NA	NA
Surgical, diagnostic, or treatment procedure being performed at time of incident (ICD-9 Codes 01-99.9)	Accident, event, circumstances, or specific agent that caused the injury or event. (ICD-9 E-Codes)	Resulting injury (ICD-9 Codes 800-999.9)

C) List any equipment used if directly involved in the incident
(Use additional sheets as necessary for complete response)

D) Outcome of Incident (Please check)

☐ Death	☐ Surgical procedure performed on the wrong site **
☐ Brain Damage	☐ Wrong surgical procedure performed **
☐ Spinal Damage	☐ Surgical repair of injuries or damage from a planned surgical procedure
☐ Surgical procedure performed on the wrong patient	** if it resulted in
☐ A procedure to remove unplanned foreign objects remaining from surgical procedure	☐ Death ☐ Brain Damage ☐ Spinal Damage
☒ Any condition that required the transfer outcome of the patient to a licensed hospital	☐ Permanent disfigurement not to include the incision scar
Outcome of transfer – e.g., death, brain damage, observation only admitted Name of facility to which patient was transferred TMH	☐ Fracture or dislocation of bones or joints ☐ Limitation of neurological, physical, or sensory function; ☐ Any condition that required the transfer outcome of the patient

E) List all persons, including license numbers if licensed, locating information, and the capacity in which they were directly involved with this incident.

Rebecca Harkins-Ivey ARNP	1947932	care provider
Wanda Brown LPN	PN5153902	assisting practitioner
Shelley Keevers RN	RN2737062	assisting with transfer

F) List witnesses, including license numbers if licensed, and locating information if not listed above

IV. ANALYSIS AND CORRECTIVE ACTION

~~A)~~ **Analysis (apparent cause) of this incident** (Use additional sheets as necessary for complete response)

Patient symptomatic for myocardial infarct during office visit for infected implant and was appropriately transferred for further evaluation and care

B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

Actions were appropriate and timely. Patient was admitted.

V. [signature] RN — RN 915912
SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT — **LICENSE NUMBER**

3/22/07 — 10:05 AM
DATE REPORT COMPLETED — **TIME REPORT COMPLETED**

Form # DH-MQA1030- created 2-00; revised 9-6-01

STATE OF FLORIDA
Charlie Crist, Governor

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

SUBMIT FORM TO:
Department of Health, Consumer Services Unit
4052 Bald Cypress Way, Bin C75
Tallahassee, Florida 32399-3275

I. OFFICE INFORMATION

Salient Medical Centers
Name of office

4602 N. Armenia Ave Suite B-3
Street Address

Tampa 33603 Hillsborough
City Zip Code County

(813) 873-7400
Telephone

William Spellman
Name of Physician or Licensee Reporting

ARNP 2873512
License Number & office registration number, if applicable

William Spellman ARNP
Patient's address for Physician or Licensee Reporting

II. PATIENT INFORMATION

Age Gender Medicaid Medicare

Patient Identification Number

3/20/2007
Date of Office Visit

Purpose of Office Visit

555.2
Diagnosis

ICD-9 Code for description of incident

NA
Level of Surgery (II) or (III)

III. INCIDENT INFORMATION

3/20/2007 1540 (340pm)
Incident Date and Time

Location of Incident:
☐ Operating Room ☐ Recovery Room
☒ Other Clinic

RECEIVED
07 APR -2 PM 2:29
CONSUMER SERVICES UNIT

Note: If the incident involved a death, was the medical examiner notified? ☐ Yes ☐ No (NA)
Was an autopsy performed? ☐ Yes ☐ No

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete response)

Pt recieved second scheduled dose of remicade approximately ½ way through pt became dysphetic, experienced hives, low blood pressure, numbness of hands & lips, tightness of chest.

B) ICD-9-CM Codes

Surgical, diagnostic, or treatment procedure being performed at time of incident (ICD-9 Codes 01-99.9)	Accident, event circumstances, or specific agent that caused the injury or event. (ICD-9 E-Codes)	Resulting injury (ICD-9 Codes 800-999.9)
	E934.9	E934.9, 708.0, 786.07

C) List any equipment used if directly involved in the incident
(Use additional sheets as necessary for complete response)

NA

D) Outcome of Incident (Please check)

☐ Death	☐ Surgical procedure performed on the wrong site **
☐ Brain Damage	☐ Wrong surgical procedure performed **
☐ Spinal Damage	☐ Surgical repair of injuries or damage from a planned surgical procedure.
☐ Surgical procedure performed on the wrong patient.	** if it resulted in:
☐ A procedure to remove unplanned foreign objects remaining from surgical procedure.	☐ Death ☐ Brain Damage ☐ Spinal Damage
☒ Any condition that required the transfer of the patient to a hospital.	☐ Permanent disfigurement not to include the incision scar ☐ Fracture or dislocation of bones or joints
Outcome of transfer – e.g., death, brain damage, ~~observation only~~ → dc'd to home same day Name of facility to which patient was transferred: St. Joseph's Hospital – ED	☐ Limitation of neurological, physical, or sensory function. ☐ Any condition that required the transfer of the patient to a hospital.

E) List all persons, including license numbers if licensed, locating information and the capacity in which they were involved in this incident, this would include anesthesiologist, support staff and other health care providers.

William Spellman NP-C - ARNP 2873512,
Jennifer Dominguez - Receptionist
Renalta Robinette - RN 2541122

F) List witnesses, including license numbers if licensed, and locating information if not listed above

[redacted]

IV. ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response)

Adverse reaction to IV Remicade

B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

Pt. pre-medicated with tylenol and benadryl. NS IV begun - O2 and IVP solu-medrol given

V. W Spellman NP-C — **SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT**

ARNP 2873512 — **LICENSE NUMBER**

3-26-2007 — **DATE REPORT COMPLETED**

1000 — **TIME REPORT COMPLETED**

STATE OF FLORIDA
Charlie Crist, Governor

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

SUBMIT FORM TO:
Department of Health, Consumer Services Unit
4052 Bald Cypress Way, Bin C75
Tallahassee, Florida 32399-3275

I. OFFICE INFORMATION

Tallahassee Plastic Surgery Clinic
Name of office

1704 Riggins Road
Street Address

Tallahassee, FL — City | 32308 — Zip Code | Leon — County

850-877-2126
Telephone

Louis Hill, M.D.
Name of Physician or Licensee Reporting

ME26697/Registration Number 53
License Number & office registration number, if applicable

Patient's address for Physician or Licensee Reporting

II. PATIENT INFORMATION

Age | Gender | Medicaid | Medicare

12/11/06-initial surgery/ 3/20/07-second

Patient ... Number

Diagnosis

Purpose of Office Visit

V50.1
ICD-9 Code for description of incident

III
Level of Surgery (II) or (III)

RECEIVED
CONSUMER SERVICES UNIT
07 MAR 22 AM 10: 13

III. INCIDENT INFORMATION

3/20/07 approx. 1:15 pm
Incident Date and Time

Location of Incident:
☒ Operating Room ☐ Recovery Room
☐ Other________

Note: If the incident involved a death, was the medical examiner notified? ☐ Yes ☐ No
Was an autopsy performed? ☐ Yes ☐ No

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete response)

Patient underwent a cosmetic breast augmentation on 12/11/06 in the office operating room. complained of asymmetry and firmness of left breast post-operatively. This did not improve with the healing process. was taken back to the operating room on 3/20/07 to remove and replace the left breast implant with a capsulotomy. At this second procedure today implant pocket from the first procedure. It was removed along with the implant, which was left out. Cultures were performed of the implant pocket to rule out infection. The patient ~~and family were~~ was informed of the incident at the time of surgery.

B) ICD-9-CM Codes

19325-mammaplasty augmentation with implant	998.4/E871.0	996.54
Surgical, diagnostic, or treatment procedure being performed at time of incident **(ICD-9 Codes 01-99.9)**	Accident, event, circumstances, or specific agent that caused the injury or event. **(ICD-9 E-Codes)**	Resulting injury **(ICD-9 Codes 800-999.9)**

C) List any equipment used if directly involved in the incident
(Use additional sheets as necessary for complete response)

none

D) Outcome of Incident (Please check)

☐ Death	☐ Surgical procedure performed on the wrong site **
☐ Brain Damage	☐ Wrong surgical procedure performed **
☐ Spinal Damage	☐ Surgical repair of injuries or damage from a planned surgical procedure.
☐ Surgical procedure performed on the wrong patient.	** if it resulted in: ☐ Death ☐ Brain Damage ☐ Spinal Damage ☐ Permanent disfigurement not to include the incision scar ☐ Fracture or dislocation of bones or joints ☐ Limitation of neurological, physical, or sensory function. ☐ Any condition that required the transfer of the patient to a hospital.
☒ A procedure to remove unplanned foreign objects remaining from surgical procedure.	
☐ Any condition that required the transfer of the patient to a hospital. Outcome of transfer – e.g., death, brain damage, observation only ______ Name of facility to which patient was transferred: ______	

E) List all persons, including license numbers if licensed, locating information and the capacity in which they were involved in this incident, this would include anesthesiologist, support staff and other health care providers.

Louis Hill, M.D. -surgeon- ME26697
Greg McLanahan, M.D.-anesthesiologist -ME82354
LaTrell Wainwright, R.N.-circulating nurse-RN3047832
Mandy Tucker, Scrub tech

F) List witnesses, including license numbers if licensed, and locating information if not listed above

None besides those listed above.

IV. ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response)

Office policy of 2 sponge/needle counts for each procedure was not followed. Only one count was documented for this case.

B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

Two sponge/needle counts will be done for each case, and the surgeon may not leave the room until the counts are correct.

V.

SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT   LICENSE NUMBER

3/20/07
DATE REPORT COMPLETED

4:30 p.m.
TIME REPORT COMPLETED

STATE OF FLORIDA
Charlie Crist, Governor

RECEIVED
CONSUMER SERVICES UNIT

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

07 APR -2 AM 8:00

SUBMIT FORM TO:
Department of Health, Consumer Services Unit
4052 Bald Cypress Way, Bin C75
Tallahassee, Florida 32399-3275

I. OFFICE INFORMATION

Hospice of Palm Beach County Inc.
Name of office

5300 East Avenue
Street Address

West Palm Beach | 33407 | Palm Beach
City | Zip Code | County

561-848-5200
Telephone

Gail Austin Cooney MD
Name of Physician or Licensee Reporting

ME44998
License Number & office registration number, if applicable

Patient's address for Physician or Licensee Reporting

II. PATIENT INFORMATION

Patient Identification Number

Diagnosis

Age Gender Medicaid Medicare

Hospice admission 01-04-07
Date of Office Visit

Purpose of Office Visit

7993
ICD-9 Code for description of incident

Level of Surgery (II) or (III)

III. INCIDENT INFORMATION

03-16-07, 1400 PM
Incident Date and Time

Location of Incident:
☐ Operating Room ☐ Recovery Room
☒ Other ALF

Note: If the incident involved a death, was the medical examiner notified? ☒ Yes ☐ No
Was an autopsy performed? ☒ Yes ☐ No

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete response)

See Attachment A

B) ICD-9-CM Codes

7993, 7387	E850.1	909.5
Surgical, diagnostic, or treatment procedure being performed at time of incident **(ICD-9 Codes 01-99.9)**	Accident, event circumstances, or specific agent that caused the injury or event. **(ICD-9 E-Codes)**	Resulting injury **(ICD-9 Codes 800-999.9)**

C) List any equipment used if directly involved in the incident
(Use additional sheets as necessary for complete response)

None

D) Outcome of Incident (Please check)

- [x] Death
- [ ] Brain Damage
- [ ] Spinal Damage
- [ ] Surgical procedure performed on the wrong patient.
- [ ] A procedure to remove unplanned foreign objects remaining from surgical procedure.
- [ ] Any condition that required the transfer of the patient to a hospital.

Outcome of transfer – e.g., death, brain damage, observation only ________
Name of facility to which patient was transferred: ________

- [ ] Surgical procedure performed on the wrong site **
- [ ] Wrong surgical procedure performed **
- [ ] Surgical repair of injuries or damage from a planned surgical procedure.

** if it resulted in:
- [ ] Death
- [ ] Brain Damage
- [ ] Spinal Damage
- [ ] Permanent disfigurement not to include the incision scar
- [ ] Fracture or dislocation of bones or joints
- [ ] Limitation of neurological, physical, or sensory function.
- [ ] Any condition that required the transfer of the patient to a hospital.

E) List all persons, including license numbers if licensed, locating information and the capacity in which they were involved in this incident, this would include anesthesiologist, support staff and other health care providers.

Eric J Pesetsky MD, ME62813, Hospice physician who wrote methadone order

F) List witnesses, including license numbers if licensed, and locating information if not listed above

Kathleen Jimenez RN, 9182529, Hospice on-call nurse who discovered medication error

IV. ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response)

See Attachment B

B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

See Attachment B

V. [signature] MD — ME44998

SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT — LICENSE NUMBER

March 29, 2007 — DATE REPORT COMPLETED

14:30 PM — TIME REPORT COMPLETED

Florida Department of Health
Physician Office, Adverse Incident Report
Hospice of Palm Beach County, Inc.
March 29, 2007
Attachment A

III. Incident Information

A) Describe circumstances of the incident (narrative) (Use additional sheets as necessary for complete response)

On or before 03-14-07, the Physician was contacted by patient's daughter because of the patient's increasing complaints of pain that was not relieved by the current treatment with oxycodone/acetaminophen given 1 tablet every 4 hours as needed. On 03-14-07, the Physician hand wrote an order for "methadone 2.5 mg by mouth Q 8 hrs X 4 days, then methadone 2.5 mg by mouth Q 12 hours ATC thereafter." This order was handed to the team nurse who then faxed the orders to the assisted living facility (Homewood ALF) and to the facility's contracted pharmacy (Colonial Pharmacy). A copy of the orders was delivered to the ALF on 03-15-07.

On 03-17-07at 11:35 AM, the Physician was called directly (he was not on-call) by the patient's private caregiver. The caregiver stated that the patient could open ███ eyes but was otherwise unresponsive. The Physician instructed the caregiver to stop the methadone and asked that the ALF nurse call him for a formal order to discontinue the medication.

On 03-17-07 at 15:50 PM, the ALF nurse called the Hospice triage to inform them of a change in the patient's status. The Hospice nurse documented that "patient started on Methadone 25 mg 3 times daily on 3/16/07 and was previously on Percocet PRN. Patient is now "out of it" and they are unable to rouse patient." An on-call Hospice nurse was sent to the ALF to assess the patient. The nurse's note, written at 17:00 PM stated that the patient was unable to verbalize except for mumbling. The Hospice physician on-call was contacted and gave the order to discontinue the methadone.

On 03-18-07 at 10:20 AM, the patient's daughter called the Physician directly (he was not on-call) to report that the patient was poorly responsive and had not taken any further methadone. He asked her to call Hospice directly to request a nurse be sent to evaluate the patient for inpatient hospice admission. At 10:23 AM the Physician contacted Hospice triage with the request. At 10:35 AM the patient's daughter called Hospice triage and reported "persistent lethargy and difficult to arouse" and asked that a nurse be sent out "now." The same on-call Hospice nurse who had assessed the patient on 03-17-07 was sent to reevaluate the patient. She documented that the patient was more alert and able to verbalize basic commands and recognize ███ caregiver. The daughter and nurse agreed to continue to monitor the patient in the ALF, as ███ appeared to be improving; the Physician was contacted by telephone and concurred. An apparent medication error was first noted by the Hospice on-call nurse and the Physician, with a discrepancy between the methadone 2.5 mg Q 8hrs ordered and the methadone 25 mg Q 8hrs that was dispensed and administered.

At 18:51 PM, the patient's daughter again contacted Hospice triage because of a significant change in the patient's condition since 16:00 PM; she asked that a nurse reevaluate the patient. Another Hospice on-call nurse was sent and found the patient "lethargic, semi-conscious." The Hospice physician on-call was contacted and the patient was transferred to the Pinecrest/Delray Hospice and Palliative Care Unit for inpatient Hospice admission. The inpatient nursing staff again assessed the patient at the time of ███ arrival at 22:05 PM. Vital signs included BP 204/95, pulse 117, respiratory rate 21, temperature 100.6°, and oxygen saturation 87%. ███ received nasal oxygen at 2 liters/minute. A Foley catheter was placed and the head of the bed elevated.

Florida Department of Health
Physician Office, Adverse Incident Report
Hospice of Palm Beach County, Inc.
March 29, 2007
Attachment A

On 03-19-07, documentation was received from the ALF and the Pharmacy that confirmed that there had been a
The patient received methadone 25 mg on 03-16-07 at 14:00 PM, 22:00 PM and on 03-17-07 at 06:00 AM. The Physician then met with the patient and two daughters to disclose the medical error and to inform them of the patient's grave condition. The patient received naloxone with no evident improvement.

On 03-21-07, a copy of the faxed order received by the Pharmacy and a copy of the original order written by the Physician were received by the Hospice COO and reviewed with the Hospice Medical Director. The original order appeared to have been altered.

On 03-23-07, the Hospice COO and Hospice Medical Director reviewed the incident with the Physician. He stated that the order in the medical record was as he had originally written it on 03-14-07. At 16:30 PM, the Hospice CEO and Hospice COO met with the patient's two daughters and informed them of the discrepancies between the original faxed order and the current order in the medical record.

03-23-07 at 17:00 PM. The patient was transferred to the Palm Beach County Medical Examiner for further evaluation.

Florida Department of Health
Physician Office, Adverse Incident Report
Hospice of Palm Beach County Inc.
March 29, 2007
Attachment B

IV. Analysis and Corrective Action

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response)

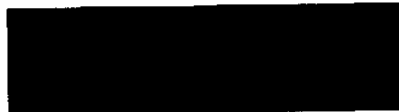
The adverse event was reviewed and four major contributing factors were defined.

1. The Physician wrote the order by hand; handwriting contributed to lack of order clarity
2. The Hospice procedure included faxing the order to the Pharmacy; the order clarity deteriorated with faxing
3. Hospice did not have a process to ensure that medications supplied by an outside pharmacy were accurately and correctly dispensed
4. Hospice Triage and On-Call staff did not compare the dispensed and administered medications with the order, as documented in the Hospice patient care data base and Hospice medical record

B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

The following corrective and proactive measures were taken.

1. Improve current processes for medication ordering
    a. Short term
        i. Physicians will telephone medication orders directly to the pharmacy whenever possible (education to Medical Staff 03-28-07)
        ii. Contracted pharmacy providers will send Hospice team copies of all filled prescriptions; team supervisor will validate accuracy
        iii. Team nurse will verify the accuracy of the facility medication record when medications are initiated or changed
        iv. Hospice staff will review medication orders before faxing to ensure clarity
    b. Long term
        i. Investigate other means of medication orders, including electronic prescribing, to eliminate need for facsimile ordering
2. Improve medication reconciliation by after-hours staff
    a. Short term
        i. Triage and On-Call staff will use the Hospice patient care data base to review and confirm current medication orders
        ii. Triage Manage will conduct performance improvement oversight to ensure compliance
    b. Long term
        i. Triage and On-Call staff will have access to an electronic medical record to improve accuracy of medication treatment plan



STATE OF FLORIDA
Jeb Bush, Governor

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

SUBMIT FORM TO:
Department of Health, Consumer Services Unit
4052 Bald Cypress Way, Bin C75
Tallahassee, Florida 32399-3275

I. OFFICE INFORMATION

Space Coast Medical Associates Name of office	225 Cone Rd Street Address
Merritt Island, Fl 32952 Brevard City / Zip Code / County	321 453-1361 Telephone
Ashish Dalal MD Name of Physician or Licensee Reporting	ME0085152 License Number & office registration number, if applicable
Patient's address for Physician or Licensee Reporting	

II. PATIENT INFORMATION

Pa[redacted]	Age / Gender / Medicaid / Medicare
Pa[redacted]	3/5/07 Date of Office Visit
Patient Identification Number [redacted]	Chemo[redacted] Purpose of Office Visit
Diagnosis	V58.11, 162.9 ICD-9 Code for description of incident
	Level of Surgery (II) or (III)

III. INCIDENT INFORMATION

3/5/07 10:15
Incident Date and Time

Location of incident:
☐ Operating Rm ☐ Recovery Rm
☒ Other Chemotherapy room

Note: If the incident involved a death, was the medical examiner notified? ☐ Yes ☐ No
Was an autopsy performed? ☐ Yes ☐ No

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete response)

[redacted] present for chemotherapy. Chemotherapy iniated @ (Taxotere - 1st dose) 10:00 am after premeds of Benadryl 50mg IVPB and Decadron 20mg IVPB. Pt confirmed taking Decadron PO per MD order x3 doses prior to tx, c̄ initial dose starting 24hrs prior to tx. 10:15. Observed pt with slight pink colored skin to face; blood shot eyes. C/o warm sensation. Infusion stopped. NS KVO. MD notified. VS 116/68 - 86 Pulse Ox 93%. O2 @ 2L via NC. Orders rcd 10:20. 2 puffs Albuterol (pts own med) and Decadron 10mg IVP. Pt c/o increasing SOB; diaphoretic 10:25 vs 178/86, P 180 Pulse Ox 88%, 911 called. Atropine 0.5ml (1:1000) [illegible] per MD order. Pt remains symptomatic. 10:30 arrival paramedics. 10:35 VS 146/114 HR 174 Pt transported to CCH via ambulance.

Form # DH-MQA1030- created 2-00; revised 3-24-03

B) ICD-9-CM Codes

V58.11		
Surgical, diagnostic, or treatment procedure being performed at time of incident **(ICD-9 Codes 01-99.9)**	Accident, event, circumstances, or specific agent that caused the injury or event. **(ICD-9 E-Codes)**	Resulting injury **(ICD-9 Codes 800-999.9)**

C) List any equipment used if directly involved in the incident
(Use additional sheets as necessary for complete response)

portable pulse oximetry and O_2

D) Outcome of Incident (Please check)

☐ Death	☐ Surgical procedure performed on the wrong site **
☐ Brain Damage	☐ Wrong surgical procedure performed **
☐ Spinal Damage	☐ Surgical repair of injuries or damage from a planned surgical procedure
☐ Surgical procedure performed on the wrong patient	** if it resulted in
☐ A procedure to remove unplanned foreign objects remaining from surgical procedure	☐ Death ☐ Brain Damage ☐ Spinal Damage ☐ Permanent disfigurement not to include the incision scar
☒ Any condition that required the transfer outcome of the patient to a licensed hospital	☐ Fracture or dislocation of bones or joints ☐ Limitation of neurological, physical, or sensory function;
Outcome of transfer – e.g., death, brain damage, observation only ____ Name of facility to which patient was transferred ____	☐ Any condition that required the transfer outcome of the patient

E) List all persons, including license numbers if licensed, locating information, and the capacity in which they were directly involved with this incident.

Mary Beth Rosser, RN	RN 2031342
Michelle Pillow, RN	RN 9187143
Jeannie Edge, RN	RN 9225269
Asish Dalal, M.D.	ME 0085152

F) List witnesses, including license numbers if licensed, and locating information if not listed above

AS ABOVE

IV. ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response)

Discontinue use of Taxanes

B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

Discontinue use of Taxanes

V. [signature] — **SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT**

ME 0085152 — **LICENSE NUMBER**

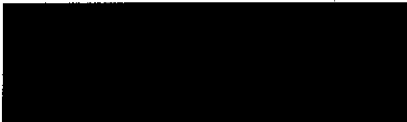
3/5/07 — **DATE REPORT COMPLETED**

5:00 pm — **TIME REPORT COMPLETED**

2 of 2 pages

Form # DH-MQA1030- created 2-00; revised 3-24-03

STATE OF FLORIDA
Jeb Bush, Governor



PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

SUBMIT FORM TO:
Department of Health, Consumer Services Unit
4052 Bald Cypress Way, Bin C75
Tallahassee, Florida 32399-3275

I. OFFICE INFORMATION

Space Coast Medical Associates
Name of office

225 Cone Road
Street Address

Merritt Island 32952 Brevard
City / Zip Code / County

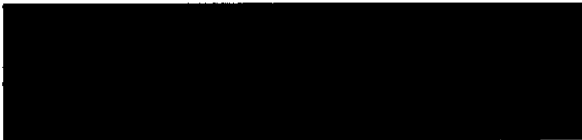
321-453-1361
Telephone

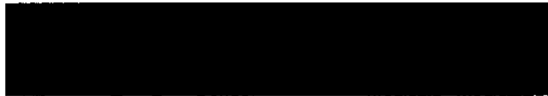
Richard Dupp Sprawls
Name of Physician or Licensee Reporting

ME 0054026
License Number & office registration number, if applicable

Patient's address for Physician or Licensee Reporting

II. PATIENT INFORMATION





3-2-07
Date of Office Visit

Patient Id

Chemo
Purpose of Office Visit

V55.11
Diagnosis

ICD-9 Code for description of incident

Level of Surgery (II) or (III)

MAY 9:55 CONSUMER SERVICES UNIT

III. INCIDENT INFORMATION

3-2-07 0945
Incident Date and Time

Location of Incident:
☐ Operating Rm ☐ Recovery Rm
☒ Other Chemotherapy Treatment Room

Note: If the incident involved a death, was the medical examiner notified? ☐ Yes ☐ No
Was an autopsy performed? ☐ Yes ☐ No

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete response)

in office for Chemotherapy Treatment. Regimen started @ 0845 with the initiation of Pre-Medication Meds Benadryl and Tagamet followed by Aloxi and Decadron. At 0937 I started Taxol Infusion. At 0945, patient c/o SOB and Dyspnea. Taxol stopped, Normal Saline start BP 102/70 P99, O_2 85%, O_2 via Nasal Cannula @ 2L/. Additional supportive meds given to include Benadryl, Dexamethasone, Ativan. Pt continues to complain of Dyspnea. Ruddy skin color with cyanosis and diaphoresis. O_2 80%, BP 83/64 P 120 No relief expressed by patient O_2 ↑ to 4L, Emergency management Called Pt transported to CCH via Ambulance

Form # DH-MQA1030- created 2-00; revised 3-24-03

B) ICD-9-CM Codes

V58.11		
Surgical, diagnostic, or treatment procedure being performed at time of incident **(ICD-9 Codes 01-99.9)**	Accident, event, circumstances, or specific agent that caused the injury or event. **(ICD-9 E-Codes)**	Resulting injury **(ICD-9 Codes 800-999.9)**

C) List any equipment used if directly involved in the incident (Use additional sheets as necessary for complete response)

D) Outcome of Incident (Please check)

☐ Death	☐ Surgical procedure performed on the wrong site **
☐ Brain Damage	☐ Wrong surgical procedure performed **
☐ Spinal Damage	☐ Surgical repair of injuries or damage from a planned surgical procedure
☐ Surgical procedure performed on the wrong patient	** if it resulted in
☐ A procedure to remove unplanned foreign objects remaining from surgical procedure	☐ Death ☐ Brain Damage
☒ Any condition that required the transfer outcome of the patient to a licensed hospital	☐ Spinal Damage ☐ Permanent disfigurement not to include the incision scar
Outcome of transfer – e.g., death, brain damage, observation only evaluated, treated, + released Name of facility to which patient was transferred Cape Canaveral Hospital	☐ Fracture or dislocation of bones or joints ☐ Limitation of neurological, physical, or sensory function; ☐ Any condition that required the transfer outcome of the patient

E) List all persons, including license numbers if licensed, locating information, and the capacity in which they were directly involved with this incident.

Kimberly Buckner, RN 9170156
Jane Stacy RN 3207082
Jeannie Edge RN 9225269
R. Duff Sprawls MD ME 0054026

F) List witnesses, including license numbers if licensed, and locating information if not listed above

as above

IV. ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response)

Taxol Reaction

B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

Discontinue Taxol; challenge patient c̄ Taxotere before ruling out taxane use.

