Department of Health and Human Services
Medicare/Medicaid/CLIA Complaint Form

Control Number: R8KB11 (OH00074116 OH00074144 OH00074148 OH00074154 OH00074159 OH00074193 OH00074225 OH00074228)

Part I - To Be Completed by Component First Receiving Complaint (SA or RO)

1. Medicare/Medicaid Identification Number
02 88 AS

Facility Name and Address
PRETERM
12000 SHAKER BOULEVARD
CLEVELAND, OH 44120

3. Date Complaint Received
0 3 3 1 1 4
M M D D Y Y

4. Receiving Component
1 State Survey Agy.
[1] 2 RO

5. Date Acknowledged
0 3 3 1 1 4
M M D D Y Y

6A. Source of Complaint
1 [4]
2 [5]
3 [ ]

1 Resident/Patient Family
2 Ombudsman
3 Facility Employee/Ex-Employ
4 Anonymous
5 Other

6B. Total Number of Complainants
0 8

7. Allegations

7.A. Category

1 [1 8]
2 [ ]
3 [ ]
4 [ ]
5 [ ]

1 Resident Abuse
2 Resident Neglect
3 Resident Rights
4 Patient Dumping
5 Environment
6 Care or Services
7 Dietary
8 Misuse of Funds/ Property
9 Certification/Un-authorized Testing
10 Proficiency Test
11 Falsification of Records / Reports
12 Unqualified Personnel
13 Quality Control
14 Specimen Handling
15 Diagnostic Erroneous Test Results
16 Fraud/False Billing
17 Fatality/Transfusion Fatality
18 Other (Specify) Death - General
19 Life Safety Code
20 State Monitoring

7.B. Findings (To be completed following investigation)

1 [0 2]
2 [ ]
3 [ ]
4 [ ]
5 [ ]

01 Substantiated
02 Unsubstantiated/ Unable to Verify

7.C. Number of Complainants per Allegation

1 [0 8]
2 [ ]
3 [ ]
4 [ ]
5 [ ]

8. Action (if multiple actions, indicate earliest action)

[1]
1 Investigate within 2 working days
2 Investigate within 10 working days
3 Investigate within 45 working days
4 Investigate during next onsite
5 Referral (Specify) _____
6 Other Action (Specify) _____
7 None

Part II - To Be Completed By Component Investigating Complaint (SA or RO)

9. Investigated by
[1]
1 State Survey Agency
2 RO
3 Other (Specify) _____

10. Complaint Survey Date
0 4 0 3 1 4
M M D D Y Y

11. Findings (Under 7B Above)
Unsubstantiated

12. Proposed Actions Taken by SA or RO

1: [2 1]
2: [ ]
3: [ ]

1 Recommend Termination (23-day)
2 Recommend Termination (90-day)
3 Recommend Intermediate Sanction
4 POC (No Sanction)
5 Fine
6 Denial of Payment for New Admissions
7 License Revocation
8 Receivership
9 Provisional License
10 Special Monitor
11 Directed POC
12 Limitation of Certificate
13 Suspension of Certificate
14 Revocation of Certificate
15 Injunction
16 Civil Monetary Penalty
17 TA & Training for Unsuccessful PT
18 State Onsite Monitoring
19 Suspension of Part of Medicare Payments
20 Suspension of All Medicare Payments
21 None
22