V. [signature] MD — ME 0054026

SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT — **LICENSE NUMBER**

3.2.07 — **DATE REPORT COMPLETED**

1500 — **TIME REPORT COMPLETED**

Form # DH-MQA1030- created 2-00; revised 3-24-03

4/3/07 (#6)

#148

STATE OF FLORIDA
Charlie Crist, Governor

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

SUBMIT FORM TO:
Department of Health, Consumer Services Unit
4052 Bald Cypress Way, Bin C75
Tallahassee, Florida 32399-3275

I. OFFICE INFORMATION

C. Randall Harrell, MD, PA
Name of office

34156 US Hwy 19 N
Street Address

Palm Harbor 34684 PINELLAS
City Zip Code County

(727) 781-0818
Telephone

C. Randall Harrell, MD
Name of Physician or Licensee Reporting

ME 56244
License Number & office registration number, if applicable

Patient's address for Physician or Licensee Reporting

II. PATIENT INFORMATION

Age Gender Medicaid Medicare

4-3-2007
Date of Office Visit

Patient Identification Number

elective cosmetic surgery
Purpose of Office Visit

Unacceptable cosmetic appearence
Diagnosis

V50.1
ICD-9 Code for description of incident

III
Level of Surgery (II) or (III)

III. INCIDENT INFORMATION

4-3-07 15:00 hrs
Incident Date and Time

Location of Incident:
☐ Operating Room ☒ Recovery Room
☐ Other

Note: If the incident involved a death, was the medical examiner notified? ☐ Yes ☐ No
Was an autopsy performed? ☐ Yes ☐ No

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete response)

* See ATTACHED

07 APR 19 PM 2:45
CONSUMER SERVICES UNIT

B) ICD-9-CM Codes

Surgical, diagnostic, or treatment procedure being performed at time of incident (ICD-9 Codes 01-99.9)	Accident, event, circumstances, or specific agent that caused the injury or event. (ICD-9 E-Codes)	Resulting injury (ICD-9 Codes 800-999.9)

C) List any equipment used if directly involved in the incident

(Use additional sheets as necessary for complete response)

N/A

D) Outcome of Incident (Please check)

- ☐ Death
- ☐ Brain Damage
- ☐ Spinal Damage
- ☐ Surgical procedure performed on the wrong patient.
- ☐ A procedure to remove unplanned foreign objects remaining from surgical procedure.
- ☒ Any condition that required the transfer of the patient to a hospital.

Outcome of transfer – e.g., death, brain damage, observation only Discharged [illegible] day

Name of facility to which patient was transferred: Helen Ellis Hospital [illegible]

- ☐ Surgical procedure performed on the wrong site **
- ☐ Wrong surgical procedure performed **
- ☐ Surgical repair of injuries or damage from a planned surgical procedure.

** if it resulted in:

- ☐ Death
- ☐ Brain Damage
- ☐ Spinal Damage
- ☐ Permanent disfigurement not to include the incision scar
- ☐ Fracture or dislocation of bones or joints
- ☐ Limitation of neurological, physical, or sensory function.
- ☐ Any condition that required the transfer of the patient to a hospital.

E) List all persons, including license numbers if licensed, locating information and the capacity in which they were involved in this incident, this would include anesthesiologist, support staff and other health care providers.

LAWRENCE FRIEDMAN, MD ME64984 Pulmonologist consulted

NAJAM JAVEED, MD ME76911 CARDIOLOGIST CONSULTED

SIVAKUMAR V. AMAR, MD ME38311 Primary care Physician and Pulmonologist.

F) List witnesses, including license numbers if licensed, and locating information if not listed above

C. Randall HARRELL, MD (ME56244), BETTY MASSELL, RN (RN2716192), ABDON Rodriguez, MD (ME29904), LAWRENCE FRIEDMAN, MD (ME64984)

IV. ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response)

[illegible] Observation at Helen Ellis Hospital

B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

Resolved [illegible]

V. [signature] R. Harrell, MD — ME56244

SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT — LICENSE NUMBER

4/16/07 — DATE REPORT COMPLETED

TIME REPORT COMPLETED

DH-MQA1030-12/06

PHYSICIANS OFFICE INCIDENT REPORT

This report is a narrative summary of [redacted] who recently underwent [redacted] which was uneventful. However, in the Recovery room she experience[redacted]. The patient was seen by a Pulmonologist and transferred to Helen Ellis Hospital, where it was determined she had a[redacted]. The patient recovered completely and did not suffer any long term adverse effects from the event. We will provide a chronological analysis of the evaluation and treatment of this patient.

Care and Treatment of the Patient

On March 19, 2007, patient [redacted], a [redacted] year old woman presented to Dr. Harrell's office for an initial consultation for an elective breast augmentation to improve the breast ptosis that had result from her previous pregnancies.
Her medical history didn't include any allergies, current medications or any medical problems. Patient denied smoking, any previous pulmonary problems, illnesses or medical conditions.

On March 23, 2007, [redacted] presented to Dr. Harrell's for her pre-operative evaluation: The risks and benefits of surgery were fully explained to the patient and informed consent was obtained. On April 3, 2007, the patient presented to Dr. Harrell's office for her breast augmentation. The patient was evaluated prior to surgery by Dr. Rodriguez, anesthesiologist. After adequate [redacted] was obtained, the patient was prepped and draped in the usual sterile fashion. Her surgery was completed as planned and completely uneventful from a surgery and anesthesia point of view. She received 2 liters of intravenous fluids during her 90 minute surgery. She arrived in the recovery room in stable condition with an oxygen saturation of a 100%, respiratory rate 20, pulse 80, B/P 123/82.

After the patient was in the recovery room for 1 hour, it was noticed by the recovery room RN Betty Massell that she had a decreased O2 saturation after being taken off her O2 face mask. Dr. Rodriguez, anesthesiologist and Dr. Harrell both listened to her lungs and noticed decreased breath sounds in both bases. At 3:03 pm. Dr. Rodriguez gave the patient Lasix 20mg IV, at 3:10 pm Dexamenthasone 8mg IV and at 4:35 pm a breathing treatment with Ipratropium Bromide inhalation solution 0.2% of Xopenex inhalation solution 1.25 mg inhalation treatment.

When the patient's pulmonary function was still not improved, her internist Dr. S Amar, (who is also a pulmonologist) was called for a second opinion. He stated she had no previous pulmonary problems and recommended seeing her the next day in his office. We wanted to get a third opinion about what would be her best management at this point. Another Pulmonologist Dr. Lawrence Friedman, Board Certified in Pulmonology was contacted and agreed to see the patient in the recovery room. Dr. Friedman wanted to rule out pulmonary embolism by having a CT scan. The patient was transferred that afternoon to

Helen Ellis hospital to have a CT scan performed. The scan ruled out pulmonary embolus but showed bilateral pulmonary edema. The patient was observed overnight and Dr. Friedman gave the diagnosis of non-cardiac pulmonary edema on unknown etiology. The patient was discharged the following day in stable condition with complete resolution of her pulmonary edema. The patient was seen by her own pulmonologist Dr. Amar, who told her that she could have taken in too much p.o. fluids the day prior to her surgery that could have caused her pulmonary edema. The patient was seen in my office on April 9, 2007 in stable condition without any pulmonary complaints.

CONCLUSION

We believe that Dr. Harrell met and exceeded the standard of care in his care and treatment of . Dr. Harrell properly performed an initial consultation and pre-operative evaluation, which did not reveal any pulmonary problems. Her surgery was uneventful but subsequent to the patient's surgical procedure, she experienced Non-cardiac pulmonary edema of unknown etiology unrelated to her intraoperative fluids (2 liters) that could not have been anticipated. Dr. Harrell responded to the patient quickly and competently by supporting her vital functions and requesting evaluations by an anesthesiologist and two pulmonary specialists. The patient was them promptly transferred to the hospital, where she was diagnosed, treated, and released without incident.

If you require any additional information, please do not hesitate to contact my office.

Very truly yours,

C. Randall Harrell, MD

4/6/07 #7

#149

07 APR 23 PM 2:58

STATE OF FLORIDA
Jeb Bush, Governor

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

SUBMIT FORM TO:
Department of Health, Consumer Services Unit
4052 Bald Cypress Way, Bin C75
Tallahassee, Florida 32399-3275

I. OFFICE INFORMATION

Sarasota Interventional Radiology
Name of office

600 North Cattlemen Road Suite 100
Street Address

Sarasota FL 34232 Sarasota
City Zip Code County

941-378-3231
Telephone

Dr. Gerald Grubbs
Name of Physician or Licensee Reporting

License Number & office registration number, if applicable

Patient's address for Physician or Licensee Reporting

II. PATIENT INFORMATION

Patient Ide

Age Gender Medicaid Medicare
4/6/7

Purpose of Office Visit

Diagnosis

ICD-9 Code for description of incident

II
Level of Surgery (II) or (III)

III. INCIDENT INFORMATION

4/6/7 1255
Incident Date and Time

Location of Incident:
☐ Operating Rm ☑ Recovery Rm
☐ Other

Note: If the incident involved a death, was the medical examiner notified? ☐ Yes ☐ No
Was an autopsy performed? ☐ Yes ☐ No

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete response)

pre Bx, Temp 101.8 HR-120 10 30A BP 133/80
post Bx temp ↑ 103.9 at 12 00 noon HR-120 BP-120/73
pt. present with Hb 8.7, Dx. lymphoma non Hodgkins.
pt arousable but very somnulent
Dr. Buck notified by Dr. Yard both agreed to
transfer pt to SMH
transfered at 1300 112/70 P-123 R-16 temp 103.6
PO2 94% 3 liters nasal cannula

Form # DH-MQA1030- created 2-00; revised 3-24-03

B) ICD-9-CM Codes

Surgical, diagnostic, or treatment procedure being performed at time of incident (ICD-9 Codes 01-99.9)	Accident, event, circumstances, or specific agent that caused the injury or event. (ICD-9 E-Codes)	Resulting injury (ICD-9 Codes 800-999.9)

C) List any equipment used if directly involved in the incident
(Use additional sheets as necessary for complete response)

D) Outcome of Incident (Please check)

- ☐ Death
- ☐ Brain Damage
- ☐ Spinal Damage
- ☐ Surgical procedure performed on the wrong patient
- ☐ A procedure to remove unplanned foreign objects remaining from surgical procedure
- ☑ Any condition that required the transfer outcome of the patient to a licensed hospital

Outcome of transfer – e.g., death, brain damage, observation only ____________
Name of facility to which patient was transferred SMH

- ☐ Surgical procedure performed on the wrong site **
- ☐ Wrong surgical procedure performed **
- ☐ Surgical repair of injuries or damage from a planned surgical procedure

*** if it resulted in*

- ☐ Death
- ☐ Brain Damage
- ☐ Spinal Damage
- ☐ Permanent disfigurement not to include the incision scar
- ☐ Fracture or dislocation of bones or joints
- ☐ Limitation of neurological, physical, or sensory function;
- ☐ Any condition that required the transfer outcome of the patient

E) List all persons, including license numbers if licensed, locating information, and the capacity in which they were directly involved with this incident.

Dr. Yard - anesthesia ME 68224
Dr. Grubbs - Procedure ME 63973
Kathleen Warren RN recovery RN 2231892

F) List witnesses, including license numbers if licensed, and locating information if not listed above

IV. ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response)

pt. somnolent but arousable tachy P-123 Temp ↑ to 103.9

B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

Dr Yard - ASA 650mg P.O at 12⁰⁰ (Dr Buck) notified per phone agreed to transfer pt to SMH (oncology)

V.

SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT ____________ LICENSE NUMBER ____________

DATE REPORT COMPLETED ____________ TIME REPORT COMPLETED ____________

Form # DH-MQA1030- created 2-00; revised 3-24-03

4/26/07 #8

#150

STATE OF FLORIDA
Charlie Crist, Governor

07 MAY 10 PM 2:31

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

SUBMIT FORM TO:
Department of Health, Consumer Services Unit
4052 Bald Cypress Way, Bin C75
Tallahassee, Florida 32399-3275

I. OFFICE INFORMATION

Name of office: Gessler Clinic, P.A.

Street Address: 635 First St. N., Winter Haven, FL

City / Zip Code / County: Winter Haven, 33881 Polk

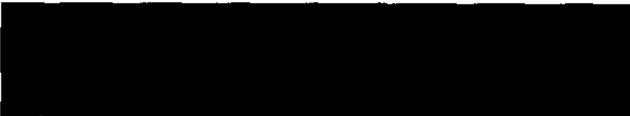
Telephone: 863-294-0670

Name of Physician or Licensee Reporting: Robert A. Rombola, M.D.

License Number & office registration number, if applicable: ME-0042497

Patient's address for Physician or Licensee Reporting:

II. PATIENT INFORMATION



Age / Gender / Medicaid / Medicare: 4/26/07

Patient Identification Number:

Purpose of Office Visit:

Diagnosis: 795.08 intraepithelial lesion mild to moderately focal 795.03 dysplasia with HPV changes 079.4

ICD-9 Code for description of incident: 867.1

Level of Surgery (II) or (III): NA

III. INCIDENT INFORMATION

Incident Date and Time: 4/26/07 - 3:45 p.m.

Location of Incident:
☐ Operating Room ☐ Recovery Room Gessler Clinic
☒ Other Procedure - Women's Division
450 E. Central Ave., Winter Haven

Note: If the incident involved a death, was the medical examiner notified? ☐ Yes ☐ No NA
Was an autopsy performed? ☐ Yes ☐ No

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete response)

Please see attached narrative.

B) ICD-9-CM Codes

795.03/079.4	867.1	867.1
Surgical, diagnostic, or treatment procedure being performed at time of incident **(ICD-9 Codes 01-99.9)**	Accident, event, circumstances, or specific agent that caused the injury or event. **(ICD-9 E-Codes)**	Resulting injury **(ICD-9 Codes 800-999.9)**

C) List any equipment used if directly involved in the incident
(Use additional sheets as necessary for complete response)

LEEP machine

D) Outcome of Incident (Please check)

☐ Death	☐ Surgical procedure performed on the wrong site **
☐ Brain Damage	☐ Wrong surgical procedure performed **
☐ Spinal Damage	☒ Surgical repair of injuries or damage from a planned surgical procedure.
☐ Surgical procedure performed on the wrong patient.	** if it resulted in:
☐ A procedure to remove unplanned foreign objects remaining from surgical procedure.	☐ Death ☐ Brain Damage ☐ Spinal Damage
☒ Any condition that required the transfer of the patient to a hospital.	☐ Permanent disfigurement not to include the incision scar ☐ Fracture or dislocation of bones or joints
Outcome of tran[redacted] death, brain damage, observation onl[redacted] Name of facility to which patient was transferred: Winter Haven Hospital	☐ Limitation of neurological, physical, or sensory function. ☒ Any condition that required the transfer of the patient to a hospital.

E) List all persons, including license numbers if licensed, locating information and the capacity in which they were involved in this incident, this would include anesthesiologist, support staff and other health care providers.

Melissa Mosier, RN - Assistant - RN9175548- Gessler Clinic, P.A.
Lisa M. Jardine, M.D. - assisted following incident - ME76581, Gessler
Robert A. Rombola, M.D. - Physician - ME-0042497 - Gessler Clinic, P.A.
Bade Akintan, M.D. - Physician - assisted following incident - Bond Clinic

F) List witnesses, including license numbers if licensed, and locating information if not listed above

See above.

IV. ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response)

Please see attached narrative.

B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

Please see attached narrative.

V. R.A. [signature] ME-0042497

SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT LICENSE NUMBER

5/9/07 10 [illegible]

DATE REPORT COMPLETED TIME REPORT COMPLETED

DH-MQA1030-12/06

GESSLER CLINIC PA 635 First Street North Winter Haven, Florida 33881 863/294-0670 Fax: 863/298-3200

Robert A. Rombola, M.D.

RE: [redacted]

To: The Florida Department of Health.

Please accept this narrative as my description of [redacted] April 26, 2007 LEEP procedure.

Prior History

[redacted] is a [redacted]-year-old [redacted] female para 1-0-0-1 who had been a patient of mine since August of 2000. Her prior medical history included a cervical conization in 1976 by Dr. Jennings and a cesarean section in 1989.

The patient's Pap smears from August of 2000 and up until November 9, 2004 were negative. Her Pap smear one year later, on November 9, 2005, was an ASCUS but negative for high risk HPV. The patient was instructed to undergo a repeat Pap smear in three to four months. Her follow-up Pap smear on April 11, 2006 revealed a low-grade lesion which was positive for high risk HPV. A colposcopy and biopsy conducted on May 08, 2006 revealed consistent findings.

On June 15, 2006, [redacted] had a LEEP conization consistent with dysplasia and both her endocervical and ectocervical margins were negative for dysplasia or malignancy. The patient's first Pap smear thereafter was on December 13, 2006 and despite negative margins on the June 15, 2006 LEEP, the patient was again found to have a low-grade lesion positive for high risk HPV. A repeat Pap smear on March 05, 2007 again showed a low-grade lesion positive for high risk HPV. [redacted] underwent another colposcopy and biopsy on April 03, 2007 which revealed CIN I-II and mild to focally moderate dysplasia with HPV changes ectocervically. Her ECC was also positive for a detached fragment of dysplasia.

Circumstances of the incident (III-A)

I scheduled the patient for either a laser or LEEP on April 26, 2007. I decided on the LEEP in order to have the tissue examined and reported upon by a pathologist. I wanted to be as thorough as possible to remove the dysplasia as this was the patient's third cone procedure. Starting right of center anteriorly to posteriorly, I removed a large portion of her anterior and posterior cervix and a good bit endocervically. I also removed a portion of tissue from the left side more or less for symmetry and to even up such. The patient tolerated the procedure well to this point with minimal bleeding.

I found the patient's cervix to be a little ragged and asymmetric anteriorly just above the endocervix. Because of this anatomy, I felt I had to make a slightly deeper cut endocervically and lower than the anterior cervical lip. While removing this endocervical tissue I saw a gush of fluid which I felt was most likely from [redacted]

remained stable at all times. My nurse was also in attendance at all times. I requested assistance and Dr. Jardine responded. We packed the vagina with 4 x 4s and placed a Foley catheter to better evaluate if the bladder was injured. We found bright red blood tinged urine at that point which confirmed the diagnosis of a bladder perforation. I then explained what had happened to the patient as was alert, responsive and stable.

Analysis (IV A)

While bladder injury is a known complication of this procedure, it is rare and I am surprised I perforated the bladder in this instance. I suspect the patient's previous cesarean section may have caused her bladder to advance somewhat and the three cervical cones had shortened her cervix. Furthermore, I felt I had to make a slightly deeper cut endocervically and lower than the anterior cervical lip in order to remove all of the affected tissue and achieve a cure. These factors probably increased her risk for this sort of injury. An alternative treatment option would have been a hysterectomy, which the patient wanted to avoid, *but* with the previous cesarean section and the cones, this option carried, in my opinion, an even greater risk for a possible bladder injury.

Corrective Action (IV B)

I ordered nursing to call an ambulance and then called Dr. Akintan, an urologist at the Bond Clinic who was on call at Winter Haven Hospital (WHH) that day, to apprise him of the situation. Dr. Akintan initially thought we could admit the patient to the hospital and keep the Foley catheter indwelling, eventually obtain x-ray studies and possibly the perforation would close spontaneously. I explained that since electro surgery caused the perforation, I wanted to be more aggressive and out of an abundance of caution close the injury immediately. I directly admitted the patient to WHH through the emergency room. The incident occurred at approximately 3:45 p.m.

The repair surgery began at approximately 5:35 p.m. Dr. Akintan opened the bladder with a vertical abdominal incision and noted a laceration of around 3.5 cm in the posterior portion. We inspected intraperitoneal and found no blood or injury. We closed the patient and sutured the opening he had created anteriorly extra-peritoneally. The patient's urine cleared soon after surgery and she was discharged within 24 hours with a Foley catheter to remain in place for approximately a week.

Both Dr. Akintan, at the Bond Clinic, and I followed the patient. By April 30, 2007 appeared to be doing well. The patient had Monsel's paste placed on the cervical bed. She had been discharged on Cipro 500 mg b.i.d. for a five day course at home.

The patient was then seen by Dr. Akintan on May 3, 2007 and her Foley catheter was removed. I saw her the afternoon of May 3, 2007, and she was voiding without difficulty or discomfort. I gently placed Premarin cream along the cervical bed, and she will continue to apply it at home at bedtime.

Sincerely,

Robert A. Rombola, M.D.

RAR/rew

STATE OF FLORIDA
Jeb Bush, Governor

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

SUBMIT FORM TO:
Department of Health, Consumer Services Unit
4052 Bald Cypress Way, Bin C75
Tallahassee, Florida 32399-3275

07 APR 16 PM 3:51
RECEIVED
CONSUMER SERVICES UNIT

?

I. OFFICE INFORMATION

Bay Area Renal Stone Center
Name of office

6002 49th St.North
Street Address

St. Petersburg 33709 Pinellas
City Zip Code County

727-521-3929
Telephone

Name of Physician or Licensee Reporting

#473
License Number & office registration number, if applicable

Patient's address for Physician or Licensee Reporting

II. PATIENT INFORMATION

Pati
Pati
Patient Identification Number
Diagnosis

Age Gender Medicaid Medicare
04/09/07

Purpose of Office Visit
997.1, 786.51, 427.9
ICD-9 Code for description of incident
111
Level of Surgery (II) or (III)

III. INCIDENT INFORMATION

04/09/07 10:30 am
Incident Date and Time

Location of Incident:
■ Operating Rm ☐ Recovery Rm
☐ Other________

Note: If the incident involved a death, was the medical examiner notified? ☐ Yes ☐ No
Was an autopsy performed? ☐ Yes ☐ No

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete response)

Patient scheduled for cystoscopy, possible ureterescopy, left ureteral shock wave lithotripsy ("SWL"), possible right renal SWL. Patient had bilateral retrogrades only. The [redacted] Patient transferred to PACU with Nitropaste intact, awakes to voice, and denies pain. EKG is irregular but no longer elevated ST. Within five minutes EKG is normal. Nitropaste is removed. Patient awakes within five minutes clutching chest and complaining of chest pain. Nitropaste 1" is applied. Within three minutes patient denies pain and nitropaste is removed. Patient was at the facility more than 40 minutes without additional problems. Patient was transferred to Northside Hospital via stretcher accompanied by Mary Gallant-Roman, RN, and Dr. Paul Knox, Anesthesiologist.

Form # DH-MQA1030- created 2-00; revised 3-24-03

B) ICD-9-CM Codes

592.1		997.1 post-oparrythmia 786.51 chest pain 427.9 arrythmia
Surgical, diagnostic, or treatment procedure being performed at time of incident (ICD-9 Codes 01-99.9)	Accident, event, circumstances, or specific agent that caused the injury or event. (ICD-9 E-Codes)	Resulting injury (ICD-9 Codes 800-999.9)

C) List any equipment used if directly involved in the incident
(Use additional sheets as necessary for complete response)

D) Outcome of incident (Please check)

☐ Death	☐ Surgical procedure performed on the wrong site **
☐ Brain Damage	☐ Wrong surgical procedure performed **
☐ Spinal Damage	☐ Surgical repair of injuries or damage from a planned surgical procedure
☐ Surgical procedure performed on the wrong patient	** If it resulted in
☐ A procedure to remove unplanned foreign objects remaining from surgical procedure	☐ Death ☐ Brain Damage ☐ Spinal Damage ☐ Permanent disfigurement not to include the incision scar
☒ Any condition that required the transfer outcome of the patient to a licensed hospital	☐ Fracture or dislocation of bones or joints ☐ Limitation of neurological, physical, or sensory function; ☐ Any condition that required the transfer outcome of the patient
Outcome of transfer – e.g., death, brain damage, observation only observation only Name of facility to which patient was transferred Northside Hospital	

E) List all persons, including license numbers if licensed, locating information, and the capacity in which they were directly involved with this incident.

Bruce Senay, MD (Urologist)
Paul Knox, MD (anesthesiologist)

F) List witnesses, including license numbers if licensed, and locating information if not listed above

Betsy Givens-Jackson, RN
Anna Brunelle, RN

IV. ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response)

transient ST elevation with sinus arrythmia and complaints of chest pain

B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

patient sent to Northside Hospital emergency room for workup

V. ME 56812

SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT — LICENSE NUMBER

DATE REPORT COMPLETED — TIME REPORT COMPLETED

Form # DH-MQA1030- created 2-00; revised 3-24-03

Endovascular vein closure
Sclero foam

Infection 2days p̄-op
admitted for Abx Tx

STATE OF FLORIDA
Jeb Bush, Governor

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

#143

SUBMIT FORM TO:
Department of Health, Consumer Services Unit
4052 Bald Cypress Way, Bin C75
Tallahassee, Florida 32399-3275

I. OFFICE INFORMATION

South Florida Vascular Associates
Name of office

2825 N. State Rd 7 Suite 303
Street Address

Margate 33063 Broward
City Zip Code County

954-975-6161
Telephone

William Julien MD
Name of Physician or Licensee Reporting

ME 59991/OSR 511
License Number & office registration number, if applicable

Patient's address for Physician or Licensee Reporting

II. PATIENT INFORMATION

Patient Name
Patient's Address
Patient Identification

Age Gender Medicaid Medicare

1-15-2007
Date of Office Visit

EVLT of (L) GSV
Purpose of Office Visit

Diagnosis Venous insufficiency Left leg

ICD-9 Code for description of incident

Level of Surgery (II) or (III)

III. INCIDENT INFORMATION

1/17/2007
Incident Date and Time

Location of Incident:
☐ Operating Rm ☐ Recovery Rm
☐ Other

Note: If the incident involved a death, was the medical examiner notified? ☐ Yes ☐ No
Was an autopsy performed? ☐ Yes ☐ No

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete response)

On 1/15/2007 underwent endovenous laser treatment and foam sclerotherapy left leg. Pt developed fever and chills on 1/17/2007. was instructed to go to the hospital for admission to assess cause of fever. During admission pt was afebrile. Blood and urine cultures were negative. Initially the WBC's were elevated but normalized within 24 hours with antibiotics. Pt was discharged within 48 hours and sent home on oral antibiotics.

Form # DH-MQA1030- created 2-00; revised 3-24-03

B) ICD-9-CM Codes

Surgical, diagnostic, or treatment procedure being performed at time of incident (ICD-9 Codes 01-99.9)	Accident, event, circumstances, or specific agent that caused the injury or event. (ICD-9 E-Codes)	Resulting injury (ICD-9 Codes 800-999.9)

C) List any equipment used if directly involved in the incident

(Use additional sheets as necessary for complete response)

D) Outcome of Incident (Please check)

- ☐ Death
- ☐ Brain Damage
- ☐ Spinal Damage
- ☐ Surgical procedure performed on the wrong patient
- ☐ A procedure to remove unplanned foreign objects remaining from surgical procedure
- ☐ Any condition that required the transfer outcome of the patient to a licensed hospital

Outcome of transfer – e.g., death, brain damage, observation only ____________

Name of facility to which patient was transferred Northwest Medical Center

- ☐ Surgical procedure performed on the wrong site **
- ☐ Wrong surgical procedure performed **
- ☐ Surgical repair of injuries or damage from a planned surgical procedure

** If it resulted in

- ☐ Death
- ☐ Brain Damage
- ☐ Spinal Damage
- ☐ Permanent disfigurement not to include the incision scar
- ☐ Fracture or dislocation of bones or joints
- ☐ Limitation of neurological, physical, or sensory function;
- ☐ Any condition that required the transfer outcome of the patient

E) List all persons, including license numbers if licensed, locating information, and the capacity in which they were directly involved with this incident.

Debra Andersen RN 78634-2

F) List witnesses, including license numbers if licensed, and locating information if not listed above

IV. ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response)

Will review sterile procedures for peri room ' unsure why [redacted] had fever but suspect transient bacteremia

B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

1) Review sterile technique
2) Begin terminal cleaning in peri room as well as endovascular suites (already being done in endovascular suite)

V.

[signature] — SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT

BJ 4043838 — LICENSE NUMBER

2-2-2007 — DATE REPORT COMPLETED

11:30Am — TIME REPORT COMPLETED

Form # DH-MQA1030- created 2-00; revised 3-24-03

3/7/07 (#3)

#1

#32

STATE OF FLORIDA
Jeb Bush, Governor

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

SUBMIT FORM TO:
Department of Health, Consumer Services Unit
052 Bald Cypress Way, Bin C75
Tallahassee, Florida 32399-3275

RECEIVED CONSUMER SERVICES UNIT 07 MAR 26 AM 7:55

I. OFFICE INFORMATION

MIAMI VEIN CENTER
Name of office

1501 SOUTH MIAMI A
Street Address

MIAMI 33129 Dade
City Zip Code County

305. 854. 1555
Telephone

JOSE I. ALMEIDA, MD
Name of Physician or Licensee Reporting

ME69886 OSR 517
License Number & office registration number, if applicable

Patient's address for Physician or Licensee Reporting

II. PATIENT INFORMATION

Patient Identification Number

Diagnosis

Age 3/7/07 Gender Medicaid Medicare

Purpose of Office Visit

ICD-9 Code for description of incident

II
Level of Surgery (II) or (III)

III. INCIDENT INFORMATION

3/7/07 4PM
Incident Date and Time

Location of Incident:
☒ Operating Rm ☐ Recovery Rm
☐ Other

Note: If the incident involved a death, was the medical examiner notified? ☐ Yes ☐ No
Was an autopsy performed? ☐ Yes ☐ No

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete response)

Surgery requiring ultrasound-guided sclerotherapy of varicose veins, resulted in allergic reaction. The patient developed [redacted] - was successfully resuscitated with Solu-Cortef and Epinephrine.
Patient sent to Coral Gables Hospital - was discharged home same day after treated in E.R.

Form # DH-MQA1030- created 2-00; revised 3-24-03

B) ICD-9-CM Codes

Surgical, diagnostic, or treatment procedure being performed at time of incident (ICD-9 Codes 01-99.9)	Accident, event, circumstances, or specific agent that caused the injury or event. (ICD-9 E-Codes)	Resulting Injury (ICD-9 Codes 800-999.9)
	Sotradecol	[redacted]

C) List any equipment used if directly involved in the incident
(Use additional sheets as necessary for complete response)

D) Outcome of Incident (Please check)

☐ Death	☐ Surgical procedure performed on the wrong site **
☐ Brain Damage	☐ Wrong surgical procedure performed **
☐ Spinal Damage	☐ Surgical repair of injuries or damage from a planned surgical procedure
☐ Surgical procedure performed on the wrong patient	** If it resulted in
☐ A procedure to remove unplanned foreign objects remaining from surgical procedure	☐ Death ☐ Brain Damage ☐ Spinal Damage ☐ Permanent disfigurement not to include the incision scar
☑ Any condition that required the transfer outcome of the patient to a licensed hospital	☐ Fracture or dislocation of bones or joints ☐ Limitation of neurological, physical, or sensory function; ☐ Any condition that required the transfer outcome of the patient
Outcome of transfer – e.g., death, brain damage, (observation only) Name of facility to which patient was transferred Coral Gables Hosp.	

E) List all persons, including license numbers if licensed, locating information, and the capacity in which they were directly involved with this incident.

Jennifer Fonino, M.A.
Gus Oliva, LPN.

F) List witnesses, including license numbers if licensed, and locating information if not listed above

IV. ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent causes) of this incident (Use additional sheets as necessary for complete response)

Allergic reaction to Sotradecol.

B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

Solucortef 240 mg IV
Epinephrine pen 0.3 g SQ
Oxygen

V. [signature]
SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT

ME69886
LICENSE NUMBER

3/21/07
DATE REPORT COMPLETED

1pm
TIME REPORT COMPLETED

Form # DH-MQA1030- created 2-00; revised 3-24-03

3/5/07. (#1)

STATE OF FLORIDA
Jeb Bush, Governor

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

SUBMIT FORM TO:
Department of Health, Consumer Services Unit
4052 Bald Cypress Way, Bin C75
Tallahassee, Florida 32399-3275

RECEIVED CONSUMER SERVICES UNIT 07 APR 19 AM 9:59

#144

I. OFFICE INFORMATION

Name of office: Strax Rejuvenation & Aesthetics Institute

Street Address: 4300 N. University Drive, Suite A202

City: Lauderhill — Zip Code: 33351 — County: Broward

Telephone: 954-749-3040

Name of Physician or Licensee Reporting: John E. Nees, M.D.

License Number & office registration number, if applicable: ME36792

Patient's address for Physician or Licensee Reporting:

II. PATIENT INFORMATION

Age — Gender — Medicaid — Medicare

Date of Office Visit: March 5, 2007

Purpose of Office Visit:

Identification Number:

Diagnosis:

ICD-9 Code for description of incident: E879.9

Level of Surgery (II) or (III): local anesthesia

III. INCIDENT INFORMATION

Incident Date and Time: March 5, 2007, 7:30 pm

Location of Incident:
☐ Operating Rm ☐ Recovery Rm
☒ Other bathroom

Note: If the incident involved a death, was the medical examiner notified? ☐ Yes ☐ No
Was an autopsy performed? ☐ Yes ☐ No

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete response)

This ███ year old ███ in excellent health with no known medical conditions, had 2 face and neck threadlifts by another surgeon on 09-03-05 and 10-19-05. Since ███ no significant improvement in facial contour, I agreed to perform a minifacelift and partial thread removal on 03-05-07. At the end of the procedure, ███ developed a right cheek hematoma which was treated effectively with evacuation, cautery, drainage and compression. ███ was taken to the bathroom before discharge where ███ felt faint. ███ was placed in a supine position and given oxygen and IV fluids. ███ was briefly hypotensive. The paramedics were called but ███ regained normal vital signs and mental status before they arrived. Due to ███ age and concerns about potential health problems, ███ was encouraged to accept transport to Florida Medical Center for evaluation. ███ had normal vital signs and a hgb/hct of 15.0/44.0 compared with 16.6/48.2 preoperatively. At FMC ███ vital signs were normal, no health concerns were found, and ███ was released from the emergency room. Followup evaluation in our clinic demonstrate continued normal health.

B) ICD-9-CM Codes

701.8	E879.9	None
Surgical, diagnostic, or treatment procedure being performed at time of incident (ICD-9 Codes 01-99.9)	Accident, event, circumstances, or specific agent that caused the injury or event. (ICD-9 E-Codes)	Resulting injury (ICD-9 Codes 800-999.9)

C) List any equipment used if directly involved in the incident
(Use additional sheets as necessary for complete response)

D) Outcome of incident (Please check)

- ☐ Death
- ☐ Brain Damage
- ☐ Spinal Damage
- ☐ Surgical procedure performed on the wrong patient
- ☐ A procedure to remove unplanned foreign objects remaining from surgical procedure
- ☒ Any condition that required the transfer outcome of the patient to a licensed hospital

Outcome of transfer – e.g., death, brain damage, observation only: observation only

Name of facility to which patient was transferred: Florida Medical Center

- ☐ Surgical procedure performed on the wrong site **
- ☐ Wrong surgical procedure performed **
- ☐ Surgical repair of injuries or damage from a planned surgical procedure

** If it resulted in

- ☐ Death
- ☐ Brain Damage
- ☐ Spinal Damage
- ☐ Permanent disfigurement not to include the incision scar
- ☐ Fracture or dislocation of bones or joints
- ☐ Limitation of neurological, physical, or sensory function;
- ☐ Any condition that required the transfer outcome of the patient

E) List all persons, including license numbers if licensed, locating information, and the capacity in which they were directly involved with this incident.

John E. Nees, M.D. ME36792

F) List witnesses, including license numbers if licensed, and locating information if not listed above

Margory Retamar, surgical technician

Christina Aragones, surgical technician

IV. ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response)

This patient appears to have had a [redacted] after assuming a standing position after surgery.

B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

[redacted] was treated with oxygen, IV fluids, and appropriate monitoring. The paramedics were called immediately due to concerns about a possible cardiovascular or cerebrovascular incident.

V. [signature] ME36792

SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT — LICENSE NUMBER

APRIL 10 2007

DATE REPORT COMPLETED — TIME REPORT COMPLETED

Form # DH-MQA1030- created 2-00; revised 3-24-03

-3/6/07 (#2)

STATE OF FLORIDA
Jeb Bush, Governor

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

#145

SUBMIT FORM TO:
Department of Health, Consumer Services Unit
4052 Bald Cypress Way, Bin C75
Tallahassee, Florida 32399-3275

I. OFFICE INFORMATION

Sarasota [redacted]
Name of office

600 North Cattlemen Rd
Street Address

Sarasota 34232 Sarasota
City Zip Code County

941-378-3231
Telephone

Gerald E. Grubbs
Name of Physician or Licensee Reporting

License Number & office registration number, if applicable

Patient's address for Physician or Licensee Reporting

II. PATIENT INFORMATION

Pati[redacted]

Pati[redacted]

Patient Identification Number [redacted]

Diagnosis

Age Gender Medicaid Medicare

3/6/7
Date of Office Vi[redacted]

Purpose of Office Visit

ICD-9 Code for description of incident

II
Level of Surgery (II) or (III)

III. INCIDENT INFORMATION

3/6/7 16:20
Incident Date and Time

Location of Incident:
☐ Operating Rm ☒ Recovery Rm
☐ Other__________

Note: If the incident involved a death, was the medical examiner notified? ☐ Yes ☐ No
Was an autopsy performed? ☐ Yes ☐ No

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete response)

After declot Fistula procedure Pt brought to PACU and observed HR↑ to 120 and Sat↓ 90% from 100%. Pt ↑ short of breath and wheezes + tachycardia Not stable to return to nursing home possible [redacted] 911 called tranfered to Dr. Hospital via EMS

1 of 2 pages
Form # DH-MQA1030- created 2-00; revised 3-24-03

B) ICD-9-CM Codes

Fistula declot		
Surgical, diagnostic, or treatment procedure being performed at time of incident (ICD-9 Codes 01-99.9)	Accident, event, circumstances, or specific agent that caused the injury or event. (ICD-9 E-Codes)	*Resulting injury* (ICD-9 Codes 800-999.9)

C) List any equipment used if directly involved in the incident
(Use additional sheets as necessary for complete response)

D) Outcome of Incident (Please check)

☐ Death	☐ Surgical procedure performed on the wrong site **
☐ Brain Damage	☐ *Wrong surgical procedure performed* **
☐ Spinal Damage	☐ Surgical repair of injuries or damage from a planned surgical procedure
☐ Surgical procedure performed on the wrong patient	** If it resulted in
☐ A procedure to remove unplanned foreign objects remaining from surgical procedure	☐ Death ☐ Brain Damage ☐ Spinal Damage
☑ Any condition that required the transfer outcome of the patient to a licensed hospital	☐ Permanent disfigurement not to include the incision scar
Outcome of transfer – e.g., death, brain damage, observation only ICU observation/treatment Name of facility to which patient was transferred Doctors Hospital	☐ Fracture or dislocation of bones or joints ☐ Limitation of neurological, physical, or sensory function; ☐ Any condition that required the transfer outcome of the patient

E) List all persons, including license numbers if licensed, locating information, and the capacity in which they were directly involved with this incident.

Kathleen Warner RN pre/post Nurse
Dr. Shagrin ME 89863
Dr. Grubbs ME 63973

F) List witnesses, including license numbers if licensed, and locating information if not listed above

Amy Sherry RN
Chris Howes RT

IV. ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response) anesthesia?

see attached note per Dr. Shagrin
see attached note per Dr. Grubbs

B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

transferred to Doctors Hospital

V. [signature] ME63973

SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT **LICENSE NUMBER**

3/6/17 1700

DATE REPORT COMPLETED **TIME REPORT COMPLETED**

Form # DH-MQA1030- created 2-00; revised 3-24-03

600 North Cattlemen Road
Suite 100 - Axcess Center
Sarasota, FL 34232-6410

941-378-3231
941-378-3253 Fax
www.sivr.net

SARASOTA
INTERVENTIONAL
RADIOLOGY
Immediate answers to critical questions.

GERALD D. GRUBBS, MD
Diplomate, American Board of Radiology
Fellowship, Cardiovascular and Interventional Radiology

PATIENT: ███
EXAM DATE: 03/06/2007
PATIENT #: ███
DATE OF BIRTH: ███
PHYSICIAN: David Showalter, M.D.

EXAMINATION: PROCEDURE NOTE

EXAM LOCATION: SARASOTA INTERVENTIONAL RADIOLOGY

FINDINGS: For approximately 10 to 15 minutes after the patient was in the recovery unit, ███ was in stable condition. However, after that period of time, the patient's heart rate increased to 120 and after having normal sats of 100% on 2 liters of oxygen by nasal cannula, the sats decreased into the 90's. The patient also had some wheezing and tachycardia and ███ lung sounds were wet to the recovery anesthesiologist. Decision was made to notify 911 and have the patient emergently transferred to a hospital for evaluation of ███ cardiac status.

Thank you again for your allowing us to participate in the care of this very pleasant patient here at Sarasota Interventional Radiology.

THIS REPORT WAS ELECTRONICALLY SIGNED
███
███

Director of Radiology, AxcessDx

GEG/ly/6580025
D: 03/12/2007 T: 03/13/2007

Not a procedure

STATE OF FLORIDA
Jeb Bush, Governor

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

SUBMIT FORM TO:
Department of Health, Consumer Services Unit
4052 Bald Cypress Way, Bin C75
Tallahassee, Florida 32399-3275

I. OFFICE INFORMATION

South Florida Vascular Associates
Name of office

2825 North State Road 7
Street Address

Margate 33063 Broward
City Zip Code County

954-975-6161
Telephone

DR William Julien
Name of Physician or Licensee Reporting

ME 59991 / OSR 511
License Number & office registration number, if applicable

Patient's address for Physician or Licensee Reporting

II. PATIENT INFORMATION

Pa[redacted]
Pa[redacted]
Patient Identification Number

Age [redacted]

1/23/2007
Date of Office Visit

left arm fistulogram
Purpose of Office Visit

End stage renal disease
Diagnosis

ICD-9 Code for description of incident

Level of Surgery (II) or (III)

III. INCIDENT INFORMATION

1/23/07 1030am
Incident Date and Time

Location of Incident:
☒ Operating Rm ☐ Recovery Rm
☐ Other__________

Note: If the incident involved a death, was the medical examiner notified? ☐ Yes ☐ No N/A
Was an autopsy performed? ☐ Yes ☐ No N/A

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete response)

Patient complained on admit to pre op of "not feeling well since defibrillator placed." Patient also complained of "being tired all the time" Patient unable to provide further details. Temp, blood pressure and heart rate noted. Heart rate 112. Upon monitoring patient supine, during left arm fistulogram patient noted to have pulse ox fluctuating 87-92% on room air. Upon scanning (fluoroscopy) patient's lungs Dr Julien discovered Right lung to be 3/4 filled with fluid. Dr Julien then spoke with patient's physician Dr Martin who sent instruction for patient to be taken by [redacted] to Florida Medical Ctr upon discharge. During hospitalization 1 month before Pt required R chest tube for large R effusion and obviously it was reaccumulated. See 1-23-07 OP Note.

J Julien

Form # DH-MQA1030- created 2-00; revised 3-24-03

B) ICD-9-CM Codes

Left arm fistulogram	N/A	N/A
Surgical, diagnostic, or treatment procedure being performed at time of incident **(ICD-9 Codes 01-99.9)**	Accident, event, circumstances, or specific agent that caused the injury or event. **(ICD-9 E-Codes)**	Resulting injury **(ICD-9 Codes 800-999.9)**

C) List any equipment used if directly involved in the incident
(Use additional sheets as necessary for complete response)

N/A

D) Outcome of Incident (Please check)

☐ Death	☐ Surgical procedure performed on the wrong site **
☐ Brain Damage	☐ Wrong surgical procedure performed **
☐ Spinal Damage	☐ Surgical repair of injuries or damage from a planned surgical procedure
☐ Surgical procedure performed on the wrong patient	** If it resulted in
☐ A procedure to remove unplanned foreign objects remaining from surgical procedure	☐ Death ☐ Brain Damage
☐ Any condition that required the transfer outcome of the patient to a licensed hospital	☐ Spinal Damage ☐ Permanent disfigurement not to include the incision scar
Outcome of transfer – e.g., death, brain damage, observation only ____ Name of facility to which patient was transferred ____	☐ Fracture or dislocation of bones or joints ☐ Limitation of neurological, physical, or sensory function; ☐ Any condition that required the transfer outcome of the patient

E) List all persons, including license numbers if licensed, locating information, and the capacity in which they were directly involved with this incident.

DR William Julien ~ endovascular surgery
LaVaughn Thomas RN ~ circulator
Ingrid Berry RT ~ scrub technologist

F) List witnesses, including license numbers if licensed, and locating information if not listed above

DR Julien ~ OR
Ingrid Berry ~ OR

IV. ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response)

Patient's physician notified - DR Martin of findings

B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

DR Julien spoke with patient's physician DR Martin. Patient instructed to go to Florida Medical Center (driven by [redacted]) upon discharge. We will continue our assessments of patients and follow through.

V. [signature] — ME 59991

SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT — **LICENSE NUMBER**

1/29/2007 — 1115

DATE REPORT COMPLETED — **TIME REPORT COMPLETED**

Form # DH-MQA1030- created 2-00; revised 3-24-03

2825 North State Road 7, Suite 205 • Margate, Fl 33063
Office: (954) 975-4161 • Fax: (954) 975-7651

IN OFFICE ENDOVASCULAR OPERATIVE NOTE

01/23/2007

RE: ████
MED REC#: ████

PROCEDURE: Left arm dialysis fistulogram with endovascular revision.

SURGEON: William Julien, M.D.

BLOOD LOSS: None.

ANESTHESIA: Local.

PREOPERATIVE DIAGNOSIS: Left arm swelling.

POSTOPERATIVE DIAGNOSIS: Central left stenosis as well as large right effusion.

HISTORY: This is a ██-year-old ████ who has a left upper arm dialysis fistula and ██ is here today because ██ has significant swelling of ██ arm. A few weeks ago ██ had a left-side defibrillator placed and subsequent to that has developed some swelling of the arm. On further questioning, ██ says ██ has been somewhat short of breath lately and does not feel particularly well. ██ also says that there were attempts at placing the pacemaker from the right side, but this was unsuccessful, and that ██ also had a right-sided chest tube during ██ hospitalization, which was around Christmastime in 2006. ██ says that in several days Dr. Matt Carr is planning on performing electrophysiologic ablation of pathways in the heart because they are overriding the pacemaker/defibrillator.

DESCRIPTION OF PROCEDURE: After obtaining informed consent, the patient was placed supine on a fluoroscopic table and the left upper arm prepped and draped in sterile fashion. Following local anesthesia, the left arm dialysis fistula was punctured in an antegrade direction using a 21-guage needle. Using Seldinger technique, a 0.018 guidewire was advanced centrally followed by a 4 French coaxial exchange dilator. The initial pressure in the fistula measured 57 mmHg. Fistulogram and central venogram was performed. A 7 French sheath was placed and then 12 mm balloon angioplasty performed at the basilic axillary vein junction and also the medial subclavian and lateral portion of the innominate vein. A modest waste was noted in all of these areas and easily ablated. Final fistulogram and central venograms were performed. The final pressure in the axis measured 47 mmHg. The patient tolerated the procedure well. The catheters were

removed and pressure was placed to the puncture site. Note should be made that the patient's oxygen saturation was between 84 and 92% throughout, prior during and after the procedure. ███ did have some mild respiratory distress.

INTERPRETATION: There is a left arm brachiobasilic fistula which has an approximately 60% stenosis of the basilic-axillary vein junction. Note is made of a new defibrillator approaching from a right to left subclavian approach. At what appears to be the entry site of the defibrillator, the subclavian vein is unremarkable in appearance, but in the medial subclavian vein there is a focal 60% stenosis and another 60% stenosis in the lateral aspect of the innominate vein. The more central innominate vein and superior vena cava are widely patent. Final images demonstrate wide patency of the above-noted areas of narrowing. Incidental note is made of a large right-sided effusion which occupies at least two-thirds of the right hemithorax. Note is also made that the patient has several stents extending from the right subclavian and out the right axillary vein, which would certainly be problematic during any attempt at trying to access the right subclavian vein from a percutaneous approach.

IMPRESSION:

1. Incidental note is made of a very large right-sided pleural effusion occupying perhaps two-thirds of the pleural space.
2. Left arm fistulogram demonstrates several modest areas of narrowing at the basilic axillary vein junction, medial subclavian vein and the left innominate vein, which would potentially account for left arm swelling and was treated with balloon angioplasty with good result. Incidental note is also made of a new left-side defibrillator/pacemaker.

DISPOSITION: Because of the patient's respiratory distress and overall poor feeling and the fluoroscopic identification of a previously undiagnosed very large right pleural effusion, the patient will be sent to the Florida Medical Center Emergency Room where a likely admission period. The case was discussed with Dr. Ed Martin, who is a nephrologist, at the time of the study, who concurred. I also briefly thereafter spoke to Dr. Todd Schwartz at Florida Medical Center, the Emergency Room physician on call, as well as Dr. Matt Carr, so that they would be aware of ███ arrival. The case was discussed with both the patient and ███

THIS IS AN UNSIGNED REPORT
William H Julien, MD
Endovascular Surgery
Board Certified in Interventional Radiology

WHJ/rs

cc: Edouard Martin, MD
Kelly Grillo, MD

Not a procedure

STATE OF FLORIDA
~~Jeb Bush~~, Governor
C CRIST

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

SUBMIT FORM TO:
Department of Health, Consumer Services Unit
4052 Bald Cypress Way, Bin C75
Tallahassee, Florida 32399-3275

I. OFFICE INFORMATION

FCI
Name of office

7154 Medical Center Dr
Street Address

Spring Hill 34608 Hernando
City Zip Code County

352 596 1926
Telephone

Monique Errick
Name of Physician or Licensee Reporting

License Number & office registration number, if applicable

Patient's address for Physician or Licensee Reporting

II. PATIENT INFORMATION

Age ☐ Gender ☐ Medicaid ☐ Medicare

1/30/07
Date of Office Visit

Office visit
Purpose of Office Visit

Patient Identification Number

metastatic pancreatic Ca.
Diagnosis

ICD-9 Code for description of incident

Level of Surgery (II) or (III)

III. INCIDENT INFORMATION

1/30/07 1030 AM
Incident Date and Time

Location of Incident:
☐ Operating Rm ☐ Recovery Rm
☑ Other Treatment RM

Note: If the incident involved a death, was the medical examiner notified? ☐ Yes ☐ No
Was an autopsy performed? ☐ Yes ☐ No

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete response)

Pt arrived ambulatory and stable, VSS. Labwork drawn from infusaport using proper technique port flushed + stabilized. When charting finished and ready to take pt to office rsd pt was non responsive. No neuro motor activity in Extremities Eyes fixed + staring into space. Pt emediately layed down feet elevated NS 1000 cc infused for hydration and try to ↑ BP. VSS unpalpable 911 called Dr Tang present.

1 of 2 pages
Form # DH-MQA1030- created 2-00; revised 3-24-03

B) ICD-9-CM Codes

Pt sitting in chair alone	(NONE)	
Surgical, diagnostic, or treatment procedure being performed at time of incident (ICD-9 Codes 01-99.9)	Accident, event, circumstances, or specific agent that caused the injury or event. (ICD-9 E-Codes)	Resulting injury (ICD-9 Codes 800-999.9)

C) **List any equipment used if directly involved in the incident**
(Use additional sheets as necessary for complete response)

D) **Outcome of Incident** (Please check)

- ☐ Death
- ☐ Brain Damage
- ☐ Spinal Damage
- ☐ Surgical procedure performed on the wrong patient
- ☐ A procedure to remove unplanned foreign objects remaining from surgical procedure
- ☑ Any condition that required the transfer outcome of the patient to a licensed hospital

Outcome of transfer – e.g., death, brain damage, observation only ______
Name of facility to which patient was transferred ______

- ☐ Surgical procedure performed on the wrong site **
- ☐ Wrong surgical procedure performed **
- ☐ Surgical repair of injuries or damage from a planned surgical procedure

** if it resulted in

- ☐ Death
- ☐ Brain Damage
- ☐ Spinal Damage
- ☐ Permanent disfigurement not to include the incision scar
- ☐ Fracture or dislocation of bones or joints
- ☐ Limitation of neurological, physical, or sensory function;
- ☐ Any condition that required the transfer outcome of the patient

E) **List all persons, including license numbers if licensed, locating information, and the capacity in which they were directly involved with this incident.**

Monique Errick BNBSN RN 2618442
Lisa DiLascio RN
Dr Tang ME 87938

F) **List witnesses, including license numbers if licensed, and locating information if not listed above**

Same as above.

IV. ANALYSIS AND CORRECTIVE ACTION

A) **Analysis** (apparent cause) **of this incident** (Use additional sheets as necessary for complete response)

911, lay pt in trendelenburg position, Initiate IV fluids to help ↑ BP. low BP d/t possible ICVA

B) **Describe corrective or proactive action(s) taken** (Use additional sheets as necessary for complete response)

911, IV fluids started, trendelenburg position.

V. Monique Errick BNBSN
SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT — LICENSE NUMBER

1/30/07 — 5pm
DATE REPORT COMPLETED — TIME REPORT COMPLETED

Form # DH-MQA1030- created 2-00; revised 3-24-03

2007

Contrast rxn

Not a procedure

STATE OF FLORIDA
Jeb Bush, Governor

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

SUBMIT FORM TO:
Agency for Health Care Administration,
Consumer Services Unit, Post Office Box 14000,
Tallahassee, Florida 32317-4000

I. OFFICE INFORMATION

Southeastern Urological Center
Name of office

2000 Centre Pointe Blvd
Street Address

Tallahassee 32308 Leon
City Zip Code County

850-309-0400
Telephone

Joseph L. Camps MD
Name of Physician or Licensee Reporting

ME 0057214
License Number & office registration number, if applicable

Same as above
Patient's address for Physician or Licensee Reporting

II. PATIENT INFORMATION

Patient Identification Number

Age Gender Medicaid Medicare

1-17-07
Date of Office Visit

CT Hematuriagram
Purpose of Office Visit

microscopic hematuria
Diagnosis

NA
ICD-9 Code for description of incident

NA
Level of Surgery (II) or (III)

III. INCIDENT INFORMATION

1-17-07 @ 2^25 pm
Incident Date and Time

Location of Incident:
☐ Operating Rm ☐ Recovery Rm
☑ Other Physician office

Note: If the incident involved a death, was the medical examiner notified? ☐ Yes ☐ No
Was an autopsy performed? ☐ Yes ☐ No

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete response)

Patient for CT Hematuriagram requiring Contrast media. At completion of exam patient's face is noted to be red and swollen with no shortness of breath or other symptoms. Dr. Camps called, O2 per mask administered, IV fluids hung through existing IV access, and medications administered including Benadryl, epinephrine and Solu cortef. O2 sat @ 95% and vital signs stabilized. EMS notified and transported to TMH and left AMA as [redacted] felt much better after [redacted] arrival.

Form # DH-MQA1030- created 2-00; revised 9-6-01

B) ICD-9-CM Codes

NA	NA	NA
Surgical, diagnostic, or treatment procedure being performed at time of incident (ICD-9 Codes 01-99.9)	Accident, event, circumstances, or specific agent that caused the injury or event. (ICD-9 E-Codes)	Resulting injury (ICD-9 Codes 800-999.9)

C) **List any equipment used if directly involved in the incident**
(Use additional sheets as necessary for complete response)

D) **Outcome of Incident** (Please check)

- ☐ Death
- ☐ Brain Damage
- ☐ Spinal Damage
- ☐ Surgical procedure performed on the wrong patient
- ☐ A procedure to remove unplanned foreign objects remaining from surgical procedure
- ☒ Any condition that required the transfer outcome of the patient to a licensed hospital

Outcome of transfer – e.g., death, brain damage, observation only ______
Name of facility to which patient was transferred TMH

- ☐ Surgical procedure performed on the wrong site **
- ☐ Wrong surgical procedure performed **
- ☐ Surgical repair of injuries or damage from a planned surgical procedure

** if it resulted in

- ☐ Death
- ☐ Brain Damage
- ☐ Spinal Damage
- ☐ Permanent disfigurement not to include the incision scar
- ☐ Fracture or dislocation of bones or joints
- ☐ Limitation of neurological, physical, or sensory function;
- ☐ Any condition that required the transfer outcome of the patient

E) List all persons, including license numbers if licensed, locating information, and the capacity in which they were directly involved with this incident.

Mary Ford RN RN2020262 RN assisting in treatment
Joseph L Compo MD ME 0057214 Physician directing treatment
Pat Lazenby RT CRT 28725 Radiology Technologist performing study
Susan Burdick LPN PN1210441 nurse recording treatment

F) List witnesses, including license numbers if licensed, and locating information if not listed above

IV. ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response)

Treatment provided patient was timely and efficient and patient was much improved prior to transport.

B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

Allergy noted in patient's medical record.

V. [signature] RN — RN 915912
SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT — LICENSE NUMBER

1-19-07 — 1900
DATE REPORT COMPLETED — TIME REPORT COMPLETED

Form # DH-MQA1030- created 2-00; revised 9-6-01

STATE OF FLORIDA
Jeb Bush, Governor

Chemo rxn.
Not a procedure

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

SUBMIT FORM TO:
Department of Health, Consumer Services Unit
4052 Bald Cypress Way, Bin C75
Tallahassee, Florida 32399-3275

I. OFFICE INFORMATION

Space Coast Medical Associates
Name of office

850 Century Medical Dr
Street Address

Titusville 32796 Brevard
City Zip Code County

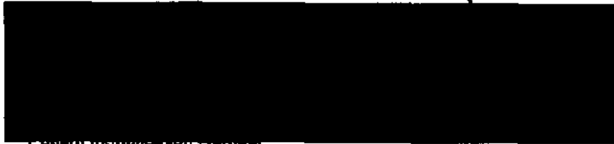
(321) 268-4200
Telephone

Ashish Dalal, MD
Name of Physician or Licensee Reporting

ME 0055152
License Number & office registration number, if applicable

see below
Patient's address for Physician or Licensee Reporting

II. PATIENT INFORMATION



Age Gender Medicaid Medicare

Date of Office Visit 1/24/07

Purpose of Office Visit Chemo tx

Lung CA
Diagnosis

ICD-9 Code for description of Incident V58.1

Level of Surgery (II) or (III)

III. INCIDENT INFORMATION

1/24/07 1315
Incident Date and Time

Location of Incident:
☐ Operating Rm ☐ Recovery Rm
☐ Other

Note: If the incident involved a death, was the medical examiner notified? ☐ Yes ☐ No
Was an autopsy performed? ☐ Yes ☐ No

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete response)

Pt in infusion center for Taxol/Carbo Tx at 1315 pt c/o SOB & very flushed in face Carboplatin infusing @ the time Infusion stopped NS 0.9% w/o Benadryl 50mg IVP O_2 2l NC O_2 Sat 90% HR 134 BP 113/61 Dr Dalal notified Dexmethasone 10mg IVP @ 1330 BP 122/62 O_2 ↑ to 10l NC @ 1320 HR 130 Pt face flushing improved c/o SOB O_2 Sat 90% on 10l NC EMS called @ 1325 Transported to PMC @ 1335

Form # DH-MQA1030- created 2-00; revised 3-24-03

B) ICD-9-CM Codes

V58.1	unknown	unknown
Surgical, diagnostic, or treatment procedure being performed at time of incident (ICD-9 Codes 01-99.9)	Accident, event, circumstances, or specific agent that caused the injury or event. (ICD-9 E-Codes)	Resulting Injury (ICD-9 Codes 800-999.9)

C) List any equipment used if directly involved in the incident (Use additional sheets as necessary for complete response)

D) Outcome of Incident (Please check)

- ☐ Death
- ☐ Brain Damage
- ☐ Spinal Damage
- ☐ Surgical procedure performed on the wrong patient
- ☐ A procedure to remove unplanned foreign objects remaining from surgical procedure
- ☒ Any condition that required the transfer outcome of the patient to a licensed hospital

Outcome of transfer – e.g., death, brain damage, observation only unknown at that time
Name of facility to which patient was transferred Parrish Medical Center

- ☐ Surgical procedure performed on the wrong site **
- ☐ Wrong surgical procedure performed **
- ☐ Surgical repair of injuries or damage from a planned surgical procedure

** if it resulted in

- ☐ Death
- ☐ Brain Damage
- ☐ Spinal Damage
- ☐ Permanent disfigurement not to include the incision scar
- ☐ Fracture or dislocation of bones or joints
- ☐ Limitation of neurological, physical, or sensory function;
- ☒ Any condition that required the transfer outcome of the patient

E) List all persons, including license numbers if licensed, locating information, and the capacity in which they were directly involved with this incident.

Melissa Alexander RN - RN9215092
Danielle Brewer RN - RN1663542
Trish Shannon RN - RN2228932
Page Chinn RN - RN9248257

F) List witnesses, including license numbers if licensed, and locating information if not listed above

Trish Shannon RN - 2228932 Page Chin RN - 9248257
Danielle Brewer RN - 1663542 Melissa Alexander RN - 9215092

IV. ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response)

Chemotherapy reaction to Carboplatin.

B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

N/A

V. [signature] — SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT
ME 0085152 — LICENSE NUMBER

1/24/07 — DATE REPORT COMPLETED
1430 — TIME REPORT COMPLETED

Not a procedure

STATE OF FLORIDA
Jeb Bush, Governor

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

SUBMIT FORM TO:
Agency for Health Care Administration,
Consumer Services Unit, Post Office Box 14000,
Tallahassee, Florida 32317-4000

07 ... -9 PM 3:09

I. OFFICE INFORMATION

Southeastern Urological Center
Name of office

2000 Centre Pointe Blvd
Street Address

Tallahassee 32308 Leon
City Zip Code County

850-309-0400
Telephone

Gregory Lamendola PA
Name of Physician or Licensee Reporting

PA 910 1919
License Number & office registration number, if applicable

Same as above
Patient's address for Physician or Licensee Reporting

II. PATIENT INFORMATION

Patient Identification Number

Age Gender Medicaid Medicare

1-02-07
Date of Office Visit

Back pain
Purpose of Office Visit

Back Pain
Diagnosis

NA
ICD-9 Code for description of incident

NA
Level of Surgery (II) or (III)

III. INCIDENT INFORMATION

1-2-07 @ 1245
Incident Date and Time

Location of Incident:
☐ Operating Rm ☐ Recovery Rm
☑ Other Dr's office

Note: If the incident involved a death, was the medical examiner notified? ☐ Yes ☐ No
Was an autopsy performed? ☐ Yes ☐ No

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete response)

Patient presents to clinic for assessment and treatment of back pain on the right and diagnosed left renal calculi. Patient progresses to increasing pain, nausea and vomiting. KUB and urinalysis are negative for stone on right. Patient has history of compression fractures of spine and this creates concern for patient to be followed in an acute care setting. Transferred via ambulance due to severity of pain, nausea & vomiting to TMH ER for assessment and continued care.

Form # DH-MQA1030- created 2-00; revised 9-6-01

B) ICD-9-CM Codes

N/A	N/A	N/A
Surgical, diagnostic, or treatment procedure being performed at time of incident (ICD-9 Codes 01-99.9)	Accident, event, circumstances, or specific agent that caused the injury or event. (ICD-9 E-Codes)	Resulting injury (ICD-9 Codes 800-999.9)

C) **List any equipment used if directly involved in the incident** (Use additional sheets as necessary for complete response)

NA

D) **Outcome of Incident** (Please check)

☐ Death	☐ Surgical procedure performed on the wrong site **
☐ Brain Damage	☐ Wrong surgical procedure performed **
☐ Spinal Damage	☐ Surgical repair of injuries or damage from a planned surgical procedure
☐ Surgical procedure performed on the wrong patient	** if it resulted in
☐ A procedure to remove unplanned foreign objects remaining from surgical procedure	☐ Death ☐ Brain Damage
☒ Any condition that required the transfer outcome of the patient to a licensed hospital	☐ Spinal Damage ☐ Permanent disfigurement not to include the incision scar
Outcome of transfer – e.g., death, brain damage, observation only assessment + discharge Name of facility to which patient was transferred TMH	☐ Fracture or dislocation of bones or joints ☐ Limitation of neurological, physical, or sensory function; ☐ Any condition that required the transfer outcome of the patient

E) **List all persons, including license numbers if licensed, locating information, and the capacity in which they were directly involved with this incident.**

Greg Lamendola PA PA9101919 care provided
Shelley Keesey RN Charge nurse - assist c̄ transfer
Susan Burdick LPN nurse assisting PA c̄ patient care

F) **List witnesses, including license numbers if licensed, and locating information if not listed above**

IV. ANALYSIS AND CORRECTIVE ACTION

A) **Analysis (apparent cause) of this incident** (Use additional sheets as necessary for complete response)

Patient presented as directed by Clinic regarding left kidney stone but was having right sided pain with nausea + vomiting. Further assessment of right sided pain was indicated for non urologic condition.

B) **Describe corrective or proactive action(s) taken** (Use additional sheets as necessary for complete response)

No corrective action needed. Transfer was indicated for continued assessment and care of non urologic condition.

V. Terry Spear RN — 915912

SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT — LICENSE NUMBER

11-5-07 — 1130

DATE REPORT COMPLETED — TIME REPORT COMPLETED

Form # DH-MQA1030- created 2-00; revised 9-6-01

10/17/07 #31

#170

STATE OF FLORIDA
Jeb Bush, Governor

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

SUBMIT FORM TO:
Department of Health, Consumer Services Unit
4052 Bald Cypress Way, Bin C75
Tallahassee, Florida 32399-3275

I. OFFICE INFORMATION

Sarasota Interventional Radiology — Name of office
600 N. Cattlemen Rd — Street Address
Sarasota — City; 34232 — Zip Code; Sarasota — County
941-378-3231 — Telephone
Dr. Grubbs — Name of Physician or Licensee Reporting
538 — License Number & office registration number, if applicable

Patient's address for Physician or Licensee Reporting

II. PATIENT INFORMATION

Age 10-17-67 Gender Medicaid Medicare

Date of Office Visit

Purpose of Office Visit

Diagnosis 162.9

ICD-9 Code for description of incident

II — Level of Surgery (II) or (III)

III. INCIDENT INFORMATION

Oct 17, 2007 @ 1337 — Incident Date and Time

Location of incident:
☐ Operating Rm ☐ Recovery Rm
☒ Other CT Scan Room

Note: If the incident involved a death, was the medical examiner notified? ☐ Yes ☐ No
Was an autopsy performed? ☐ Yes ☐ No

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete response)

See attached report from Anest.

Form # DH-MQA1030- created 2-00; revised 3-24-03

B) ICD-9-CM Codes

162.9		
Surgical, diagnostic, or treatment procedure being performed at time of incident **(ICD-9 Codes 01-99.9)**	Accident, event, circumstances, or specific agent that caused the injury or event. **(ICD-9 E-Codes)**	Resulting injury **(ICD-9 Codes 800-999.9)**

C) List any equipment used if directly involved in the incident
(Use additional sheets as necessary for complete response)

D) Outcome of Incident (Please check)

☐ Death	☐ Surgical procedure performed on the wrong site **
☐ Brain Damage	☐ Wrong surgical procedure performed **
☐ Spinal Damage	☐ Surgical repair of injuries or damage from a planned surgical procedure
☐ Surgical procedure performed on the wrong patient	** If it resulted in
☐ A procedure to remove unplanned foreign objects remaining from surgical procedure	☐ Death ☐ Brain Damage ☐ Spinal Damage ☐ Permanent disfigurement not to include the incision scar
☒ Any condition that required the transfer outcome of the patient to a licensed hospital	☐ Fracture or dislocation of bones or joints ☐ Limitation of neurological, physical, or sensory function; ☐ Any condition that required the transfer outcome of the patient
Outcome of transfer – e.g., death, brain damage, observation only ______ Name of facility to which patient was transferred Doctor's Hospital	

E) List all persons, including license numbers if licensed, locating information, and the capacity in which they were directly involved with this incident.

Dr. Laura Yard - Anesthesiologist - 68224
Dr. Gerald Grubbs - Radiologist - ME 63973
Lisa Trapuzzo - CRNA - ARNP - 1937542
Christina Howes - Rad Tech - 39938

F) List witnesses, including license numbers if licensed, and locating information if not listed above

IV. ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response)

Pt went into [redacted]

B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

Anest gave appropriate medications to treat pt's condition
Transported to Doctor's Hosp.

V.

SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT   LICENSE NUMBER

DATE REPORT COMPLETED   TIME REPORT COMPLETED

Form # DH-MQA1030- created 2-00; revised 3-24-03

800 North Cattlemen Road
Suite 100 - Axcess Center
Sarasota, FL 34232-6410

941-378-3231
941-378-3253 Fax
www.sivr.net

SARASOTA
INTERVENTIONAL
RADIOLOGY
Immediate answers to critical questions

GERALD E. GRUBBS, MD
Diplomate, American Board of Radiology
Fellowship, Cardiovascular and Interventional Radiology

PATIENT:
EXAM DATE: 10/17/2007
PATIENT #:
DATE OF BIRTH:
REFERRING: Scott A. Tetreault, MD

EXAMINATION: CT GUIDED THORACIC VERTEBROPLASTY OF THE T6 VERTEBRAL BODY

EXAM LOCATION: Sarasota Interventional Radiology.

INDICATIONS: A patient with a history [redacted] presents with severe back pain and has a [redacted] Prior to this fracture, [redacted] has never been diagnosed with osteoporosis.

PROCEDURE CODES:

1. CT guided thoracic vertebroplasty (22520-53)
2. CT guidance for needle placement (77012-53)
3. CT supervision of cement deposition (72292-53)
4. Ancef (J0690) - 1,000 mg
5. Versed (J2250) - 1 mg
6. Ancef (J0690) - 1000 mg.
7. Fentanyl (J3010) - 100 mcg

TECHNIQUE: An informed written consent had been obtained and the patient was placed prone on the CT gantry table. [redacted] was given and monitored by Oasis Anesthesia.

The back was sterilely prepped and draped in the standard fashion. A safe left-sided transpedicular access site was selected, and the skin was sterilely prepped and draped in the standard fashion. 0.25% Marcaine was used for superficial and deep anesthesia.

A 13 gauge spinal needle was selected for treatment.

~~Just as the needle was being introduced, the patient's blood pressure dropped and subsequently, [redacted] heart rate also dropped to around the 40 to 45 range~~. This necessitated urgent treatment with ephedrine, which the patient did not respond to, but the patient did respond to an intravenous bolus of epinephrine. The patient subsequently went into a supraventricular tachyarrhythmia, requiring treatment with intravenous lidocaine, to which [redacted] did respond. Given the anesthesia

600 North Cattlemen Road
Suite 100 - Axcess Center
Sarasota, FL 34232-6410

941-378-3231
941-378-3253 Fax
www.sivr.net

SARASOTA
INTERVENTIONAL
RADIOLOGY
Immediate answers to critical questions

GERALD E. GRUBBS, MD
Diplomate, American Board of Radiology
Fellowship, Cardiovascular and Interventional Radiology

PATIENT:
EXAM DATE: 10/17/2007
PATIENT #:
DATE OF BIRTH:
REFERRING: Scott A. Tetreault, MD

complications during the procedure, the procedure had to be terminated at this point and all needles were removed.

The patient was subsequently transferred via EMS to Doctors Hospital.

IMPRESSION:
ABORTED THORACIC T6 VERTEBROPLASTY, AS DESCRIBED ABOVE.

Thank you for allowing us to participate in the care of your patient.

THIS REPORT WAS ELECTRONICALLY SIGNED
GERALD E. GRUBBS, M.D.
Board Certified Radiologist

GEG/vk/
DD: 10/22/2007 DT: 10/22/2007

800 North Cattlemen Road
Suite 100 - Axcess Center
Sarasota, FL 34232-6410

941-378-3231
941-378-3253 Fax
www.sivr.net

SARASOTA
INTERVENTIONAL
RADIOLOGY
Immediate answers to critical questions.

GERALD E. GRUBBS, MD
Diplomate, American Board of Radiology
Fellowship, Cardiovascular and Interventional Radiology

PATIENT: [redacted]
EXAM DATE: 10/15/2007
PATIENT #: [redacted]
DATE OF BIRTH: [redacted]
REFERRING: **Scott A. Tetreault, MD**

EXAMINATION: HISTORY AND PHYSICAL/OUTPATIENT CONSULTATION (99244)

EXAM LOCATION: Sarasota Interventional Radiology

HISTORY OF PRESENTING ILLNESS: The patient is a [redacted]-year-old [redacted] with a history of anemia and newly diagnosed osteoporosis. Without any history of any significant trauma, the patient presented with severe back pain. An MRI scan recently completed shows a T6 compression fracture.

We have been asked to see this patient in consultation for CT guided percutaneous thoracic vertebroplasty.

PAST MEDICAL HISTORY: The patient is a former smoker with a 30 pack-year history. The patient stopped smoking two weeks ago. The patient does not use alcohol. The patient denies any history of cerebrovascular disease. The patient does have coronary artery disease with a history of prior myocardial infarction. The patient denies diabetes mellitus but does have hypertension. The patient denies COPD. The patient does have hyperlipidemia and hypercholesterolemia. The patient has no history of significant infectious disease or known coagulopathy. The patient has had transfusions in the past. The patient has a history of stage IV lung cancer.

PAST SURGICAL HISTORY: Coronary artery bypass graft surgery. The patient also has had an appendectomy and tubal ligation.

FAMILY HISTORY: Both the patient's mother and father died of cardiac-related problems. The patient has one brother and one sister both of whom are in good health.

SOCIAL HISTORY: The patient is divorced and retired. [redacted] has four children.

ALLERGIES: No known drug allergies.

600 North Cattlemen Road
Suite 100 - Axcess Center
Sarasota, FL 34232-6410

941-378-3231
941-378-3253 Fax
www.sivr.net

SARASOTA
INTERVENTIONAL
RADIOLOGY
Immediate answers to critical questions.

GERALD E. GRUBBS, MD
Diplomate, American Board of Radiology
Fellowship, Cardiovascular and Interventional Radiology

PATIENT:
EXAM DATE: **10/15/2007**
PATIENT #:
DATE OF BIRTH:
REFERRING: **Scott A. Tetreault, MD**

MEDICATIONS: Lasix, 20 mg daily. Metoprolol, 50 mg daily. Lunesta, 2 mg at bedtime. Lexapro, 10 mg daily. Hydrocodone as needed and Oxycodone as needed.

ANESTHESIA HISTORY: The patient has had IV conscious sedation and general anesthesia in the past without complications.

PREVIOUS IMAGING STUDIES: A recent MRI scan performed at Axcess Diagnostics was reviewed at the time of consultation.

REVIEW OF SYSTEMS:
Constitutional symptoms: The patient states overall health is good.
Eyes: Presbyopia and myopia.
Ears, nose, mouth and throat: Dentures.
Cardiovascular: Unremarkable.
Respiratory: Unremarkable.
Gastrointestinal: Unremarkable.
Genitourinary: Unremarkable.
Musculoskeletal: New onset back pain.
Skin: Unremarkable.
Neurologic: Unremarkable.
Psychiatric: Depression.
Endocrine: Unremarkable.
Hematologic/Lymphatic: Anemia.
Allergic/Immunologic: Unremarkable.

PHYSICAL EXAMINATION:
In general, the patient is a pleasant well-developed, well-nourished mildly alert and oriented times 3, in no acute distress.

Vital signs: Pulse 97; Respiratory rate 18; Blood pressure 136/62; height ; weight pounds. Oxygen saturation 93% on room air.
HEENT: Normocephalic, atraumatic.
Neurologic: Appropriate affect, alert and oriented times 3.
Cardiovascular: Regular rate and rhythm.
Lungs: Clear. Decreased breath sounds in the bases, especially on the right.

800 North Cattlemen Road
Suite 100 - Axcess Center
Sarasota, FL 34232-6410

941-378-3231
941-378-3253 Fax
www.sivr.net

SARASOTA
INTERVENTIONAL
RADIOLOGY
Immediate answers to critical questions

GERALD E. GRUBBS, MD
Diplomate, American Board of Radiology
Fellowship, Cardiovascular and Interventional Radiology

PATIENT: [redacted]
EXAM DATE: 10/15/2007
PATIENT #: [redacted]
DATE OF BIRTH: [redacted]
REFERRING: **Scott A. Tetreault, MD**

Abdomen: Nondistended, nontender, positive bowel sounds.
Genitourinary: Not done.
Musculoskeletal: Normal gait. All four extremities are neurovasculatly intact.
Extremities: No clubbing, cyanosis, or edema.
Skin: Warm to the touch, with normal skin turgor.

IMPRESSION:

1. STAGE IV LUNG CANCER.
2. ANEMIA.
3. HISTORY OF FORMER TOBACCO USE.
4. HYPERLIPIDEMIA.
5. HYPERCHOLESTEROLEMIA.
6. HYPERTENSION.
7. NEW ONSET T6 VERTEBRAL BODY COMPRESSION FRACTURE.
8. SEVERE BACK PAIN DUE TO REASON ABOVE.

SW/ps

PLAN: CT guided thoracic vertebroplasty. The benefits, risks, and alternatives of the procedure were discussed at length with the patient. The risks incuded but were not limited to bleeding, infection, and failure of the procedure to completely alleviate the patient's back pain. Without documented history of trauma, we will also proceed with CT guided percutaneous biopsy to make certain this is not a pathologic compression fracture.

The patient understands the benefits, risks, and alternatives and wishes to proceed. The procedure has been urgently added to this week's schedule here at Sarasota Interventional Radiology.

Thank you again for allowing us the opportunity to participate in the care of this very pleasant [redacted].

THIS REPORT WAS ELECTRONICALLY SIGNED
GERALD E. GRUBBS, M.D.
Board Certified Radiologist

GEG/trw/[redacted]

10/29/07 (#32)

#171

STATE OF FLORIDA
Charlie Crist, Governor

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

SUBMIT FORM TO:
Department of Health, Consumer Services Unit
4052 Bald Cypress Way, Bin C75
Tallahassee, Florida 32399-3275

I. OFFICE INFORMATION

Advanced Imaging & Interventional Institute
Name of office

2730 McMullen Booth Road
Street Address

Clearwater, FL 33761 Pinellas
City Zip Code County

727-791-7300
Telephone

Gerald Niedzwiecki MD
Name of Physician or Licensee Reporting

ME 70649 / OSR521
License Number & office registration number, if applicable

Patient's address for Physician or Licensee Reporting

II. PATIENT INFORMATION

10-29-07

Patient Identification Number

Lung Cancer
Diagnosis

Purpose of Office Visit

762.4 275.9
ICD-9 Code for description of incident

II
Level of Surgery (II) or (III)

III. INCIDENT INFORMATION

10-29-07
Incident Date and Time

Location of Incident:
☐ Operating Room ☐ Recovery Room
☒ Other Angio Lab

Note: If the incident involved a death, was the medical examiner notified? ☐ Yes ☐ No
Was an autopsy performed? ☐ Yes ☐ No

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete response)

See Organizational Incident report (attached)

07 ... -5 ... 2:35

B) ICD-9-CM Codes

86.Ø7 (Port Placement)	511.8 [redacted])	511.8 (Hemothorax)
Surgical, diagnostic, or treatment procedure being performed at time of incident **(ICD-9 Codes 01-99.9)**	Accident, event, circumstances, or specific agent that caused the injury or event. **(ICD-9 E-Codes)**	Resulting injury **(ICD-9 Codes 800-999.9)**

C) List any equipment used if directly involved in the incident
(Use *additional sheets* as *necessary* for complete response)

D) Outcome of Incident (Please check)

☐ Death ☐ Brain Damage ☐ Spinal Damage ☐ Surgical procedure performed on the wrong patient. ☐ A procedure to remove unplanned foreign objects remaining from surgical procedure. ☒ Any condition that required the transfer of the patient to a hospital. Outcome of transfer – e.g., death, brain damage, (observation only) Name of facility to which patient was transferred: Mease Countryside Hospital, Safety Harbor FL	☐ Surgical procedure performed on the wrong site ** ☐ Wrong surgical procedure performed ** ☐ Surgical repair of injuries or damage from a planned surgical procedure. ** If it resulted in: ☐ Death ☐ Brain Damage ☐ Spinal Damage ☐ Permanent disfigurement not to include the incision scar ☐ Fracture or dislocation of bones or joints ☐ Limitation of neurological, physical, or sensory function. ☐ Any condition that required the transfer of the patient to a hospital.

E) List all persons, including license numbers if licensed, locating information and the capacity in which they were involved in this incident, this would include anesthesiologist, support staff and other health care providers.

Jeanne Kimball, RN RN706652 - pre & post care RN
Regan Talley RN RN2700912 - Angio Lab RN
Shelly Bugman CRT CRT38177 - Cardiovascular Tech. / Gerald Niedzwiecki MD ME 70649
Cindy Taylor RN RN2202132 Pre & Post Care RN

F) List witnesses, including license numbers if licensed, and locating information if not listed above

IV. ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response)

During (R) IJ chest Port placement, Pt had [redacted] which when Appropriately investigated showed possible Hemothorax which was Treated with chest tube. Pt was stable throughout & was transferred to Hospital for Continued monitoring.

B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

Event Handled appropriately with Timely Diagnosis and Treatment. Event most Likely precipitated By [crossed out].

V. [signature] — **SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT**
ME 70649 — **LICENSE NUMBER**

10-30-07 — **DATE REPORT COMPLETED**
1:00 PM — **TIME REPORT COMPLETED**

ADVANCED IMAGING & INTERVENTIONAL INSTITUTE

INCIDENT REPORT

DATE 10-29-07 NAME [redacted] DOB [redacted]

SS# [redacted]

ADDRESS [redacted]

PHONE NUMBER(S) [redacted]

PLACE OF INCIDENT AI³- angio / Post Care.

DESCRIPTION OF INCIDENT Patient had chest port inserted. [illegible] [illegible] hypotensive [illegible] during procedure, then satisfactory vital signs 90/50 & pulse 100's, R=20, O2SAT=99-100%. At 1515 patient stated [redacted] felt really weak and short of breath. CT scan of chest done. Hemothorax present. #11F [illegible] chest tube inserted to 1500ml blood removed. Patient states it was easier to breathe after the blood was removed. Arrangement were made to transfer patient to Mean C/S Hospital, ICU. Dr. Steck, Dr Schmidt contacted by Dr [illegible]. Orders sent. 1710 to Mean C/S Hospital by EMS in stable

WITNESS(S) [illegible]. Jeannette Hull

PERSON COMPLETING REPORT Jeannette A Hull

PHYSICIAN NOTIFIED present.

FOLLOW-UP

STATE OF FLORIDA
Charlie Crist, Governor

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

SUBMIT FORM TO:
Department of Health, Consumer Services Unit
4052 Bald Cypress Way, Bin C75
Tallahassee, Florida 32399-3275

I. OFFICE INFORMATION

Space Coast Medical Associates
Name of office

850 Century Medical Drive
Street Address

Titusville | 32796 | Brevard
City | Zip Code | County

321-268-4200
Telephone

Dr. Ashish Dalal
Name of Physician or Licensee Reporting

ME 0085152
License Number & office registration number, if applicable

Patient's address for Physician or Licensee Reporting

II. PATIENT INFORMATION

Patient Identification Number

Breast cancer
Diagnosis

Age | Gender | Medicaid, Medicare

10-29-07
Date of Office Visit

Purpose of Office Visit

174.9
ICD-9 Code for description of incident

Level of Surgery (II) or (III)

III. INCIDENT INFORMATION

10-29-07 10:05 am
Incident Date and Time

Location of Incident
☐ Operating Room ☐ Recovery Room
☑ Other Doctors office

Note: If the incident involved a death, was the medical examiner notified? ☐ Yes ☐ No N/A
Was an autopsy performed? ☐ Yes ☐ No N/A

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete response)

Taxol infusion stopped after approx. 5 minutes after infusion began. Pt. states "I feel funny. I feel like I am going to faint" Speech slurred B/P 68/36 pulse 149. Pupils dilated. Pt. non-responsive approx 2-3 minutes. Dr. Dalal at bedside along with Barbara Ellis RN, Kimberly Buckner RN, Melissa Alexander RN, Edwin Hill RN. Dexamethasone 10mg IVP, O_2 administered at 3LPM. Increased to 6LPM per MD. B/P 80/61. 10:30AM. Pt. transferred to Parrish Medical Center by ambulance.

DH-MQA1030-12/06

APR.19.2007 14:13 #5293 P.001 /002

B) ICD-9-CM Codes

174.9	V58.1	
Surgical, diagnostic, or treatment procedure being performed at time of incident (ICD-9 Codes 01-99.9)	Accident, event, circumstances, or specific agent that caused the injury or event. (ICD-9 E-Codes)	Resulting injury (ICD-9 Codes 800-999.9)

C) List any equipment used if directly involved in the incident AED
(Use additional sheets as necessary for complete response)

Infusion pump Taxol 320mg IV O2 via Nasal Cannula

D) Outcome of Incident (Please check)

☐ Death	☐ Surgical procedure performed on the wrong site **
☐ Brain Damage	☐ Wrong surgical procedure performed **
☐ Spinal Damage	☐ Surgical repair of injuries or damage from a planned surgical procedure.
☐ Surgical procedure performed on the wrong patient.	** if it resulted in:
☐ A procedure to remove unplanned foreign objects remaining from surgical procedure.	☐ Death ☐ Brain Damage ☐ Spinal Damage ☐ Permanent disfigurement not to include the incision scar ☐ Fracture or dislocation of bones or joints ☐ Limitation of neurological, physical, or sensory function.
☑ Any condition that required the transfer of the patient to a hospital.	☑ Any condition that required the transfer of the patient to a hospital.
Outcome of transfer – e.g., death, brain damage, observation only: To ER Name of facility to which patient was transferred: Parrish Medical Center	

E) List all persons, including license numbers if licensed, locating information and the capacity in which they were involved in this incident, this would include anesthesiologist, support staff and other health care providers.

Barbara Ellis RN 9251805
Melissa Alexander RN 9215092
Kim Buckner RN 9170156
Edwin Hill RN 9193500
Dr. Ashish Dalal ME 0085152

F) List witnesses, including license numbers if licensed, and locating information if not listed above

Michelle Lewis, Medical Asst.

IV. ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response)

Reaction to Taxol (Chemotherapy)

B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

Benadryl give 50mg Prior to Infusion Dexamethasone 10mg IVP 10:10 am
Dexamethasone 10mg Prior To Infusion O2 placed via Nasal Cannula
AED used

V. [signature] ME 85152 ME 0085152
SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT **LICENSE NUMBER**

11/2/07 1:00 PM
DATE REPORT COMPLETED **TIME REPORT COMPLETED**

STATE OF FLORIDA
Jeb Bush, Governor

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

SUBMIT FORM TO:
Agency for Health Care Administration,
Consumer Services Unit, Post Office Box 14000
Tallahassee, Florida 32317-4000

I. OFFICE INFORMATION

Southeastern Urological Center
Name of office

2000 Centre Pointe Blvd
Street Address

Tallahassee 32308 Leon
City Zip Code County

850-309-0400
Telephone

Scott B. Sellinger MD
Name of Physician or Licensee Reporting

ME0051896
License Number & office registration number, if applicable

Same as above
Patient's address for Physician or Licensee Reporting

II. PATIENT INFORMATION

Age Gender Medicaid Medicare

Patient Identification Number

10-11-07
Date of Office Visit

Assess Need for [redacted]
Purpose of Office Visit

Diagnosis [redacted] status

NA
ICD-9 Code for description of incident

NA
Level of Surgery (II) or (III)

III. INCIDENT INFORMATION

10-11-07 @ 1:30 pm
Incident Date and Time

Location of Incident:
☐ Operating Rm ☐ Recovery Rm
☒ Other physician office

Note: If the incident involved a death, was the medical examiner notified? ☐ Yes ☐ No
Was an autopsy performed? ☐ Yes ☐ No

A) Describe circumstances of the incident (narrative)

(use additional sheets as necessary for complete response)

Patient arrived for assessment of urinary retention after catheter placement in ER last night. Patient is in wheelchair, lethargic but responsive to verbal stimuli and can squeeze the nurse's hand. B/P low & pulse slow but strong. Determined to transfer to hospital for continued care and assessment of lethargy. Patient was admitted for continued care.

Form # DH-MQA1030- created 2-00; revised 9-6-01

B) ICD-9-CM Codes

NA	NA	NA
Surgical, diagnostic, or treatment procedure being performed at time of incident (ICD-9 Codes 01-99.9)	Accident event, circumstances or specific agent that caused the injury or event. (ICD-9 E-Codes)	Resulting injury (ICD-9 Codes 800-999.9)

C) List any equipment used if directly involved in the incident

(Use additional sheets as necessary for complete response)

NA

D) Outcome of Incident (Please check)

☐ Death	☐ Surgical procedure performed on the wrong site **
☐ Brain Damage	☐ Wrong surgical procedure performed **
☐ Spinal Damage	☐ Surgical repair of injuries or damage from a planned surgical procedure
☐ Surgical procedure performed on the wrong patient	** if it resulted in
☐ A procedure to remove unplanned foreign objects remaining from surgical procedure	☐ Death ☐ Brain Damage
☒ Any condition that required the transfer outcome of the patient to a licensed hospital	☐ Spinal Damage ☐ Permanent disfigurement not to include the incision scar
Outcome of transfer – e.g., death, brain damage, observation only ________ Name of facility to which patient was transferred TMH	☐ Fracture or dislocation of bones or joints ☐ Limitation of neurological, physical, or sensory function; ☐ Any condition that required the transfer outcome of the patient

E) *List all persons, including license numbers if licensed, locating information, and the capacity in which they were directly involved with this incident.*

Scott B Sellinger MD - ME 005 1896 - treating physician
Linda Crane LPN - PN 454431 nurse caring for patient
Shelley Keever RN RN 2737062 nurse assisting with transport
Terry J. Spear RN RN915912 nurse assisting with transport

F) List witnesses, including license numbers if licensed, and locating information if not listed above

as above

IV. ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response)

Patient required [redacted]

B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

None needed - Actions were appropriate

V. Terry Spear RN — 9591-2

SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT — LICENSE NUMBER

10-15-07 — DATE REPORT COMPLETED

12:00 pm — TIME REPORT COMPLETED

RECEIVED DEPARTMENT OF HEALTH CONSUMER SERVICES UNIT 2007 OCT 25 AM 7:16

RECEIVED CONSUMER SERVICES UNIT 2007 OCT 25 AM 7:16

STATE OF FLORIDA
Charlie Crist, Governor

X

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

SUBMIT FORM TO:
Department of Health, Consumer Services Unit
4052 Bald Cypress Way, Bin C75
Tallahassee, Florida 32399-3275

OFFICE INFORMATION

Pediatric Specialties
Name of Office

2000 SW Archer Road
Street Address

Gainesville | 32610 | Alachua
City | Zip Code | County

352-265-8250
Telephone

Donald Novak, M.D., Medical Director
Name of Physician or Licensee Reporting

ME60426
License Number & office registration number, if applicable

2000 SW Archer Road, Gainesville, FL 32610
Patient's address for Physician or Licensee Reporting

II. PATIENT INFORMATION

Patient Identification Number

Diagnosis

Age | Gender | Medicaid | Medicare

10/08/07
Date of Office Visit

Purpose of Office Visit

958.1
ICD-9 Code for description of incident

Level II Clinic
Level of Surgery (II) or (III)

III. INCIDENT INFORMATION

10/08/07 approx 9am
Incident Date and Time

Location of Incident:
☐ Operating Room ☐ Recovery Room
☒ Other exam room

Note: *If the incident involved a death, was the medical examiner notified?* ☒ Yes ☐ No
Was an autopsy performed? ☒ Yes ☐ No

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete response)

Patient is a [redacted] year old child who was being evaluated at the Pediatric Endocrinology Clinic for short stature. At [redacted] appointment on 8/20/07, the patient was found to have a growth velocity of 4.1 cm per year, below the 1.2 percentile, which is 3 standard deviations below the mean. It was decided that [redacted] would be evaluated for growth hormone deficiency with the intent of starting [redacted] on growth hormone replacement in the near future. An appointment was scheduled for 10/08/07 for a growth hormone stimulation test. The order was written for Arginine 5.75 grams to be administered in clinic IV X1. [redacted] was also to be administered Glucagon 0.35 mg IV X1 at the same appointment. On 10/08/07, the parents picked up the prescription from the pharmacy to take to the Pediatric Specialties clinic. Two 300 ml bottles of Arginine HCl 10% inj were dispensed by pharmacy. The nurse checked the dosage with one of the physicians in the clinic prior to infusion. During the administration of the Arginine, the child complained of headache and nausea and pounded on [redacted] head. Another physician in the clinic was asked to see the patient. At that point, the child was resting in [redacted] mother's arms and was no longer complaining. The infusions were completed by 1014. The child remained in the clinic until 1330 for serial blood draws for the cortisol and growth hormone. The child was discharged home with [redacted] parents to return as scheduled in December. At approximately 2330 the parents brought the child to the ED at Shands AGH [redacted] was admitted to AGH for further evaluation. During the admission, the child developed mental status changes requiring admission to the ICU [redacted] hydrocephalus. At approximately 8 AM on 10/10[redacted] F for neurosurgical consultation and management [redacted] neurological decline. The child w[redacted] and the [redacted]

B) ICD-9-CM Codes

99.29	858.1	963.2
Surgical, diagnostic, or treatment procedure being performed at time of incident (ICD-9 Codes 01-99.9)	Accident, event, circumstances, or specific agent that caused the injury or event. (ICD-9 E-Codes)	Resulting injury (ICD-9 Codes 800-999.9)

C) List any equipment used if directly involved in the incident (Use additional sheets as necessary for complete response)

D) Outcome of Incident (Please check)

- ☑ Death
- ☐ Brain Damage
- ☐ Spinal Damage
- ☐ Surgical procedure performed on the wrong patient.
- ☐ A procedure to remove unplanned foreign objects remaining from surgical procedure.
- ☐ Any condition that required the transfer of the patient to a hospital.

Outcome of transfer – e.g., death, brain damage, observation only ____
Name of facility to which patient was transferred: ____

- ☐ Surgical procedure performed on the wrong site **
- ☐ Wrong surgical procedure performed **
- ☐ Surgical repair of injuries or damage from a planned surgical procedure.

*** if it resulted in:*

- ☐ Death
- ☐ Brain Damage
- ☐ Spinal Damage
- ☐ Permanent disfigurement not to include the incision scar
- ☐ Fracture or dislocation of bones or joints
- ☐ *Limitation of neurological, physical, or sensory function.*
- ☐ Any condition that required the transfer of the patient to a hospital.

E) List all persons, including license numbers if licensed, locating information and the capacity in which they were involved in this incident, this would include anesthesiologist, support staff and other health care providers.

Beth Joyner, RN2736752, RN who administered the medication for the diagnostic test in the clinic

Julie DiPerna, PS23935, Shands Medical Plaza outpatient pharmacist who ordered the medication

Edna Irizarry, PS39379, Shands Medical Plaza outpatient pharmacist who dispensed the medication

F) List witnesses, including license numbers if licensed, and locating information if not listed above

IV. ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response)

This drug is not stocked in the outpatient pharmacy and had to be ordered from the wholesaler. The pharmacist who took the call was not sure how much would be needed so ordered 2 bottles of the drug to be sure enough would be available. Each bottle contains 30 grams of (continued on separate page)

B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

This diagnostic test will no longer be performed in this outpatient setting but instead in the Pediatrics Infusion Center where medications are dose customized, prepared by infusion trained pharmacists and administered by infusion trained nursing staff. The pharmacist and nurse will be counseled.

V. [signature] ____ SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT — ME 50426 LICENSE NUMBER

10/24/07 DATE REPORT COMPLETED — 4:45 pm TIME REPORT COMPLETED

Arginine in 300 ml. The parents picked up the prescription from the pharmacy *to take* to the clinic. The pharmacy prepared label states "TAKE TO CLINIC TO INFUSE 5.75 GM" on both bottles. In addition it was handwritten in on the label, "1 of 2" and on the other bottle it was handwritten on the label, "2 of 2". *The nurse in the clinic,* who was the same nurse who called in the order, checked the child's weight with the dose ordered which was correct, with one of the physicians in the clinic prior to infusion. The nurse then administered both bottles *of approximately 600 ml assuming* that the pharmacy dispensed the correct dosage. The pharmacists did not include the volume to be dispensed on the label prior to dispensing drug. *Pharmacists* in the *outpatient settings* are not infusion trained and do not provide customized dosages. The nurse should have been suspicious when she received two 300 ml bottles for a small, young patient and she should have double checked the volume being administered.

STATE OF FLORIDA
Charlie Crist, Governor

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

SUBMIT FORM TO:
Department of Health, Consumer Services Unit
4052 Bald Cypress Way, Bin C75
Tallahassee, Florida 32399-3275

I. OFFICE INFORMATION

Pediatric Specialties
Name of office

2000 SW Archer Road
Street Address

Gainesville | 32610 | Alachua
City | *Zip Code* | *County*

352-265-6250
Telephone

Donald Novak, M.D., Medical Director
Name of Physician or Licensee Reporting

ME50428
License Number & office registration number, if applicable

2000 SW Archer Road, Gainesville, FL 32610
Patient's address for Physician or Licensee Reporting

II. PATIENT INFORMATION

Patient Identification Number

Short Stature
Diagnosis

Age Gender Medicaid Medicare

10/08/07
Date of Office Visit

Growth Hormone Stimulation Test
Purpose of Office Visit

958.1
ICD-9 Code for description of incident

Level II Clinic
Level of Surgery (II) or (III)

III. INCIDENT INFORMATION

10/08/07 approx 9am
Incident Date and Time

Location of Incident:
☐ *Operating Room* ☐ Recovery Room
☑ Other exam room

Note: *If the incident involved a death, was the medical examiner notified?* ☑ Yes ☐ No
Was an autopsy performed? ☑ Yes ☐ No

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete response)

Patient is a ▇ year old child who was being evaluated at the Pediatric Endocrinology Clinic for short stature. At ▇ appointment on 8/20/07, the patient was found to have a growth velocity of 4.1 cm per year, below the 1.2 percentile, which is 3 standard deviations below the mean. It was decided that ▇ would be evaluated for growth hormone deficiency with the intent of starting ▇ on growth hormone replacement in the near future. An appointment was scheduled for 10/08/07 for a growth hormone stimulation test. The order was written for Arginine 5.75 grams to be administered in clinic IV X1. ▇ was also to be administered Glucagon 0.35 mg IV X1 at the same appointment. On 10/08/07, the parents picked up the prescription from the pharmacy to take to the Pediatric Specialties clinic. Two 300 ml bottles of Arginine HCl 10% Inj were dispensed by pharmacy. The nurse checked the dosage with one of the physicians in the clinic prior to infusion. During the administration of the Arginine, the child complained of headache and nausea and pounded on ▇ head. Another physician in the clinic was asked to see the patient. At that point, the child was resting in ▇ mother's arms and was no longer complaining. The infusions were completed by 1014. The child remained in the clinic until 1330 for serial blood draws for the cortisol and growth hormone. The child was discharged home with ▇ parents to return as scheduled in December. At approximately 2330 the parents brought the child to the ED at Shands AGH for dehydration, nausea and vomiting. ▇ was admitted to AGH for further evaluation. During the admission, the child developed mental status changes requiring admission to the ICU. Head CT findings revealed cerebellar edema with herniation and secondary hydrocephalus. At approximately 8 AM on 10/10/07 the child was transferred to SUF for neurosurgical consultation and management of the acute neurological decline. The child was declared brain dead on 10/10/07 and the child expired on that date.

B) ICD-9-CM Codes

99.29	858.1	963.2
Surgical, diagnostic, or treatment procedure being performed at time of incident **(ICD-9 Codes 01-99.9)**	Accident, event, circumstances, or specific agent that caused the injury or event. **(ICD-9 E-Codes)**	Resulting injury **(ICD-9 Codes 800-999.9)**

C) List any equipment used if directly involved in the incident
(Use additional sheets as necessary for complete response)

D) *Outcome of Incident* (Please check)

- ☑ Death
- ☐ Brain Damage
- ☐ Spinal Damage
- ☐ Surgical procedure performed on the wrong patient.
- ☐ A procedure to remove unplanned foreign objects *remaining from surgical procedure.*
- ☐ Any condition that required the transfer of the patient to a hospital.

Outcome of transfer – e.g., death, brain damage, observation only ______

Name of facility to which patient was transferred: ______

- ☐ Surgical procedure performed on the wrong site **
- ☐ Wrong surgical procedure performed **
- ☐ Surgical repair of injuries or damage from a planned surgical procedure.

** if it resulted in:

- ☐ Death
- ☐ Brain Damage
- ☐ Spinal Damage
- ☐ Permanent disfigurement not to include the *incision scar*
- ☐ Fracture or dislocation of bones or joints
- ☐ Limitation of neurological, physical, or sensory function.
- ☐ Any condition that required the transfer of the patient to a hospital.

E) List all persons, including license numbers if licensed, locating information and the capacity in which they were involved in this incident, this would include anesthesiologist, support staff and other health care providers.

Beth Joyner, RN2735762, RN who administered the medication for the diagnostic test in the clinic

Julie DiPerna, PS23936, Shands Medical Plaza outpatient pharmacist who ordered the medication

Edna Irizarry, PS39379, Shands Medical Plaza outpatient pharmacist who distpensed the medication

F) List witnesses, including license numbers if licensed, and locating information if not listed above

IV. ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response)

This drug is not stocked in the outpatient pharmacy and had to be ordered from the wholesaler. The pharmacist who took the call was not sure how much would be needed so ordered 2 bottles of the drug to be sure enough would be available. Each bottle contains 30 grams of (continued on seperate page)

B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

This diagnostic test will no longer be performed in this outpatient setting but instead in the Pediatrics Infusion Center where medications are dose customized, prepared by infusion trained pharmacists and administered by infusion trained nursing staff. The pharmacist and nurse will be counseled.

V. [signature] - Univ. of Florida Physicians ______ ME 50426

SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT — LICENSE NUMBER

10/24/07 — 11.45 pm

DATE REPORT COMPLETED — TIME REPORT COMPLETED

Arginine in 300 ml. The parents picked up the prescription from the pharmacy to take to the clinic. The pharmacy prepared label states "TAKE TO CLINIC TO INFUSE 5.75 GM" on both bottles. In addition it was handwritten in on the label, "1 of 2" and on the other bottle it was handwritten on the label, "2 of 2". The nurse in the clinic, who was the same nurse who called in the order, checked the child's weight with the dose ordered which was correct, with one of the physicians in the clinic prior to infusion. The nurse then administered both bottles of approximately 600 ml assuming that the pharmacy dispensed the correct dosage. The pharmacists did not include the volume to be dispensed on the label prior to dispensing drug. Pharmacists in the outpatient settings are not infusion trained and do not provide customized dosages. The nurse should have been suspicious when she received two 300 ml bottles for a small, young patient and she should have double checked the volume being administered.

STATE OF RIDA
Charlie Crist, ..vernor

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

SUBMIT FORM TO:
Department of Health, Consumer Services Unit
4052 Bald Cypress Way, Bin C75
Tallahassee, Florida 32399-3275

I. OFFICE INFORMATION

Pediatric Specialties
Name of office

2000 SW Archer Road
Street Address

Gainesville 32610 Alachua
City Zip Code County

352-265-8250
Telephone

Donald Novak, M.D., Medical Director
Name of Physician or Licensee Reporting

ME50426
License Number & office registration number, if applicable

2000 SW Archer Road, Gainesville, FL 32610
Patient's address for Physician or Licensee Reporting

II. PATIENT INFORMATION

Patient Identification Number

Short Stature
Diagnosis

Age Gender ☐ Medicaid ☐ Medicare

10/08/07
Date of Office Visit

Growth Hormone Stimulation Test
Purpose of Office Visit

958.1
ICD-9 Code for description of incident

Level II Clinic
Level of Surgery (II) or (III)

III. INCIDENT INFORMATION

10/08/07 approx 9am
Incident Date and Time

Location of incident:
☐ Operating Room ☐ Recovery Room
☑ Other exam room

Note: If the incident involved a death, was the medical examiner notified? ☑ Yes ☐ No
Was an autopsy performed? ☑ Yes ☐ No

A) Describe circumstances of the incident (narrative)

(use additional sheets as necessary for complete response)

Patient is a [redacted] year old child who was being evaluated at the Pediatric Endocrinology Clinic for short stature. At [redacted] appointment on 8/20/07, the patient was found to have a growth velocity of 4.1 cm per year, below the 1.2 percentile, which is 3 standard deviations below the mean. It was decided that [redacted] would be evaluated for growth hormone deficiency with the intent of starting [redacted] on growth hormone replacement in the near future. An appointment was scheduled for 10/08/07 for a growth hormone stimulation test. The order was written for Arginine 5.75 grams to be administered in clinic IV X1. [redacted] was also to be administered Glucagon 0.35 mg IV X1 at the same appointment. On 10/08/07, the parents picked up the prescription from the pharmacy to take to the Pediatric Specialties clinic. Two 300 ml bottles of Arginine HCl 10% inj were dispensed by pharmacy. The nurse checked the dosage with one of the physicians in the clinic prior to infusion. During the administration of the Arginine, the child complained of headache and nausea and pounded on [redacted] head. Another physician in the clinic was asked to see the patient. At that point, the child was resting in [redacted] mother's arms and was no longer complaining. The infusions were completed by 1014. The child remained in the clinic until 1330 for serial blood draws for the cortisol and growth hormone. The child was discharged home with [redacted] parents to return as scheduled in December. At approximately 2330 the parents brought the child to the ED at Shands AGH for dehydration, nausea and vomiting. [redacted] was admitted to AGH for further evaluation. During the admission, the child developed mental status changes requiring admission in the ICU. Head CT findings revealed cerebellar edema with herniation and secondary hydrocephalus. At approximately 8 AM on 10/10/07 the child was transferred to SUF for neurosurgical consultation and management of the acute neurological decline. The child was declared brain dead on 10/10/07 and the child expired on that date.

B) ICD-9-CM Codes

99.29	558.1	963.2
Surgical, diagnostic, or treatment procedure being performed at time of incident (ICD-9 Codes 01-99.9)	Accident, event, circumstances, or specific agent that caused the injury or event. (ICD-9 E-Codes)	Resulting injury (ICD-9 Codes 800-999.9)

C) List any equipment used if directly involved in the incident
(Use additional sheets as necessary for complete response)

D) Outcome of Incident (Please check)

- ☒ Death
- ☐ Brain Damage
- ☐ Spinal Damage
- ☐ Surgical procedure performed on the wrong patient.
- ☐ A procedure to remove unplanned foreign objects remaining from surgical procedure.
- ☐ Any condition that required the transfer of the patient to a hospital.

Outcome of transfer – e.g., death, brain damage, observation only ______
Name of facility to which patient was transferred: ______

- ☐ Surgical procedure performed on the wrong site **
- ☐ Wrong surgical procedure performed **
- ☐ Surgical repair of injuries or damage from a planned surgical procedure.

** If it resulted in:

- ☐ Death
- ☐ Brain Damage
- ☐ Spinal Damage
- ☐ Permanent disfigurement not to include the incision scar
- ☐ Fracture or dislocation of bones or joints
- ☐ Limitation of neurological, physical, or sensory function.
- ☐ Any condition that required the transfer of the patient to a hospital.

E) List all persons, including license numbers if licensed, locating information and the capacity in which they were involved in this incident, this would include anesthesiologist, support staff and other health care providers.

Beth Joyner, RN2735762, RN who administered the medication for the diagnostic test in the clinic

Julie DiPerna, PS23935, Shands Medical Plaza outpatient pharmacist who ordered the medication

Edna Irisarry, PS30379, Shands Medical Plaza outpatient pharmacist who dispensed the medication

F) List witnesses, including license numbers if licensed, and locating information if not listed above

IV. ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response)

This drug is not stocked in the outpatient pharmacy and had to be ordered from the wholesaler. The pharmacist who took the call was not sure how much would be needed so ordered 2 bottles of the drug to be sure enough would be available. Each bottle contains 30 grams of (continued on separate page)

B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

This diagnostic test will no longer be performed in this outpatient setting but instead in the Pediatrics Infusion Center where medications are dose customized, prepared by infusion trained pharmacists and administered by infusion trained nursing staff. The pharmacist and nurse will be counseled.

V. [signature] Univ. of Florida Physicians — SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT

ME 50426 — LICENSE NUMBER

10/24/07 — DATE REPORT COMPLETED

4:45 pm — TIME REPORT COMPLETED

Arginine in 300 ml. The parents picked up the prescription from the pharmacy to take to the clinic. The pharmacy prepared label states "TAKE TO CLINIC TO INFUSE 5.75 GM" on both bottles. In addition it was handwritten in on the label, "1 of 2" and on the other bottle it was handwritten on the label, "2 of 2". The nurse in the clinic, who was the same nurse who called in the order, checked the child's weight with the dose ordered which was correct, with one of the physicians in the clinic prior to infusion. The nurse then administered both bottles of approximately 600 ml assuming that the pharmacy dispensed the correct dosage. The pharmacists did not include the volume to be dispensed on the label prior to dispensing drug. Pharmacists in the outpatient settings are not infusion trained and do not provide customized dosages. The nurse should have been suspicious when she received two 300 ml bottles for a small, young patient and she should have double checked the volume being administered.

STATE OF FLORIDA
Charlie Crist, Governor

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

SUBMIT FORM TO:
Department of Health, Consumer Services Unit
4052 Bald Cypress Way, Bin C75
Tallahassee, Florida 32399-3275

I. OFFICE INFORMATION

Gastrointestinal Diagnostic Centers
Name of office

2245 North University Dr.
Street Address

Pembroke Pines 33024 Broward
City Zip Code County

954-963-0898
Telephone

Brian Doorech, M.D
Name of Physician or Licensee Reporting

OSR 175
License Number & office registration number, if applicable

[redacted]

[redacted]

Age 10/26/07 Gender Medicaid Medicare
Date of Office Visit
anemia
Purpose of Office Visit

Patient [redacted] Number

Diagnosis

ICD-9 Code for description of incident

II
Level of Surgery (II) or (III)

III. INCIDENT INFORMATION

10/26/07 approximately 1400
Incident Date and Time

Location of Incident:
☐ Operating Room ☐ Recovery Room
☒ Other hospital (911 from home)

Note: If the incident involved a death, was the medical examiner notified? ☐ Yes ☐ No
Was an autopsy performed? ☐ Yes ☐ No

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete response)

Pt underwent uneventful [redacted] on the a.m of 10/26/07. [redacted] was discharged from the facility at approximately 10:30 am in stable condition. At approximately 1:30 pm pt arrived in ER of Memorial Hosp Pembroke via 911 c̄ c[redacted]. Pt arrested ultimately passed away. [redacted] as per county medical examiner [redacted] due to severe CAD and ASHD. Please note, pt had full cardiac clearance prior to procedure. Procedure was NOT listed as a contributing factor.

B) ICD-9-CM Codes

Post Colonoscopy	Acute MI	death
Surgical, diagnostic, or treatment procedure being performed at time of incident (ICD-9 Codes 01-99.9)	Accident, event, circumstances, or specific agent that caused the injury or event. (ICD-9 E-Codes)	Resulting injury (ICD-9 Codes 800-999.9)

C) List any equipment used if directly involved in the incident
(Use additional sheets as necessary for complete response)

pt was treated in ER

D) Outcome of Incident (Please check)

☑ Death	☐ Surgical procedure performed on the wrong site **
☐ Brain Damage	☐ Wrong surgical procedure performed **
☐ Spinal Damage	☐ Surgical repair of injuries or damage from a planned surgical procedure.
☐ Surgical procedure performed on the wrong patient.	** if it resulted in: ☐ Death ☐ Brain Damage ☐ Spinal Damage ☐ Permanent disfigurement not to include the incision scar ☐ Fracture or dislocation of bones or joints ☐ Limitation of neurological, physical, or sensory function. ☐ Any condition that required the transfer of the patient to a hospital.
☐ A procedure to remove unplanned foreign objects remaining from surgical procedure.	
☐ Any condition that required the transfer of the patient to a hospital.	
Outcome of transfer – e.g., death, brain damage, observation only ______ Name of facility to which patient was transferred: Memorial Hospital Pembroke	

E) List all persons, including license numbers if licensed, locating information and the capacity in which they were involved in this incident, this would include anesthesiologist, support staff and other health care providers.

Pt was discharged from facility to home. Pt was taken to Memorial Hospital Pembroke via 911 approximately 3 hours after discharge

F) List witnesses, including license numbers if licensed, and locating information if not listed above

Staff of Memorial Hospital Pembroke

IV. ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response)

Pt suffered acute MI colonoscopy was not considered a contributing factor. Pt was under the care of a cardiologist for known cardiac disease

B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

Pt had complete + thorough consult with Dr. Doorerk (myself) + I explained all risks, benefits + alternatives including barium enema + virtual colonoscopy. Procedure was performed under MAC anesthesia by MD anesthesiologist ā cardiology clearance was obtained

V.

[signature] ______ ME 33567
SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT — LICENSE NUMBER

10/31/07 ______ 1415
DATE REPORT COMPLETED — TIME REPORT COMPLETED

11/1/07 (#33)

STATE OF FLORIDA
Jeb Bush, Governor

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

SUBMIT FORM TO:
Department of Health, Consumer Services Unit
4052 Bald Cypress Way, Bin C75
Tallahassee, Florida 32399-3275

I. OFFICE INFORMATION

Sarasota Interventional Radiology — Name of office
1000 N. Cattleman Rd, Suite 100 — Street Address
Sarasota, FL 34232 — City, Zip Code; Sarasota — County
(941) 378-3231 — Telephone
Name of Physician or Licensee Reporting: ______
538 — License Number & office registration number, if applicable
Patient's address for Physician or Licensee Reporting: ______

II. PATIENT INFORMATION

11/1/07 — Date of Office Visit
Purpose of Office Visit: ______
Diagnosis: ______
ICD-9 Code for description of incident: — IV Sedation
Level of Surgery (II) or (III)

III. INCIDENT INFORMATION

11/1/07 @ ~~1000am~~ error RR 1100am — Incident Date and Time

Location of Incident: ☒ Operating Rm ☐ Recovery Rm ☐ Other ______

Note: If the incident involved a death, was the medical examiner notified? ☐ Yes ☐ No
Was an autopsy performed? ☐ Yes ☐ No

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete response)

11/1/07 @ 1100 Pt received in PACU ̄p fistulogram. Pt ̄c very ~~[illegible]~~ breathing. Pt somnolent but responsive. Vitals on arrival to PACU 140/74, 94, 32, 99% 3L NC. Pt's nephrologist notified, Dr. Emperio. Discussed pt's condition and it is decided to transport pt to Sarasota Memorial Hospital-ER. EMS arrives @ ~~1015am~~ error 1115am pt tx'd to SMH. Family notified.

1 of 2 pages
Form # DH-MQA1030- created 2-00; revised 3-24-03

B) ICD-9-CM Codes

Surgical, diagnostic, or treatment procedure being performed at time of incident (**ICD-9 Codes 01-99.9**)	Accident, event, circumstances, or specific agent that caused the injury or event. (**ICD-9 E-Codes**)	Resulting injury (**ICD-9 Codes 800-999.9**)

C) List any equipment used if directly involved in the incident
(Use additional sheets as necessary for complete response)

D) Outcome of Incident (Please check)

☐ Death	☐ Surgical procedure performed on the wrong site **
☐ Brain Damage	☐ Wrong surgical procedure performed **
☐ Spinal Damage	☐ Surgical repair of injuries or damage from a planned surgical procedure
☐ Surgical procedure performed on the wrong patient	** if it resulted in
☐ A procedure to remove unplanned foreign objects remaining from surgical procedure	☐ Death ☐ Brain Damage ☐ Spinal Damage ☐ Permanent disfigurement not to include the incision scar
☐ Any condition that required the transfer outcome of the patient to a licensed hospital	☐ Fracture or dislocation of bones or joints ☐ Limitation of neurological, physical, or sensory function; ☐ Any condition that required the transfer outcome of the patient
Outcome of transfer – e.g., death, brain damage, observation only ______ Name of facility to which patient was transferred Sarasota Memorial Hospital	

E) List all persons, including license numbers if licensed, locating information, and the capacity in which they were directly involved with this incident.

Dr Vard ME 68224
Beth Fortunato NX25097
Dr Grubbe ME 103973
Roxanne Rodriguez RN 9204732

F) List witnesses, including license numbers if licensed, and locating information if not listed above

IV. ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response)

B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

V. [signature] ME 103973

SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT **LICENSE NUMBER**

11/1/07 1200

DATE REPORT COMPLETED **TIME REPORT COMPLETED**

Form # DH-MQA1030- created 2-00; revised 3-24-03

600 North Cattlemen Road
Suite 100 - Axcess Center
Sarasota, FL 34232-8410

941-378-3231
941-378-3253 Fax
www.sivr.net

SARASOTA
INTERVENTIONAL
RADIOLOGY
Immediate answers to critical questions.

GERALD E. GRUBBS, MD
Diplomate, American Board of Radiology
Fellowship, Cardiovascular and Interventional Radiology

PATIENT: [redacted]
EXAM DATE: 11/01/2007
PATIENT #: [redacted]
DATE OF BIRTH: [redacted]
REFERRING: Dennis Imperio, MD

EXAMINATION: AV DIALYSIS FISTULOGRAM, RIGHT UPPER EXTREMITY VENOGRAM, AND SUPERIOR VENA CAVAGRAM; CENTRAL INNOMINATE VENOUS ANGIOPLASTY

EXAM LOCATION: SARASOTA INTERVENTIONAL RADIOLOGY

INDICATIONS: The patient with a right upper extremity fistula. The patient previously had a fistulogram, which showed a severe innominate stenosis. This could not be accessed from the arm back in early September. [redacted] did return and from a right common femoral vein access the lesion was successfully crossed and successfully treated to 10 mm. The post angioplasty venogram looked better but it was apparent that the lesion could probably be dilated to 12 or 14 mm. The patient is here for a followup visit.

PROCEDURE CODES:

1. Arteriovenous dialysis fistulogram (36145/75790)
2. Upper extremity venogram.
3. Superior vena cavagram.
4. Selective catheterization of the superior vena cava
5. Superior vena cavagram.
6. Central venous angioplasty (36476/75978)
7. Versed (J2250) - 4 mg
8. Fentanyl (J3010) - 100 mcg
9. Lidocaine (J2001) - 100 mg
10. Nonionic contrast material (Q9949) - 50 cc
11. Saline solution (J2820) - 500 cc

ANESTHESIA: [redacted]

ANESTHESIOLOGIST: Dr. Yard

PROCEDURE: After informed written consent was obtained, the patient was placed supine on the angio interventional table. Intravenous conscious sedation was given and monitored by Oasis Anesthesia Services throughout the procedure.

600 North Cattlemen Road
Suite 100 - Axcess Center
Sarasota, FL 34232-6410

941-378-3231
941-378-3253 Fax
www.sivr.net

SARASOTA
INTERVENTIONAL
RADIOLOGY
Immediate answers to critical questions.

GERALD E. GRUBBS, MD
Diplomate, American Board of Radiology
Fellowship, Cardiovascular and Interventional Radiology

PATIENT:
EXAM DATE: **11/01/2007**
PATIENT #:
DATE OF BIRTH:
REFERRING: **Dennis Imperio, MD**

The arm was sterilely prepped and draped in the standard fashion. 1% lidocaine was used for local anesthesia. A 22-gauge MicroStick needle was used to access the arteriovenous dialysis fistula near the antecubital fossa with the needle tip directed towards the venous anastomosis. A 0.018-inch guidewire was advanced through the needle and the needle was removed. A 4 French sequential dilator was then advanced over the guidewire. Hand injection with digital subtraction imaging was then performed for evaluation of the fistula. The fistula is widely patent. There is dual venous egress through the cephalic and basilic venous system but mostly through the basilic venous system. There is partial duplication of the basilic as well.

Centrally, the axillary and subclavian veins were patent. There had been recurrence of the high-grade innominate vein stenosis. The superior vena cava is patent.

The dilator was then removed and a7 French short sheath was advanced over the guidewire.

A 5 French diagnostic catheter was advanced over the guidewire and this catheter was needed to successfully cross the innominate stenosis. It was very difficult to cross even with an angled catheter, an angled glide wire, and eventually a stiff angled glide wire were necessary to get a glide catheter to actually cross this stenosis.

Once this stenosis was crossed, hand injection with digital subtraction imaging was performed with the catheter in the superior vena cava to make certain that the catheter and guidewire had taken an intraluminal course and not dissected. Once this was confirmed, the stiff angled glide wire was readvanced through the catheter and the catheter was removed. A 12 cm x 4 cm angioplasty balloon was then positioned across the innominate stenosis and two overlapping prolonged inflations were performed.

Followup venography showed good morphologic result and looked identical to the previous post angioplasty pictures.

600 North Cattlemen Road
Suite 100 - Axcess Center
Sarasota, FL 34232-6410

941-378-3231
941-378-3253 Fax
www.sivr.net

SARASOTA
INTERVENTIONAL
RADIOLOGY
Immediate answers to critical questions.

GERALD E. GRUBBS, MD
Diplomate, American Board of Radiology
Fellowship, Cardiovascular and Interventional Radiology

PATIENT:
EXAM DATE: **11/01/2007**
PATIENT #:
DATE OF BIRTH:
REFERRING: **Dennis Imperio, MD**

During the balloon angioplasty procedure, th[redacted] right atrium and the patient had several runs of premature ventricular contractions so the decision was made to terminate all interventions at this point.

The catheters and sheaths were subsequently removed. The patient was transferred to the recovery unit. [redacted] initially was somewhat somnolent due to the large volume of sedation [redacted] received and was somewhat respiratory distressed. EMS was notified. By the time they came the patient was awake, alert, and oriented and having occasional premature ventricular contractions but the decision was made to still transfer [redacted] to Sarasota Memorial Hospital for observation.

IMPRESSION:

1. SUCCESSFUL CENTRAL VENOUS ANGIOPLASTY OF A RECURRENT INNOMINATE STENOSIS AS DESCRIBED ABOVE. A GOOD MORPHOLOGIC RESULT WAS OBTAINED.
2. THE FISTULA ITSELF IS UNREMARKABLE.

Thank you for allowing us to participate in the care of your patient here at Sarasota Interventional Radiology.

THIS REPORT WAS ELECTRONICALLY SIGNED
GERALD E. GRUBBS, M.D.
Board Certified Radiologist

GEG/ly/
DD: 11/01/2007 DT: 11/02/2007

11/7/07 (#34)

#173

STATE OF FLORIDA
Jeb Bush, Governor

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

?✓

SUBMIT FORM TO:
Department of Health, Consumer Services Unit
4052 Bald Cypress Way, Bin C75
Tallahassee, Florida 32399-3275

I. OFFICE INFORMATION

SW FL FACIAL PLASTIC SURGERY ASSOC. INC.
Name of office

9407 CYPRESS LAKE DRIVE STE A
Street Address

FT. MYERS 33919 LEE
City / Zip Code / County

239-437-3900
Telephone

STEPHEN PRENDIVILLE MD
Name of Physician or Licensee Reporting

ME81906
License Number & office registration number, if applicable

9407 CYPRESS LAKE DR. STE. A FT. MYERS, FL 33919
Patient's address for Physician or Licensee Reporting

II. PATIENT INFORMATION

Patient Identification Number

Diagnosis

Age / Gender / Medicaid / Medicare

11/7/07
Date of Office Visit

POST-OP
Purpose of Office Visit

ICD-9 Code for description of incident

III
Level of Surgery (II) or (III)

III. INCIDENT INFORMATION

11/7/07 10Am VISIT
Incident Date and Time

Location of Incident:
☐ Operating Rm ☐ Recovery Rm
☐ Other UNABLE TO IDENTIFY

Note: If the incident involved a death, was the medical examiner notified? ☐ Yes ☐ No
Was an autopsy performed? ☐ Yes ☐ No

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete response)

SEE ATTACHED 11/7/2007 LETTER

07 NOV 13 AM 10:26
CONSUMER SERVICES UNIT

Form # DH-MQA1030- created 2-00; revised 3-24-03

B) ICD-9-CM Codes

041.11
041.10, STAPHYLOCOCCAL AUREUS ~~[illegible]~~ → MRSA

Surgical, diagnostic, or treatment procedure being performed at time of incident (ICD-9 Codes 01-99.9)	Accident, event, circumstances, or specific agent that caused the injury or event. (ICD-9 E-Codes)	~~Resulting injury (ICD-9 Codes 800-999.9)~~

C) List any equipment used if directly involved in the incident
(Use additional sheets as necessary for complete response)

D) Outcome of Incident (Please check)

- ☐ Death
- ☐ Brain Damage
- ☐ Spinal Damage
- ☐ Surgical procedure performed on the wrong patient
- ☐ A procedure to remove unplanned foreign objects remaining from surgical procedure
- ☐ Any condition that required the transfer outcome of the patient to a licensed hospital

Outcome of transfer – e.g., death, brain damage, observation only ____________
Name of facility to which patient was transferred ____________

- ☐ Surgical procedure performed on the wrong site **
- ☐ Wrong surgical procedure performed **
- ☐ Surgical repair of injuries or damage from a planned surgical procedure

** if it resulted in

- ☐ Death
- ☐ Brain Damage
- ☐ Spinal Damage
- ☐ Permanent disfigurement not to include the incision scar
- ☐ Fracture or dislocation of bones or joints
- ☐ Limitation of neurological, physical, or sensory function;
- ☐ Any condition that required the transfer outcome of the patient

E) List all persons, including license numbers if licensed, locating information, and the capacity in which they were directly involved with this incident.

RUTHANN PITARO OFFICE MANAGER

F) List witnesses, including license numbers if licensed, and locating information if not listed above

IV. ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response)

SEE ATTACHED

B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

PT SENT TO DR. LUTAREWYCH (INFECTIOUS DISEASE CONSULT) FOR TREATMENT + IS STILL BEING SEEN DAILY. (SEE NOTES ATTACHED) DR. PACNDWILLE SEEING PT DAILY.

V.

______________ **SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT**

ME 81906 **LICENSE NUMBER**

11- -07 **DATE REPORT COMPLETED**

______________ **TIME REPORT COMPLETED**

Form # DH-MQA1030- created 2-00; revised 3-24-03

prendiville
STEPHEN PRENDIVILLE, MD · FACIAL PLASTIC SURGERY

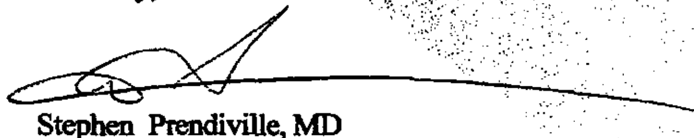
November 7, 2007
Ronica Kluge , MD
RE:

Dear Dr. Kluge,

Thank you for seeing my patient, . is a very nice year old who underwent rhytidectomy (facelift) on 10/30/2007. The procedure was uncomplicated and the patient did well postop. was treated prophylactically with oral ciprofloxacin because is pencillin allergic. On postoperative day 7 (yesterday), the patient presented for suture removal with moderate inflammation and erythma in the submental space and right preauricular region. Needle aspiration of the submental area revealed turbid fluid. The patient was taken back to the OR and the submental incision opened. No frank pus was obtained, but the area was cultured. A penrose drain was left in the submental space. The patient was placed prophylactically on Levaquin and Clindamycin while cultures were pending. The patient returned to my office today with equivalent (not worse) inflammation. However, I would have expected some improvement given course of therapy. The patient revealed that had an ear infection 9/05/07 that was seen by Dr. Laskowski in Naples. A culture from that day revealed heavy growth of Staph aureus (sensitive to oxacillin, bactrim, vanco) and heavy growth of pseudomonas (sensitive to fortaz, imipinem, and zosyn, but resistant to gentamicin, and cipro). was treated with Levaquin and topical otic drops. I am concerned that the infectious process involving right ear was not completely treated and this may be a source of infection after facelift. I would ask that you evaluate for treatment with intravenous antibiotics pending culture results. I have also given a script for oral bactrim. I will follow up with closely.

Please do not hesitate to call me if you have any questions.

Sincerely,



Stephen Prendiville, MD

9407 Cypress Lake Drive, Suite A • Fort Myers, Florida 33919 • tel: 239.437.3900 • fax: 239.437.3969
www.drprendiville.com

11/14/07 #35

#174

STATE OF FLORIDA
Jeb Bush, Governor

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

SUBMIT FORM TO:
Department of Health, Consumer Services Unit
4052 Bald Cypress Way, Bin C75
Tallahassee, Florida 32399-3275

RECEIVED CONSUMER SERVICES UNIT 07 ... 8:53

I. OFFICE INFORMATION

Sarasota Interventional Radiology — Name of office
600 N. Cattlemen Rd — Street Address
Sarasota 34232 Sarasota — City, Zip Code, County
941-378-3231 — Telephone
Dr. Gerald Grubbs — Name of Physician or Licensee Reporting
License Number & office registration number, if applicable
Patient's address for Physician or Licensee Reporting

II. PATIENT INFORMATION

Patient Name
Age Gender Medicaid Medicare
Patient's Address
Date of Office Visit 11-14-07
Patient Identification Number
Purpose of Office Visit
Diagnosis
ICD-9 Code for description of incident
Level of Surgery (II) or (III)

III. INCIDENT INFORMATION

11/14/07 — Incident Date and Time

Location of Incident:
☐ Operating Rm ☐ Recovery Rm
☒ Other CT SCAN

Note: If the incident involved a death, was the medical examiner notified? ☐ Yes ☐ No
Was an autopsy performed? ☐ Yes ☐ No

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete response)

Pt was positioned prone on CT table and scanned for procedure. Upon start of procedure - Dr. Laura Yard gave patient [redacted]. after several minutes pt began dropping SaO_2 rate. At that pt procedure was stopped pt removed from scanner and placed supine on stretcher. Vial signs were monitored at all times. Pt [redacted] own but HR c̄ BP were WNL. We started breathing for [redacted] using Ambu bag & oral airway & 911 was called. [redacted] was then transferred by EMS.

Form # DH-MQA1030- created 2-00; revised ...

B) ICD-9-CM Codes

Surgical, diagnostic, or treatment procedure being performed at time of incident (ICD-9 Codes 01-99.9)	Accident, event, circumstances, or specific agent that caused the injury or event. (ICD-9 E-Codes)	Resulting Injury (ICD-9 Codes 800-999.9)

C) List any equipment used if directly involved in the incident
(Use additional sheets as necessary for complete response)
NONE

D) Outcome of incident (Please check)

☐ Death	☐ Surgical procedure performed on the wrong site **
☐ Brain Damage	☐ Wrong surgical procedure performed **
☐ Spinal Damage	☐ Surgical repair of injuries or damage from a planned surgical procedure
☐ Surgical procedure performed on the wrong patient	** if it resulted in
☐ A procedure to remove unplanned foreign objects remaining from surgical procedure	☐ Death ☐ Brain Damage ☐ Spinal Damage ☐ Permanent disfigurement not to include the incision scar
☒ Any condition that required the transfer outcome of the patient to a licensed hospital	☐ Fracture or dislocation of bones or joints ☐ Limitation of neurological, physical, or sensory function;
Outcome of transfer – e.g. death, brain damage, observation only [redacted] Name of facility to which patient was transferred Doctors Hospital	☐ Any condition that required the transfer outcome of the patient

E) List all persons, including license numbers if licensed, locating information, and the capacity in which they were directly involved with this incident.

Dr Laura Yard - Anest
Dr Gerald Grubbs - Radiologist
Chris Howes - Rad Tech 39938

F) List witnesses, including license numbers if licensed, and locating information if not listed above

IV. ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response)

B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

V. [signature] 63973

SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT — LICENSE NUMBER

DATE REPORT COMPLETED — TIME REPORT COMPLETED

Form # DH-MQA1030- created 2-00; revised 3-24-03

600 North Cattlemen Road
Suite 100 - Axcess Center
Sarasota, FL 34232-6410

941-378-3231
941-378-3253 Fax
www.sivr.net

SARASOTA
INTERVENTIONAL
RADIOLOGY
Immediate answers to critical questions.

GERALD E. GRUBBS, MD
Diplomate, American Board of Radiology
Fellowship, Cardiovascular and Interventional Radiology

PATIENT:
EXAM DATE: **11/14/2007**
PATIENT #:
DATE OF BIRTH:
REFERRING: **James E. Knapp, MD**

EXAMINATION: CT GUIDED T12 THORACIC VERTEBROPLASTY

EXAM LOCATION: SARASOTA INTERVENTIONAL RADIOLOGY

INDICATIONS: The patient with prior T7 vertebroplasty. The patient with new onset back pain and recent diagnosis of a T12 compression fracture.

PROCEDURE CODES:

1. Thoracic vertebroplasty (22520-)
2. CT guidance for needle placement (77012)
3. Versed (J2250) - 3 mg
4. Fentanyl (J3010) - 200 mcg

ANESTHESIA: Level II conscious sedation

ANESTHESIOLOGIST: Dr. Yard

PROCEDURE: After informed written consent was obtained, the patient was placed prone on the CT gantry table. Localizing images were obtained through the back. Safe left sided transpedicular access site was selected.

was given and monitored by Oasis Anesthesia Services throughout the procedure as described above.

The back was sterilely prepped and draped in the standard fashion. 025% Marcaine was used for superficial and deep anesthesia.

As the transpedicular needle was being advanced, the patient's 02 saturations dropped and the patient became tachycardic. This required aborting the procedure so the patient could be rolled in a supine position and an oral airway was created and the patient was oxygenated using an Ambu bag. 911 was subsequently consulted and the patient was transferred to Doctors Hospital. Once anesthesia wore off was discharged the same day.

We will make arrangements for the patient to return in the near future for completion of the T12 vertebroplasty.

600 North Cattlemen Road
Suite 100 - Axcess Center
Sarasota, FL 34232-6410

941-378-3231
941-378-3253 Fax
www.sivr.net

SARASOTA
INTERVENTIONAL
RADIOLOGY
Immediate answers to critical questions.

GERALD E. GRUBBS, MD
Diplomate, American Board of Radiology
Fellowship, Cardiovascular and Interventional Radiology

PATIENT: [redacted]
EXAM DATE: **11/14/2007**
PATIENT #: [redacted]
DATE OF BIRTH: [redacted]
REFERRING: **James E. Knapp, MD**

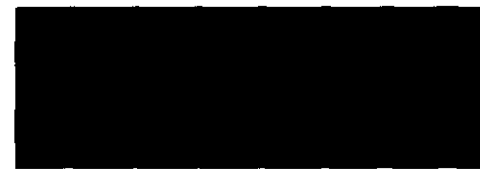
IMPRESSION:
ABORTED T12 VERTEBROPLASTY [redacted] PLEASE SEE DISCUSSION ABOVE.

Thank you for allowing us to participate in the care of your patient here at Sarasota Interventional Radiology.

THIS REPORT WAS ELECTRONICALLY SIGNED
GERALD E. GRUBBS, M.D.
Board Certified Radiologist

GEG/ly/[redacted]
DD: 11/18/2007 DT: 11/19/2007

11/30/07 (#30)



#35

STATE OF FLORIDA
Charlie Crist, Governor

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

SUBMIT FORM TO:
Department of Health, Consumer Services Unit
4052 Bald Cypress Way, Bin C75
Tallahassee, Florida 32399-3275

I. OFFICE INFORMATION

Name of office: PLASTIC SURGERY SPECIALISTS OF SOUTH FL.

Street Address: 1150 N. 35th AVE, #550

City: HOLLYWOOD Zip Code: 33021 County: BROWARD

Telephone: 954 987 8100

Name of Physician or Licensee Reporting: YOAV BARNAVON

License Number & office registration number, if applicable: OSR 25

Patient's address for Physician or Licensee Reporting: SEE BELOW

II. PATIENT INFORMATION

Age Gender Medicaid Medicare

Patient Identification Number

Diagnosis

Date of Office Visit: 11/30/07

Purpose of Office Visit

ICD-9 Code for description of incident: 427.5

Level of Surgery (II) or (III): III

III. INCIDENT INFORMATION

Incident Date and Time: 11/30/07 · 11:35 AM – 12 NOON

Location of Incident:
☒ Operating Room ☐ Recovery Room
☐ Other________

Note: If the incident involved a death, was the medical examiner notified? ☒ Yes ☐ No
Was an autopsy performed? ☒ Yes ☐ No

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete response)

SEE ATTACHED

07 DEC 17 AM 11:38

B) ICD-9-CM Codes

(CPT) 19326-50	UNDETERMINED	427.5
Surgical, diagnostic, or treatment procedure being performed at time of incident (ICD-9 Codes 01-99.9)	Accident, event, circumstances, or specific agent that caused the injury or event. (ICD-9 E-Codes)	Resulting Injury (ICD-9 Codes 800-999.9)

C) List any equipment used if directly involved in the incident
(Use additional sheets as necessary for complete response)

N A

D) Outcome of Incident (Please check)

☐ Death	☐ Surgical procedure performed on the wrong site **
☐ Brain Damage	☐ Wrong surgical procedure performed **
☐ Spinal Damage	☐ Surgical repair of injuries or damage from a planned surgical procedure.
☐ Surgical procedure performed on the wrong patient.	** If it resulted in: ☐ Death ☐ Brain Damage ☐ Spinal Damage ☐ Permanent disfigurement not to include the incision scar ☐ Fracture or dislocation of bones or joints ☐ Limitation of neurological, physical, or sensory function. ☐ Any condition that required the transfer of the patient to a hospital.
☐ A procedure to remove unplanned foreign objects remaining from surgical procedure.	
■ Any condition that required the transfer of the patient to a hospital.	
Outcome of transfer – e.g. death, brain damage, observation only [redacted] Name of facility to which patient was transferred: MEMORIAL REGIONAL HOSPITAL	

E) List all persons, including license numbers if licensed, locating information and the capacity in which they were involved in this incident, this would include anesthesiologist, support staff and other health care providers.

YOAV BARNAVON MD, SURGEON ME 47713
SHIMON CARMEL MD, ANAESTHESIOLOGIST, ME 41639, MEMORIAL REG HO[illegible]
TASHA NUNZIATO RN, CIRCULATING/RECOVERY, RN 2870442, 365 SE 9 [illegible] DANIA BE[illegible] 33004
PAM MARTINDALE, SURGICAL TECH, 1470 NW 122nd AVE PEMBROKE PINES FL 33026

F) List witnesses, including license numbers if licensed, and locating information if not listed above

IV. ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response)

SEE ATTACHED

B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

SEE ATTACHED

V. [signature]
SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT

ME 47713
LICENSE NUMBER

12/14/07
DATE REPORT COMPLETED

900 AM
TIME REPORT COMPLETED

III A. Circumstances of the Incident

A year old healthy appearing female first presented to my office on 4-19-05 for consultation regarding breast augmentation. She was seen for a second consultation two years later and thereafter scheduled surgery. She disclosed a history of smoking five cigarettes per day (which she promised to quit for five weeks prior to surgery) and had a remote history of bronchitis. The patient denied any other medical conditions. She did report a penicillin allergy which manifested as a rash.

She was seen in my office on November 19, 2007 for a preoperative history and physical exam. Her preoperative laboratory evaluation, which consisted of a CBC and urine pregnancy test, revealed a slightly decreased hemoglobin/hematocrit (11.3/32.9 with normal being 12/36). This is not uncommon in menstruating females. All other values were normal. She was classified as an due to a history of smoking.

On November 30, 2007, the patient presented for bilateral transaxillary augmentation mammoplasty in my office surgical facility. She was interviewed preoperatively by our MD anesthesiologist and our surgical RN as well as me. Baseline vital signs on the day of surgery were: BP 99/52, heart rate 70, and regular respirations of 18 per minute.

After obtaining a complete and informed consent, marking and examining the patient in an examination room, the patient was taken to the operating room. Level III anesthesia was administered by anesthesiologist Shimon Carmel, MD, using (LMA). Anesthesia administration began at 9:45 am. The patient received a test dose of cefazolin followed by one gram IV without any apparent adverse effect.

Surgery began at 10:08 am and was uneventful until approximately 11:35am, when near the end of the case, the anesthesiologist asked me to stop. He He advised me to perform a She had rebound tachycardia and increased blood pressure. The patient maintained 100% oxygen saturation throughout the surgery. The Dressings were applied and arrangements were being made for transfer to the hospital for overnight observation.

As the patient Medications were administered by the anesthesiologist and the patient regained a pulse. 911 was called at 11:57 am. A foley catheter was inserted and the patient received 20 mg of Lasix x 2 doses.

As the patient was now stabilized, I spoke to the patient's in my office about the impending emergency medical transfer to the hospital. The patient suddenly deteriorated again and resuscitation efforts were ongoing when EMS arrived. The patient was then

transferred to Memorial Regional Hospital's ER while being ventilated with an Ambu bag and having a rapid but present pulse. The anesthesiologist accompanied the patient in the emergency vehicle and I joined them in the ER as the hospital and my medical office building are physically connected.

Upon arrival at the emergency room, the patient did not have a pulse but was successfully resuscitated again by the ER staff. The patient's condition over the next several hours remained unstable. Labs drawn in the ER showed a potassium level of 2.5 and acidosis.

During this time, family members began arriving in the ER and the patient's [redacted] then revealed that the patient was bulimic. At that time, another family member confirmed a history of self-induced vomiting.

Despite extensive resuscitative measures over a period of four hours, the patient's condition continued to deteriorate. The patient was eventually transferred to the ICU where shortly thereafter, she expired at 5:09 pm. The medical examiner was notified. The results of the autopsy are pending at this time.

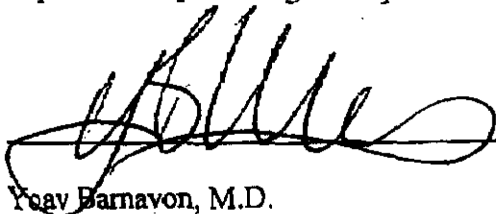
IV. Analysis and Corrective Action

As soon as possible after the event, I met with the anesthesiologist and the pulmonologist/intensivist who ran the code to discuss this incident. The office facility healthcare risk manager was notified to ensure compliance with state reporting requirements.

Although the cause of death is still undetermined, based on my conversations with the above practitioners, it was considered [redacted] which resulted in the sequence of events that led to her eventual tragic demise.

This unfortunate incident revealed a lack of communication by the patient with the healthcare practitioners responsible for her care. Under routine circumstances, a [redacted] year old, healthy individual for this procedure would not require any further work up than was done. Had the patient's bulimia been disclosed, she would not have been considered a candidate for surgery. In my 15 years of office surgical practice I have never had a patient death in the office or at the hospital subsequent to an office procedure performed.

In view of this case, we have intensified our efforts to educate our patients regarding the importance of providing a complete history.



12/14/07

Yoav Barnavon, M.D. Date

STATE OF FLORIDA
Jeb Bush, Governor

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

SUBMIT FORM TO:
Department of Health, Consumer Services Unit
4052 Bald Cypress Way, Bin C75
Tallahassee, Florida 32399-3275

07 DEC -5 AM 10:16
CONSUMER SERVICES UNIT
RECEIVED

I. OFFICE INFORMATION

the Back Center - Brevard Orthopaedic.
Name of office

315 E NASA Blvd
Street Address

Melbourne 32901 Brevard
City Zip Code County

321 723 7716
Telephone

Dr L. Voepel
Name of Physician or Licensee Reporting

ME 85032
License Number & office registration number, if applicable

SAME
Patient's address for Physician or Licensee Reporting

II. PATIENT INFORMATION

Patient Name

[redacted]
Diagnosis

Age Gender Medicaid Medicare

11-28-07.
Date of Office Visit

Purpose of Office Visit

ICD-9 Code for description of incident

Level of Surgery (II) or (III)

III. INCIDENT INFORMATION

11-28-07 14[10]
Incident Date and Time

Location of Incident:
☐ Operating Rm ☐ Recovery Rm
☑ Other pre op area.

Note: If the incident involved a death, was the medical examiner notified? ☐ Yes ☐ No
Was an autopsy performed? ☐ Yes ☐ No

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete response)

14[10] Pt entered pre-op area c/o shakiness, lightheadedness knees weak, dizziness, tremors + pt unable to walk to room. Assist to sit on floor. Slight tremors persisted VS 98/74 - 128 - 28 O2 92 FSBS 132.
Dr Voepel in attendance.
14[15] Responsive, speech sl. slurred 911 called. 98/78 104 - 28 O2 94
14[30] Pt transported to Holmes Regional Med Center via squad.

Form # DH-MQA1030- created 2-00; revised 3-24-03

B) ICD-9-CM Codes

724.2 724.6		
Surgical, diagnostic, or treatment procedure being performed at time of incident **(ICD-9 Codes 01-99.9)**	Accident, event, circumstances, or specific agent that caused the injury or event. **(ICD-9 E-Codes)**	Resulting injury **(ICD-9 Codes 800-999.9)**

C) List any equipment used if directly involved in the incident
(Use additional sheets as necessary for complete response)

D) Outcome of Incident (Please check)

☐ Death	☐ Surgical procedure performed on the wrong site **
☐ Brain Damage	☐ Wrong surgical procedure performed **
☐ Spinal Damage	☐ Surgical repair of injuries or damage from a planned surgical procedure
☐ Surgical procedure performed on the wrong patient	** if it resulted in
☐ A procedure to remove unplanned foreign objects remaining from surgical procedure	☐ Death ☐ Brain Damage ☐ Spinal Damage ☐ Permanent disfigurement not to include the incision scar
☑ Any condition that required the transfer outcome of the patient to a licensed hospital	☐ Fracture or dislocation of bones or joints ☐ Limitation of neurological, physical, or sensory function; ☐ Any condition that required the transfer outcome of the patient
Outcome of transfer – e.g., death, brain damage, observation only ____ Name of facility to which patient was transferred ____	

E) List all persons, including license numbers if licensed, locating information, and the capacity in which they were directly involved with this incident.

Debbie Hambel RN RN2785252
JoJo MacDonald ARNP 46009
Maureen Douglas RN 2069822
Dr L Voepel - ME85032

F) List witnesses, including license numbers if licensed, and locating information if not listed above

IV. ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response)

Syncopal episode vs seizure.

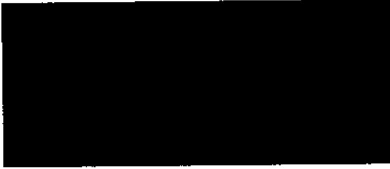
B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

Pt adv to see PCP for workup & clearance prior to next injection

V.

[signature]	ME85032
SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT	**LICENSE NUMBER**
11-28-07	1515
DATE REPORT COMPLETED	**TIME REPORT COMPLETED**

Form # DH-MQA1030- created 2-00; revised 3-24-03



STATE OF FLORIDA
Jeb Bush, Governor

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

SUBMIT FORM TO:
Department of Health, Consumer Services Unit
4052 Bald Cypress Way, Bin C75
Tallahassee, Florida 32399-3275

I. OFFICE INFORMATION

Sarasota Interventional Radiology
Name of office

Sarasota 34232 Sarasota
City Zip Code County

Dr. Grubbs
Name of Physician or Licensee Reporting

Patient's address for Physician or Licensee Reporting

600 North Cattlemen Rd
Street Address Sarasota, FL 34232

941-378-3231
Telephone

License Number & office registration number, if applicable

II. PATIENT INFORMATION

Patient's Address

Patient Identification Number

Diagnosis

Age Gender Medicaid/Medicare

11/13/07
Date of Office Visit

Angiogram with ...
Purpose of Office Visit

ICD-9 Code for description of incident

Level of Surgery (II) or (III)

III. INCIDENT INFORMATION

11/13/07 @1540
Incident Date and Time

Location of Incident:
☐ Operating Rm ☑ Recovery Rm
☐ Other ______

Note: If the incident involved a death, was the medical examiner notified? ☐ Yes ☐ No
Was an autopsy performed? ☐ Yes ☐ No

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete response)

Request and given bedpan @ 1530. Requested to remain on bedpan. 1540 - Removed bedpan with 3/4 full of jellied/gelatinous dark Burgundy substance noted. BP 10/54; HR 83; Sat 100% ō O2 NC @ 2L; Resp 18. denied pain or dizziness or shortness of breath. Call placed to Dr. J. Larkin @ 1545. Call placed to 911 immediately upon speaking ō Dr. Larkin 2nd Bedpan full of same above listed substance. EMS arrived @ 1555. Taken to Hospital (Sarasota Memorial) @ 1605

Form # DH-MQA1030- created 2-00; revised 3-24-03

RECEIVED DEC -3 CONSUMER SERVICES

B) ICD-9-CM Codes

Surgical, diagnostic, or treatment procedure being performed at time of incident (ICD-9 Codes 01-99.9)	Accident, event, circumstances, or specific agent that caused the injury or event. (ICD-9 E-Codes)	Resulting Injury (ICD-9 Codes 800-999.9)

C) **List any equipment used if directly involved in the incident**
(Use additional sheets as necessary for complete response)

D) **Outcome of Incident** (Please check)

☐ Death	☐ Surgical procedure performed on the wrong site **
☐ Brain Damage	☐ Wrong surgical procedure performed **
☐ Spinal Damage	☐ Surgical repair of injuries or damage from a planned surgical procedure
☐ Surgical procedure performed on the wrong patient	** if it resulted in
☐ A procedure to remove unplanned foreign objects remaining from surgical procedure	☐ Death ☐ Brain Damage ☐ Spinal Damage ☐ *Permanent disfigurement not to include the* incision scar ☐ Fracture or dislocation of bones or joints ☐ Limitation of neurological, physical, or sensory function; ☐ Any condition that required the transfer outcome of the patient
☒ Any condition that required the transfer outcome of *the patient to a licensed hospital* Outcome of transfer – e.g., death, brain damage, observation only ______ Name of facility to which patient was transferred ______	

E) **List all persons, including license numbers if licensed, locating information, and the capacity in which they were directly involved with this incident.**

Dianne McBroom ; Roxanne Rodriguez; Dr. Yard; Amy Sherry
Chris Howes RN(RT)(CT(E)

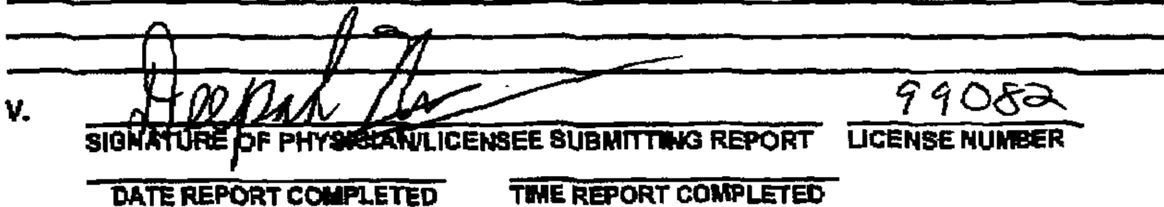
F) **List witnesses, including license numbers if licensed, and locating information if not listed above**

Same as above

IV. ANALYSIS AND CORRECTIVE ACTION

A) **Analysis (apparent cause) of this incident** (Use additional sheets as necessary for complete response)

B) **Describe corrective or proactive action(s) taken** (Use additional sheets as necessary for complete response)



V. SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT — LICENSE NUMBER 99082

DATE REPORT COMPLETED — TIME REPORT COMPLETED

Form # DH-MQA1030- created 2-00; revised 3-24-03

SAMSON SHOWALTER LEPORE
vascular specialists

PATIENT: [redacted]
EXAM DATE: 11/13/2007
PATIENT #: [redacted]
DATE OF BIRTH: [redacted]
PHYSICIAN: Michael R. Lepore, M.D.

EXAMINATION: ANGIOGRAM

EXAM LOCATION: Sarasota Interventional Radiology

PREOPERATIVE DIAGNOSIS:

1. Pancreatic cancer.
2. Left lower extremity ischemia with gangrene.
3. Right lower extremity ischemia with claudication.
4. Prostate cancer.

POST OPERATIVE DIAGNOSIS: Same.

PROCEDURE:

1. Ultrasound assisted right femoral arterial puncture.
2. Aortogram.
3. Bilateral lower extremity runoff.
4. Selective catheterization of left superficial femoral artery.
5. Selective views through catheter and left superficial femoral artery of below knee popliteal/tibial vessels.
6. Catheter withdrawn into right external iliac with selective angiogram.

DETAILS OF PROCEDURE: After informed consent was obtained, the patient was taken to the Interventional Suite and prepped and draped in the standard surgical fashion. after anesthesia was established [redacted] (10 cc of 1% lidocaine) into the right groin and [redacted] of over 30 minutes duration a micropuncture needle was used to obtain access to the patient's right femoral artery. This was quite easy to do. A wire was then placed in the patient's abdominal aorta under fluoroscopic guidance. A micropuncture catheter was then placed and a glidewire was placed over this. A 4 French catheter was then placed and over the glidewire an omni flush catheter was then placed in the patient's abdominal aorta. An abdominal aortogram was obtained and heavily calcified origins of both renals were seen but they were widely patent. The aorta had no evidence of any aneurysm. There is no evidence of any aortic stenosis.

RUSSELL H. SAMSON, MD, FACS, RVT • DAVID P. SHOWALTER, MD, FACS • MICHAEL R. LEPORE JR., MD, FACS • RICARDO E. MORALES, RVT, PA-C • TRICIA HERMANS, PA-C • KIM E. SCHLOSBERG, PA-

600 North Cattleman Road, Suite 220, Sarasota, FL 34232
Tel: 941-371-6565 • Fax: 941-377-7731
www.veinsandarteries.com

SAMSON SHOWALTER LEPORE
vascular specialists

PATIENT: [redacted]
EXAM DATE: **11/13/2007**
PATIENT #: [redacted]
DATE OF BIRTH: [redacted]
PHYSICIAN: ***Michael R. Lepore, M.D.***

The catheter was then placed at the aortic bifurcation and an aortogram with runoff was then done. This revealed calcified vessels that were patent up to the below knee segment. The vessels in the left below knee revealed multiple stenoses and occlusions that were difficult to see. The selective catheterization was then done of the left superficial femoral artery from the right using a glidewire and the omni flush catheter. Selective injections were done in multiple views which revealed a patent distal superficial femoral artery, patent popliteal artery but heavily diseased tibial. The anterior tibial had a 2 cm length occlusion with multiple collaterals. Peroneal occluded after its origin. The posterior tibial had multiple segments of stenoses as well as occlusion. The last occlusion was approximately 10 cm long. The runoff into the foot was by way of the left anterior tibial.

The catheter was then withdrawn to the patient's right external iliac artery and angiogram revealed patent common iliac, external iliac, common femoral artery. The stick site was in the common femoral artery. A star close device was used for percutaneous closure of our arteriotomy.

FINDINGS:

1. Bilateral single renal vessels that are widely patent.
2. Calcified aorta with no stenoses or aneurysms.
3. Patent common iliac, external iliac, and internal iliac arteries bilaterally.
4. *Patent but mildly calcified superficial femoral, common femoral, and deep* profunda femoral bilaterally.
5. Patent mildly calcified superficial femoral and popliteal vessels bilaterally.
6. On the left lower extremity, anterior tibial artery occlusion 3 cm for a segment with multiple stenoses within it. Runoff to the foot is by way of the anterior tibial providing collateral into the foot. The posterior tibial artery is occluded for nearly 10 cm and has multiple segments of stenosis prior to that after its takeoff.
7. The peroneal artery occludes shortly after its takeoff and does not reconstitute in the lower leg.
8. In the right lower extremity, there only exists a peroneal artery, which is the main runoff into the foot.

RUSSELL H. SAMSON, MD, FACS, RVT • DAVID P. SHOWALTER, MD, FACS • MICHAEL R. LEPORE JR., MD, FACS • RICARDO E. MORALES, RVT, PA-C • TRICIA HERMANS, PA-C • KIM E. SCHLOSBERG, PA-C

600 North Cattlemen Road, Suite 220, Sarasota, FL 34232
Tel: 941-371-6565 • Fax: 941-377-7731
www.veinsandarteries.com

PATIENT: [redacted]
EXAM DATE: 11/13/2007
PATIENT #: [redacted]
DATE OF BIRTH: [redacted]
PHYSICIAN: **Michael R. Lepore, M.D.**

Thank you for allowing us to participate in the care of your patient.

THIS REPORT WAS ELECTRONICALLY SIGNED
DEEPAK G. NAIR, MD

DGN/ly/[redacted]
DD: 11/13/2007 DT: 11/13/2007

RUSSELL H. SAMSON, MD, FACS, RVT • DAVID P. SHOWALTER, MD, FACS • MICHAEL R. LEPORE JR., MD, FACS • RICARDO E. MORALES, RVT, PA-C • TRICIA HERMANS, PA-C • KIM E. SCHLOSBERG, PA-

600 North Cattlemen Road, Suite 220, Sarasota, FL 34232
Tel: 941-371-6565 • Fax: 941-377-7731
www.veinsandarteries.com

STATE OF FLORIDA
Jeb Bush, Governor

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

SUBMIT FORM TO:
Department of Health, Consumer Services Unit
4052 Bald Cypress Way, Bin C75
Tallahassee, Florida 32399-3275

I. OFFICE INFORMATION

Cardiology Consultants, PA
Name of office

6151 N. 9th. Ave. Ste. 200
Street Address

Pensacola 32504 Escambia
City Zip Code County

850-857-1700
Telephone

Nancy A. Biddlehoover RN, BSN.
Name of Physician or Licensee Reporting

N/A
License Number & office registration number, if applicable

N/A
Patient's address for Physician or Licensee Reporting

II. PATIENT INFORMATION

Patient Identification Number

Age Gender Medicaid Medicare

11-02-2007
Date of Office Visit

CAD, Paroxysmal Atrial Fibrillation,
Diagnosis S/P Ventricular Fibrillation Arrest.

Purpose of Office Visit
427.1 and 427.5
ICD-9 Code for description of incident

NA
Level of Surgery (II) or (III)

III. INCIDENT INFORMATION

11-02-2007 9:33 AM
Incident Date and Time

Location of Incident:
☐ Operating Rm ☐ Recovery Rm
☑ Other Physician's Office Stress Lab

Note: *If the incident involved a death, was the medical examiner notified?* ☐ Yes ☐ No
Was an autopsy performed? ☐ Yes ☐ No

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete response)

See Attached

Form # DH-MQA1030- created 2-00; revised 3-24-03

B) ICD-9-CM Codes

93015	NONE	NONE
Surgical, diagnostic, or treatment procedure being performed at time of incident (ICD-9 Codes 01-99.9)	Accident, event, circumstances, or specific agent that caused the injury or event. (ICD-9 E-Codes)	Resulting injury (ICD-9 Codes 800-999.9)

C) List any equipment used if directly involved in the incident
(Use additional sheets as necessary for complete response)
N/A

D) Outcome of Incident (Please check)

☐ Death	☐ Surgical procedure performed on the wrong site **
☐ Brain Damage	☐ Wrong surgical procedure performed **
☐ Spinal Damage	☐ Surgical repair of injuries or damage from a planned surgical procedure
☐ Surgical procedure performed on the wrong patient	** if it resulted in
☐ A procedure to remove unplanned foreign objects remaining from surgical procedure	☐ Death ☐ Brain Damage ☐ Spinal Damage ☐ Permanent disfigurement not to include the incision scar
☑ Any condition that required the transfer outcome of the patient to a licensed hospital	☐ Fracture or dislocation of bones or joints ☐ Limitation of neurological, physical, or sensory function;
Outcome of transfer – e.g., death, brain damage, observation only ______ Name of facility to which patient was transferred Sacred Heart Hospital	☐ Any condition that required the transfer outcome of the patient

E) List all persons, including license numbers if licensed, locating information, and the capacity in which they were directly involved with this incident.

Elias G. Skoufis, MD FACC ME 76085, 5151 N. 9th Ave. Suite 200 Pensacola. Diagnostic Covering MD-
Patricia Parsons, RN 2975422, 5151 N. 9th Ave Suite 200 Pensacola. Nurse - Primary Nurse
Tina Hamilton Cerullo RN 9196234, 5151 N. 9th Ave Suite 200 Pensacola, Nurse - Assisting Nurse)
Maureen Kruse, ARNP 9247493, 5151 N. 9th Ave Suite 200 Pensacola, ARNP - Assist c̄ Code
Douglas S. Baker, PA-C 9102852, 5151 N. 9th Ave. Suite 200 Pensacola, PA-C - Assist c̄ Code.

F) List witnesses, including license numbers if licensed, and locating information if not listed above

______

IV. ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response)

See Attached

B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

See Attached

V. Nancy A. Kidlehoover [signature] — SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT

137742 — LICENSE NUMBER

Feb 13, 2008 — DATE REPORT COMPLETED

2 pm — TIME REPORT COMPLETED

Form # DH-MQA1030- created 2-00; revised 3-24-03

III. Incident Information

A) Describe circumstances of the incident (narrative)

Patient in office for Nuclear GXT. Baseline EKG showed normal sinus rhythm with resting heart rate of 57 bpm. Exercised on treadmill for (4) minutes when rhythm changed from sinus tachycardia to ventricular fibrillation versus polymorphic ventricular tachycardia. The patient was assisted to the ground. ██ lost consciousness, blood pressure and pulse.

IV. Analysis and Corrective Action

A) Analysis (apparent cause) of this incident

This is a known and consented complication of graded exercise testing.

B) Describe corrective or proactive action(s) taken

Bag and mask ventilation and chest compressions were immediately started. The patient was defibrillated with 200 joules with continued ventricular fibrillation and then with 300 joules, and concurrently ██ was also given 1 mg of epinephrine. Atrial fibrillation rhythm noted at 120 bpm with a palpable pulse, BP 140/72. Patient regained consciousness. Oxygen at 100% per non-rebreathing mask in place. Baby Aspirin (4) tabs given by mouth. Nitroglycerine 0.4mg. sublingually administered. Patient transferred via EMS to Hospital Emergency Dept. and scheduled for same day cardiac catheterization and cardioversion. Cardiac Cath results: Severe three vessel coronary artery disease. Preserved left ventricular function. Successful D/C cardioversion from atrial fibrillation to NSR.
Patient had successful Coronary Artery bypass grafting times five on 11-05-07 and tolerated the procedure well. Discharged from hospital on 11-10-07.

STATE OF FLORIDA
Jeb Bush, Governor

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

SUBMIT FORM TO:
Department of Health, Consumer Services Unit
4052 Bald Cypress Way, Bin C75
Tallahassee, Florida 32399-3275

I. OFFICE INFORMATION

Cardiology Consultants, PA
Name of office

5151 North 9th Ave. Suite 200
Street Address

Pensacola 32504 Escambia
City Zip Code County

850-857-1700
Telephone

Nancy A. Ridlehoover, RN BSN
Name of Physician or Licensee Reporting

N/A
License Number & office registration number, if applicable

N/A
Patient's address for Physician or Licensee Reporting

II. PATIENT INFORMATION

Age Gender Medicaid Medicare

11-16-07
Date of Office Visit

Patient Identification Number

Purpose of Office Visit

Diagnosis

427.89
ICD-9 Code for description of incident

N/A
Level of Surgery (II) or (III)

III. INCIDENT INFORMATION

11-16-2007 @ 11:28 AM
Incident Date and Time

Location of Incident:
☐ Operating Rm ☐ Recovery Rm
☑ Other Physician's Office

Note: If the incident involved a death, was the medical examiner notified? ☐ Yes ☐ No
Was an autopsy performed? ☐ Yes ☐ No

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete response)

See Attachment

Form # DH-MQA1030- created 2-00; revised 3-24-03

B) ICD-9-CM Codes

78465	None	None
Surgical, diagnostic, or treatment procedure being performed at time of incident (ICD-9 Codes 01-99.9)	Accident, event, circumstances, or specific agent that caused the injury or event. (ICD-9 E-Codes)	Resulting Injury (ICD-9 Codes 800-959.9)

C) List any equipment used if directly involved in the incident (Use additional sheets as necessary for complete response).

N/A

D) Outcome of Incident (Please check)

- ☐ Death
- ☐ Brain Damage
- ☐ Spinal Damage
- ☐ Surgical procedure performed on the wrong patient
- ☐ A procedure to remove unplanned foreign objects remaining from surgical procedure
- ☑ Any condition that required the transfer outcome of the patient to a licensed hospital

Outcome of transfer – e.g., death, brain damage, observation only ______

Name of facility to which patient was transferred: Sacred Heart Hospital - Pensacola, Florida

- ☐ Surgical procedure performed on the wrong site **
- ☐ Wrong surgical procedure performed **
- ☐ Surgical repair of injuries or damage from a planned surgical procedure

** if it resulted in

- ☐ Death
- ☐ Brain Damage
- ☐ Spinal Damage
- ☐ Permanent disfigurement not to include the incision scar
- ☐ Fracture or dislocation of bones or joints
- ☐ Limitation of neurological, physical, or sensory function.
- ☐ Any condition that required the transfer outcome of the patient

E) *List all persons, including license numbers if licensed, locating information, and the capacity in which they were directly involved with this incident.*

Thomas D. Paine, MD, FACC ME 87460, 5151 N. 9th Ave Suite 200 Pensacola (Responding Physician)
Robert H. Spencer, MD, FACC ME 95966, 5151 N 9th Ave Suite 200 Pensacola (Responding Physician)
Jill Short, RN 5151 N. 9th Ave Suite 200 Pensacola, EP-[illegible] [illegible]
[illegible] RN-[illegible], 5151 N 9th Ave, Suite 200 Pensacola, [illegible]

F) List witnesses, including license numbers if licensed, and locating information if not listed above

As Above

IV. ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response)

See attachment

B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

See Attachment

V. Nancy A. Hillhouse ______ 137742

SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT — LICENSE NUMBER

Jan. 14, 2008 — 10:57 Am

DATE REPORT COMPLETED — TIME REPORT COMPLETED

Form # DH-MQA1030- created 2-00, revised 5-24-03

Description of circumstances of the incident:

Patient . Resting EKG demonstrated a sinus rhythm at a rate of 62 with borderline first degree AV block. There is an incomplete left bundle branch block with diffuse ST-T wave changes. Patient has ICD. exercised on the treadmill 7 minutes and 9 seconds reaching a heart rate of 136 bpm before developing
The patient did not lose consciousness but received a total of five (5) shocks.

Analysis and Corrective Action:

A) *Analysis (apparent cause) of this incident:*

Underlying severe CAD and Left Ventricular dysfunction. S/P ICD with periodic outpatient defibrillator firings. Outpatient stress test done for pre-op cancer surgery, required for anesthesia. also reported defibrillator fired the previous week. Device interrogation after this event revealed an occurrence of ventricular tachycardia, and shocks were given appropriately. Because the patient walks four miles a day, it was elected to proceed with exercise stress testing.

B) *Description of corrective or proactive action(s) taken:*

was administered a total of 10 mg. of Lopressor and 150 mg. of Lidocaine and continued to have wide QRS tachycardia some of which appeared to be atrial fibrillation or atrial flutter with a ventricular rate of 260. Oxygen applied at 3 Liters per N/C and IV Normal Saline hung. There was a right bundle branch morphology in V1. remained alert during the events with normal blood pressure. A magnet was applied to the defibrillator to try to reduce the number of shocks but still had additional shocks despite placement. did have interrogation of the device and it was noted that it actually was an atrial tachycardia. The patient converted to atrial fibrillation with intermittent ventricular pacing. The patient continued to have short burst of tachycardia. At 16 minutes and 51 seconds post exercise the patient appeared to be in a stable atrial fibrillation with ventricular response of approximately 70 bpm. There was diffuse additional ST depression of up to 3 mm. The patient did complain of chest discomfort but this then resolved. The patient was admitted for observation and consideration of antiarrhythmic therapy. Patient was started on Tikosyn 250 mg twice daily in the hospital. was discharged 11-19-2007 and to remain on Tikosyn at home. Follow-up Office Visit 12/04/2007 patient is reluctant to take Tikosyn and Metoprolol as ordered,

stating it causes headaches. Long discussion by Provider with patient re: need for beta blockers and Tikosyn due to history of ventricular tachycardia requiring multiple shocks. Imdur discontinued to address complaint of headache. Patient understands the need for continued beta blockers.

STATE OF FLORIDA

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

RECEIVED CONSUMER SERVICES UNIT 07 NOV ... PM 1:45

I. OFFICE INFORMATION

Oncology & Hematology Assoc. of West Broward
Name of Office

7431 N. University Dr. Suite 110
Street Address

Tamarac — 33321 — Broward
City — Zip Code — County

954-726-0035
Telephone

Rohan Faria MD
Name of Physician or Licensee Reporting

ME 73674
License Number

Same as Above
Locating Information for Physician or Licensee Reporting

II. PATIENT INFORMATION

Age: 11/07/07 — Gender — Medicaid — Medicare

D...

Purpose of Office Visit

Diagnosis

146.0
ICD-9 Code for Diagnosis

III. INCIDENT INFORMATION

11/07/07 1240
Incident Date and Time

Location of Incident:
☐ Operating Rm ☐ Recovery Rm
☒ Other ______

Note: If the incident involved a death, was the medical examiner notified? ☐ Yes ☐ No N/A
Was an autopsy performed? ☐ Yes ☐ No N/A

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete response)

Patient had completed infusion of Erbitux 422 mg. Infusion lasted from 1045-1240. Prior to start of Erbitux, [redacted] had received IV Benadryl 25 mg and Tylenol 500 mg po. [redacted] had no c/o throughout infusion. Following infusion [redacted] got up to the BR, [redacted] sat back in chair. 1245: B/P 160/100, pt dyspneic, O_2 applied per N/C. Dr. Faria notified - saw patient. Benadryl 25 mg and Decadron 10 mg given IVP per MD orders. Accucheck done per orders - glucose - 137. Pt continues c SOB, despite O_2 @ 4L. Pulse oximeter shows sat @ 83%. 1300: Dr. Faria in to see patient again: B/P 160/100, P-83, RR-24. Dr. Faria examined patient; EMT called per his order. EMT responded @ 1305. Pt transported by EMT to UCH @ 1320. Pt awake + alert @ time of transport.
S. Rothenberg RN

Form # DH-MQA1030- created 2-00

B) ICD-9-CM Codes

91.413, 96.415		
Surgical, diagnostic, or treatment procedure being performed at time of incident (ICD-9 Codes 01-99.9)	Accident, event, circumstances, or specific agent that caused the injury or event. (ICD-9 E-Codes)	Resulting injury (ICD-9 Codes 800-999.9)

C) **List any equipment used if directly involved in the incident**
(Use additional sheets as necessary for complete response)

N/A

D) **Outcome of Incident** (Please check)

☐ Death	☐ Surgical procedure performed on the wrong site **
☐ Brain Damage	☐ Wrong surgical procedure performed **
☐ Spinal Damage	☐ Surgical repair of injuries or damage from a planned surgical procedure
☐ Surgical procedure performed on the wrong patient	** If it resulted in
☐ A procedure to remove unplanned foreign objects remaining from surgical procedure	☐ Death ☐ Brain Damage ☐ Spinal Damage ☐ Permanent disfigurement not to include the incision scar ☐ Fracture or dislocation of bones or joints ☐ Limitation of neurological, physical, or sensory function; ☐ Any condition that required the transfer of the patient
☑ Any condition that required the transfer of the patient to a licensed hospital	

E) **List all persons, including license numbers if licensed, locating information, and the capacity in which they were directly involved with this incident.**

Vojwatee Barry RN 1433692
Nancy Peluso RN 952582
Susan Rothenberg RN 1148592
Rohan Faria MD ME 73674

F) **List witnesses, including license numbers if licensed, and locating information if not listed above**

N/A

IV. ANALYSIS AND CORRECTIVE ACTION

A) **Analysis (apparent cause) of this incident** (Use additional sheets as necessary for complete response)

Patient developed respiratory [redacted] was documented to be in [redacted] and improved [redacted] immediately after [redacted] received IV lasix. [redacted] had apparently been asked to ~~[illegible]~~ decrease lasix by [redacted] PCP.

B) **Describe corrective or proactive action(s) taken** (Use additional sheets as necessary for complete response)

Close follow up with [redacted] cardiologist and PCP to monitor [redacted] CHF

V. [signature] ME 73674

SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT — LICENSE NUMBER

11.12.07 — 1300

DATE REPORT COMPLETED — TIME REPORT COMPLETED

Form # DH-MQA1030- created 2-00

STATE OF FLORIDA
Jeb Bush, Governor

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

SUBMIT FORM TO:
Department of Health, Consumer Services Unit
4052 Bald Cypress Way, Bin C75
Tallahassee, Florida 32399-3275

07 NOV 15 PM 1:45 CONSUMER SERVICES UNIT RECEIVED

I. OFFICE INFORMATION

Name of office: SALIENT MED CENTER
Street Address: 1601 W. BAY DR
City: Largo Zip Code: 33770 County: Pinellas
Telephone: 727. 674. 9990
Name of Physician or Licensee Reporting: BARBARA COURSON ARNP
License Number & office registration number, if applicable: HCC 6761
Patient's address for Physician or Licensee Reporting: 1601 W. Bay Dr. Largo

II. PATIENT INFORMATION

Age Gender Medicaid Medicare

Date of Office Visit: 11/5/07

Patient Identification Number

Purpose of Office Visit

Diagnosis

ICD-9 Code for description of incident: 995. 3

Level of Surgery (II) or (III): N/A

III. INCIDENT INFORMATION

Incident Date and Time: 11/5/07 905/am

Location of Incident:
☐ Operating Rm ☐ Recovery Rm
☒ Other TREATMENT Room

Note: If the incident involved a death, was the medical examiner notified? ☐ Yes ☐ No > N/A
Was an autopsy performed? ☐ Yes ☐ No

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete response)

PT TO RECEIVE IV RITUXAN. PT IN PROCESS of RECEIVING PRE-MEDS which included Tylenol Gm ? po, BENADRYL 50 mg po. Solu-medrol 100 mg IV. PT had already received Tylenol + Benadryl + Solu-medrol completed when [redacted] all over, rash on mucus membrane inside mouth + a hive on (L) cheek. 250 cc NS started, 3L nasal O2 face red, speech "thick". TREATED WITH IVP Benadryl 50 mg TKO. NEVER HAD RESPIRATORY ISSUE. CALLED 911 for hosp transfer. Determined pt. actually allergic TO Benadryl. Physician notified. PT NEVER REC'D RITUXAN.

Form # DH-MQA1030- created 2-00; revised 3-24-03

B) ICD-9-CM Codes

90766	po Benadryl	999.2 995.3
Surgical, diagnostic, or treatment procedure being performed at time of incident (ICD-9 Codes 01-99.9)	Accident, event, circumstances, or specific agent that caused the injury or event. (ICD-9 E-Codes)	Resulting injury (ICD-9 Codes 800-999.9)

Sponsored by WP Benadryl prior to determination of cause.

C) List any equipment used if directly involved in the incident
(Use additional sheets as necessary for complete response)

D) Outcome of Incident (Please check)

☐ Death	☐ Surgical procedure performed on the wrong site **
☐ Brain Damage	☐ Wrong surgical procedure performed **
☐ Spinal Damage	☐ Surgical repair of injuries or damage from a planned surgical procedure
☐ Surgical procedure performed on the wrong patient	** if it resulted in
☐ A procedure to remove unplanned foreign objects remaining from surgical procedure	☐ Death ☐ Brain Damage
☒ Any condition that required the transfer outcome of the patient to a licensed hospital	☐ Spinal Damage ☐ Permanent disfigurement not to include the incision scar
Outcome of transfer – e.g., death, brain damage, observation only ✓ Name of facility to which patient was transferred Largo Medical Center	☐ Fracture or dislocation of bones or joints ☐ Limitation of neurological, physical, or sensory function; ☐ Any condition that required the transfer outcome of the patient

E) List all persons, including license numbers if licensed, locating information, and the capacity in which they were directly involved with this incident.

832512 Nancy Ward RN – Giving premeds
2736842 Teresa Lavrino RN – " " stopped IV
2916742 / Barbara Cousin ARNP – Gave Benadryl called physician + 911

F) List witnesses, including license numbers if licensed, and locating information if not listed above

IV. ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent cause) of this incident *(Use additional sheets as necessary for complete response)*

Pt [redacted] even though had had Xyleal PM without incident pt admits to past allergic type reaction but had no idea to what!

B) Describe corrective or proactive action(s) taken *(Use additional sheets as necessary for complete response)*

Will try to give Rituxan again without Benadryl & with decadron instead of solu-medrol

V. Barbara J Cousin — **SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT**
2916742 — **LICENSE NUMBER**

11/12/07 — **DATE REPORT COMPLETED**
3:35 pm — **TIME REPORT COMPLETED**

Form # DH-MQA1030- created 2-00; revised 3-24-03

STATE OF FLORIDA

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

I. OFFICE INFORMATION

Oncology + Hematology Associates of West Broward
Name of office

7431 North University Dr. Suite 110
Street Address

Tamarac | 33321 | Broward
City | Zip Code | County

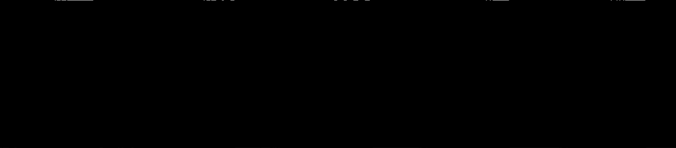
954-726-0035
Telephone

Keith Goldstein MD
Name of Physician or Licensee Reporting

ME 94967
License Number

As Above
Locating Information for Physician or Licensee Reporting

II. PATIENT INFORMATION



Age | Gender | Medicaid | Medicare

11/15/07
Date of Office Visit

[illegible] infusion
Purpose of [illegible]

Patient Identification Number

utero ovarian sarcoma
Diagnosis

183.8
ICD-9 Code for Diagnosis

III. INCIDENT INFORMATION

11/15/07 1310
Incident Date and Time

Location of Incident:
☐ Operating Rm ☐ Recovery Rm
☒ Other chemotherapy infusion room

Note: If the incident involved a death, was the medical examiner notified? ☐ Yes ☐ No N/A
Was an autopsy performed? ☐ Yes ☐ No N/A

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete response)

Patient receiving hydration p̄ receiving Ifex 4gms IV, 2 doses of Mesna 800mg IV, ~~[illegible]~~ [illegible] Kytril 1mg ē Decadron 5mg IV. Patients eyes open but no response to commands. B/P 146/82, pulse rapid + irregular @ 128. Pt [redacted] on pinch on dorsal forearm. Responded c̄ a grunt when name was called. also present were small spastic tics in hands and feet. Dr. Goldstein aware, assessed patient and recommended EMT's be called. Call placed to 911. Patient transported to hospital via ambulance @ 1400.

Form # DH-MQA1030- created 2-00

B) ICD-9-CM Codes

96413, 96415, 90761

Surgical, diagnostic, or treatment procedure being performed at time of incident (ICD-9 Codes 01-99.9)	Accident, event, circumstances, or specific agent that caused the injury or event. (ICD-9 E-Codes)	Resulting injury (ICD-9 Codes 800-999.9)
96413, 96415, 90761		

C) List any equipment used if directly involved in the incident N/A

(Use additional sheets as necessary for complete response)

D) Outcome of Incident (Please check)

- ☐ Death
- ☐ Brain Damage
- ☐ Spinal Damage
- ☐ Surgical procedure performed on the wrong patient
- ☐ A procedure to remove unplanned foreign objects remaining from surgical procedure
- ☒ Any condition that required the transfer of the patient to a licensed hospital
- ☐ Surgical procedure performed on the wrong site **
- ☐ Wrong surgical procedure performed **
- ☐ Surgical repair of injuries or damage from a planned surgical procedure

** if it resulted in

- ☐ Death
- ☐ Brain Damage
- ☐ Spinal Damage
- ☐ Permanent disfigurement not to include the incision scar
- ☐ Fracture or dislocation of bones or joints
- ☐ Limitation of neurological, physical, or sensory function;
- ☐ Any condition that required the transfer of the patient

E) List all persons, including license numbers if licensed, locating information, and the capacity in which they were directly involved with this incident.

Eileen TATE RN

SANDY BUTLER MEDICAL ASSISTANT

KEITH GOLDSTEIN MD ME 94967

F) List witnesses, including license numbers if licensed, and locating information if not listed above

[redacted] (PATIENT'S [redacted])

IV. ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response)

Ifex induced [redacted]

B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

V. [signature] ME 94967

SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT — LICENSE NUMBER

11/19/07 — DATE REPORT COMPLETED

0830 — TIME REPORT COMPLETED

Form # DH-MQA1030- created 2-00

STATE OF FLORIDA
Charlie Crist, Governor

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

SUBMIT FORM TO:
Department of Health, Consumer Services Unit
4052 Bald Cypress Way, Bin C75
Tallahassee, Florida 32399-3275

I. OFFICE INFORMATION

SeaView Research, Inc.
Name of office

3898 NW 7th St.
Street Address

Miami — 33126 — Dade
City — Zip Code — County

(305) 649-6556
Telephone

Stuart I. Harris, MD
Name of Physician or Licensee Reporting

ME 53516
License Number & office registration number, if applicable

Patient's address for Physician or Licensee Reporting

II. PATIENT INFORMATION

Patient Identification Number

Healthy Research Participant
Diagnosis

Age — Gender — Medicaid — Medicare

11/24/2007
Date of Office Visit

Pharmacology Research Participant
Purpose of Office Visit

99.7 ( )
ICD-9 Code for description of incident

N/A
Level of Surgery (II) or (III)

III. INCIDENT INFORMATION

11/24/2007 12:42
Incident Date and Time

Location of Incident:
☐ Operating Room ☐ Recovery Room
xx Other Clinic

Note: If the incident involved a death, was the medical examiner notified? ☐ Yes ☐ No N/A
Was an autopsy performed? ☐ Yes ☐ No N/A

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete response)

See attached narrative

07 DEC 03 AM 11:32
CONSUMER SERVICES UNIT RECEIVED

B) ICD-9-CM Codes

99.7	E931	None
Surgical, diagnostic, or treatment procedure being performed at time of incident **(ICD-9 Codes 01-99.9)**	Accident, event, circumstances, or specific agent that caused the injury or event. **(ICD-9 E-Codes)**	Resulting injury **(ICD-9 Codes 800-999.9)**

C) List any equipment used if directly involved in the incident
(Use additional sheets as necessary for complete response)

None

D) Outcome of Incident *(Please check)*

☐ Death	☐ Surgical procedure performed on the wrong site **
☐ Brain Damage	☐ Wrong surgical procedure performed **
☐ Spinal Damage	☐ Surgical repair of injuries or damage from a planned surgical procedure.
☐ Surgical procedure performed on the wrong patient.	** If it resulted in:
☐ A procedure to remove unplanned foreign objects remaining from surgical procedure.	☐ Death ☐ Brain Damage ☐ Spinal Damage
XX Any condition that required the transfer of the patient to a hospital.	☐ Permanent disfigurement not to include the incision scar ☐ Fracture or dislocation of bones or joints
Outcome of transfer – e.g., death, brain damage, observation only Observation Only Name of facility to which patient was transferred: Metropolitan Hospital ER Miami, FL	☐ Limitation of neurological, physical, or sensory function. ☐ Any condition that required the transfer of the patient to a hospital.

E) List all persons, including license numbers if licensed, locating information and the capacity in which they were involved in this incident, this would include anesthesiologist, support staff and other health care providers.

Susan Siut RN RN 9231761 SeaView Research, Miami, FL
Sherine Andrea Wilson RN RN2757072 SeaView Research, Miami, FL
Nurses who administered medications to patient and placed IV.

F) List witnesses, including license numbers if licensed, and locating information if not listed above

Ricardo Hernandez, technician SeaView Research, Miami, FL

IV. ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response)

Allergic reaction to medication (no prior history)

B) Describe corrective or proactive action(s) taken *(Use additional sheets as necessary for complete response)*

I believe transfer to the hospital for observation was warranted due to the severity of the reaction as well as the fact that the diagnostic and monitoring capabilities of a hospital might be required for a recrudescence.

V. [signature] MD ME53516
SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT LICENSE NUMBER

12/10/2007 11AM
DATE REPORT COMPLETED TIME REPORT COMPLETED

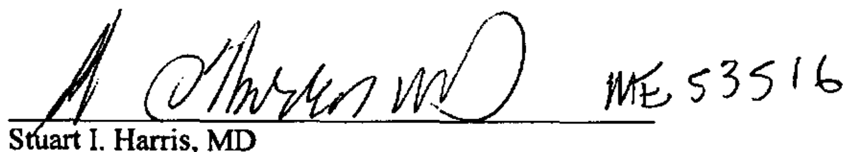
DH-MQA1030-12/06
Page 2 of 2

Susan Siut, RN 12/10/2007

I am an Investigator in a FDA registered Phase I clinical trial sponsored by Immtech Pharmaceuticals. On 11/24/2007 at 8:12 am, [redacted], a research volunteer, was administered a single 100 mg oral dose of pafuramidime maleate according to Immtech Pharmaceuticals bioequivalence Protocol C07-020. The drug is an investigational oral anti-malarial chemically related to pentamidine – a commonly used anti-parasitic drug. Approximately 4 ½ hours later [redacted] began experiencing shaking chills, tachycardia and had vital signs of BP 139/91, Pulse 137, Resp. 20 and temp 36.6C. Nurse Wilson notified me by phone. While in route to the clinic I ordered Benadryl 50 mg IM, placement of an IV catheter, ECG and repeat vitals.

Upon arrival a few minutes after 1:00 pm, I assessed the subject who was lying in bed with shaking chills and slight agitation. ECG showed sinus tachycardia. Specifically, there was no respiratory distress, urticaria, or angioedema. I ascertained that the subject was experiencing a hypersensitivity reaction to the medication and immediately proceeded to have the nurses administer IV saline and IV solumedrol (125 mg) in addition to the previously administered IM Benadryl. I also sat the patient up to give [redacted] oral Tylenol which [redacted] refused due to nausea. A BP taken at that time in the sitting position was 88/52, Pulse 112 and the subject was noticeably more agitated. We placed [redacted] in the supine position with legs elevated at which point [redacted] immediately appeared more comfortable with BP rising to 136/85, Pulse 112. Blood sugar was 87 and pulse-ox 100% on nasal canula. Fire rescue was called and an additional 10mg of Benadryl was administered IV. Epinephrine was withheld due to the patient's age, absence of respiratory involvement and rapid stabilization. By 1:45 pm when Fire Rescue arrived the patient was noticeably improved and able to walk to the stretcher for transfer to the Metropolitan Hospital ER where I spoke to Dr. Ramos to inform him of the situation. Myocardial infarction was ruled out in the ER and the patient was discharged in good condition later that evening at approximately 6:00 PM. Following the incident the patient complained of some palpitations and sleeplessness but has had no significant sequelae.

The research protocol in which the patient participated is registered with the FDA and the sponsor (Immtech Pharmaceuticals) is submitting the incident to the FDA as is required for investigational drugs. Similar reactions have not previously been reported with this oral formulation, but anaphalactoid reactions are known to occur with injectable pentamadine – a related compound. Attached is a letter from the manufacturer verifying that they have received the information regarding this incident and are complying with all Federal Regulations.



Stuart I. Harris, MD

Physician Office Adverse Incident Report

STATE OF FLORIDA
Jeb Bush, Governor

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

07 NOV -7 PM 4:01

SUBMIT FORM TO:
Agency for Health Care Administration,
Consumer Services Unit, Post Office Box 14000,
Tallahassee, Florida 32317-4000

I. OFFICE INFORMATION

Southeastern Urological Center
Name of office

2000 Centre Pointe Blvd
Street Address

Tallahassee 32308 Leon
City Zip Code County

850-309-0400
Telephone

Byron Blasko ARNP
Name of Physician or Licensee Reporting

1554842
License Number & office registration number, if applicable

Same as above
Patient's address for Physician or Licensee Reporting

II. PATIENT INFORMATION

[redacted]

Age Gender Medicaid Medicare

11-05-07
Date of Office Visit

[redacted]
Purpose of Office Visit

...ification Number

[redacted]
Diagnosis

N/A
ICD-9 Code for description of incident

N/A
Level of Surgery (II) or (III)

III. INCIDENT INFORMATION

11-05-07 @ 10 30 Am
Incident Date and Time

Location of Incident:
☐ Operating Rm ☐ Recovery Rm
☑ Other Physician office

Note: If the incident involved a death, was the medical examiner notified? ☐ Yes ☐ No
Was an autopsy performed? ☐ Yes ☐ No

A) Describe circumstances of the incident (narrative)

(use additional sheets as necessary for complete response)

Patient arrived for scheduled office visit. When being assessed by the practitioner, the patient noted ~~a new onset mid chest pain~~ that [redacted] described as being different. [redacted] also felt light headed prior to entering exam room. Vital signs assessed and were generally within normal limits. Possible myocardial infarct sent to ER via EMS transport for continued medical care for cardiac issues.

Form # DH-MQA1030- created 2-00; revised 9-6-01

B) ICD-9-CM Codes

NA	NA	NA
Surgical, diagnostic, or treatment procedure being performed at time of incident (ICD-9 Codes 01-99.9)	Accident, event, circumstances, or specific agent that caused the injury or event. (ICD-9 E-Codes)	Resulting Injury (ICD-9 Codes 800-999.9)

C) List any equipment used if directly involved in the incident
(Use additional sheets as necessary for complete response)

D) Outcome of Incident (Please check)

☐ Death	☐ Surgical procedure performed on the wrong site **
☐ Brain Damage	☐ Wrong surgical procedure performed **
☐ Spinal Damage	☐ Surgical repair of injuries or damage from a planned surgical procedure
☐ Surgical procedure performed on the wrong patient	** if it resulted in
☐ A procedure to remove unplanned foreign objects remaining from surgical procedure	☐ Death ☐ Brain Damage ☐ Spinal Damage ☐ Permanent disfigurement not to include the incision scar
☒ Any condition that required the transfer outcome of the patient to a licensed hospital	☐ Fracture or dislocation of bones or joints ☐ Limitation of neurological, physical, or sensory function;
Outcome of transfer – e.g., death, brain damage, observation only admit to hospital Name of facility to which patient was transferred TMH	☐ Any condition that required the transfer outcome of the patient

E) List all persons, including license numbers if licensed, locating information, and the capacity in which they were directly involved with this Incident.

Byron Blasko ARNP 155 4842 care provider
Ralph H. Kelton MD ME0C20010 supervising physician
Shelley Lerner RN - RN-2737062 Charge nurse assisting in transfer
Valentina Harris MA

F) List witnesses, including license numbers if licensed, and locating information if not listed above

IV. *ANALYSIS AND CORRECTIVE ACTION*

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response)

Notified patient had had a [illegible]

B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

None needed. Transfer appropriate

V. [signature] RN9159/2
SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT LICENSE NUMBER

11-6-07 10:00Am
DATE REPORT COMPLETED TIME REPORT COMPLETED

Form # DH-MQA1030- created 2-00; revised 9-6-01

5/16/07 (#10)

#152

STATE OF FLORIDA
Jeb Bush, Governor

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

SUBMIT FORM TO:
Agency for Health Care Administration, Consumer Services Unit, Post Office Box 14000, Tallahassee, Florida 32317-4000

2007 AUG 13 PM 3:08
PRACTITIONER REGULATION LEGAL

I. OFFICE INFORMATION

Name of office: GASTROINTESTINAL DIAGNOSTIC CENTERS
Street Address: 2215 N. UNIVERSITY DR
City: PEMBROKE PINES Zip Code: 33024 County: BROWARD
Telephone: (954) 963-0888
Name of Physician or Licensee Reporting: NORA KELLY RN
License Number & office registration number, if applicable: 74588-2 MS
Patient's address for Physician or Licensee Reporting:

II. PATIENT INFORMATION

Patient N[redacted]
Patient's [redacted]
Patient Identification Number
Diagnosis: 280.0 V12.71
Age Gender Medicaid Medicare
Date of Office Visit: 5/16/07
Purpose of Office Visit: 280.0 V12.71
ICD-9 Code for description of incident: 863.53
Level of Surgery (II) or (III)

III. INCIDENT INFORMATION

Incident Date and Time: JULY 18, 2007 8:20AM

Location of Incident:
☐ Operating Rm ☐ Recovery Rm
☑ Other GI SUITE ROOM 2

Note: If the incident involved a death, was the medical examiner notified? ☐ Yes ☐ No
Was an autopsy performed? ☐ Yes ☐ No

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete response)

SEE ATTACHED SHEET

Form # DH-MQA1030- created 2-00; revised 9-6-01

B) ICD-9-CM Codes

280.0 V12.71	562.10	863.53
Surgical, diagnostic, or treatment procedure being performed at time of incident (ICD-9 Codes 01-99.9)	Accident, event, circumstances, or specific agent that caused the injury or event. (ICD-9 E-Codes)	Resulting injury (ICD-9 Codes 800-999.9)

C) List any equipment used if directly involved in the incident
(Use additional sheets as necessary for complete response)

OLYMPUS CF 100 COLONOSCOPE

D) Outcome of Incident (Please check)

☐ Death	☐ Surgical procedure performed on the wrong site **
☐ Brain Damage	☐ Wrong surgical procedure performed **
☐ Spinal Damage	☐ Surgical repair of injuries or damage from a planned surgical procedure
☐ Surgical procedure performed on the wrong patient	** If it resulted in
☐ A procedure to remove unplanned foreign objects remaining from surgical procedure	☐ Death ☐ Brain Damage ☐ Spinal Damage
☑ Any condition that required the transfer outcome of the patient to a licensed hospital	☐ Permanent disfigurement not to include the incision scar ☐ Fracture or dislocation of bones or joints
Outcome of transfer – e.g., death, brain damage, observation only Surgical repair Name of facility to which patient was transferred Memorial Hospital Pembroke	☐ Limitation of neurological, physical, or sensory function; ☐ Any condition that required the transfer outcome of the patient

E) List all persons, including license numbers if licensed, locating information, and the capacity in which they were directly involved with this incident.

BRIAN DOOREGK	MD	ME 85567
CHRIS CARLIN	RN	RN 9300671
DAVID HEAD	MD	ME 78598
NED JAMES	GI TECH	

F) List witnesses, including license numbers if licensed, and locating information if not listed above

IV. ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response)

Sigmoid colon diverticulosis
fixed sigmoid colon

B) Describe corrective or proactive action(s) taken (Use additional sheets as necessary for complete response)

Possibility of perforation is listed on our informed consent sheet

V. [signature] 74588.2 ME 85567
SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT **LICENSE NUMBER**

8/10/01 — **DATE REPORT COMPLETED**
2:00pm — **TIME REPORT COMPLETED**

Form # DH-MQA 1030- created 2-00; revised 9-6-01

RE: [redacted]

Attachment for III. A)

8/10/2007

The risks, including perforation, benefits and alternatives to colonoscopy were reviewed and discussed in detail before the procedure and informed consent was obtained. The patient was prepped at home using the TriLyte preparation kit as instructed. The [redacted] was started after [redacted] was achieved by Dr. David Head. The upper endoscopy was completed without issue and colonoscopy was started as sedation was maintained by Dr. Brian Dooreck. The procedure was limited to the sigmoid colon due to a fixed sigmoid colon and the presence of moderate to severe diverticulosis. The procedure was terminated after 5 minutes because of the high suspicion of a [redacted] diverticulum. All air was removed from the colon. The patient's vital signs remained stable and [redacted] awoke from anesthesia with no complaints of pain. EMS was immediately notified of need for hospital transport. The ER physician and colorectal surgeon at Memorial Hospital Pembroke were called prior to EMS arriving by Dr. Dooreck. Ampicillin 2 grams IV and Gentamycin 60mg IV were administered prior to transport. [redacted] the sigmoid colon was performed without complication. [redacted] recovery was uneventful and without issue. [redacted] July 19th and the family has already been contacted regarding [redacted] follow up care.

BD

JUN-29-2007 FRI 12:00 AM FAX NO. P. 01

#153

STATE OF FLORIDA
Jeb Bush, Governor

✓?

PHYSICIAN OFFICE ADVERSE INCIDENT REPORT

SUBMIT FORM TO:
Department of Health, Consumer Services Unit
4052 Bald Cypress Way, Bin C75
Tallahassee, Florida 32399-3275

I. OFFICE INFORMATION

South Florida Center for Cosmetic Surgery 91 Middle River Dr #213
Name of office — Street Address

Fort Lauderdale, FL 33304, Broward, 954-565-7575
City — Zip Code — County — Telephone

Timothy Alexander, M.D. OSR # 491
Name of Physician or Licensee Reporting — License Number & office registration number, if applicable

Patient's address for Physician or Licensee Reporting

II. PATIENT INFORMATION

Age — Gender: 05.16.2007 — Medicaid — Medicare
Date of Office Visit
Purpose of Office Visit
Diagnosis
ICD-9 Code for description of incident: R Breast s/p Breast Augmentation (05.18.2001)
Level of Surgery (II) or (III): Level III

III. INCIDENT INFORMATION

06.16.07
Incident Date and Time

Location of Incident:
☐ Operating Rm ☐ Recovery Rm
☒ Other ________

Note: If the incident involved a death, was the medical examiner notified? ☐ Yes ☐ No
Was an autopsy performed? ☐ Yes ☐ No

A) Describe circumstances of the incident (narrative)
(use additional sheets as necessary for complete response)

Patient underwent uneventful right breast capsule release under [redacted] on 05.16.07. Patient was seen postoperatively in office on 05.17.07, 05.23.07 without complications. Patient was then seen 06.13.07 for [redacted] one-month follow up visit and was prescribed Ciprofloxacin 500mg po bid due to redness noted around surgical incision. Patient was seen 06.14.07 where pus was noted and cultured. Patient then evaluated on 06.15.07 and showed noted improvement. Plan was to have patient

continue with antibiotic therapy and return to office 06.18.07. Patient did not show for scheduled appointment. It was made apparent when patient's mother was reached 06.19.07 that patient had been

admitted to Aventura Hospital over the weekend (06.16.07 Plan at this time was to have implant removed from a plastic surgeon on staff at Aventura Hospital (Dr. Glipstein) multiple attempts have been made to reach Dr. Glipstein & were unsuccessful. The implant was removed which was confirmed by patients mother on 06.20.07.

B) ICD-9-CM Codes

Surgical, diagnostic, or treatment procedure being performed at time of incident (ICD-9 Codes 01-99.9)	Accident, event, circumstances, or specific agent that caused the injury or event. (ICD-9 E-Codes)	Resulting injury. (ICD-9 Codes 800-999.9)

C) List any equipment used if directly involved in the incident (Use additional sheets as necessary for complete response)

D) Outcome of incident (Please check)

- ☐ Death
- ☐ Brain Damage
- ☐ Spinal Damage
- ☐ Surgical procedure performed on the wrong patient
- ☐ A procedure to remove unplanned foreign objects remaining from surgical procedure
- ☐ Any condition that required the transfer outcome of the patient to a licensed hospital

Outcome of transfer – e.g., death, brain damage, observation only ________
Name of facility to which patient was transferred ________

- ☐ Surgical procedure performed on the wrong site **
- ☐ Wrong surgical procedure performed **
- ☐ Surgical repair of injuries or damage from a planned surgical procedure

** If it resulted in

- ☐ Death
- ☐ Brain Damage
- ☐ Spinal Damage
- ☐ Permanent disfigurement not to include the incision scar
- ☐ Fracture or dislocation of bones or joints
- ☐ Limitation of neurological, physical, or sensory function;
- ☐ Any condition that required the transfer outcome of the patient

E) List all persons, including license numbers if licensed, locating information, and the capacity in which they were directly involved with this incident.

Timothy Alexander M.D. ME # 35285

F) List witnesses, including license numbers if licensed, and locating information if not listed above

IV. ANALYSIS AND CORRECTIVE ACTION

A) Analysis (apparent cause) of this incident (Use additional sheets as necessary for complete response)

Patient had implant removed from right breast from plastic surgeon other than the operating surgeon.

B) Describe corrective or protective action(s) taken (Use additional sheets as necessary for complete response)

Continue attempts to reach patient regarding status. Attempts will continue until patient status verified.

V. [signature] ME # 35285

SIGNATURE OF PHYSICIAN/LICENSEE SUBMITTING REPORT — LICENSE NUMBER

06.27.07 — 1200

DATE REPORT COMPLETED — TIME REPORT COMPLETED

Form # DH-MQA1030- created 2-00; revised 3-24-03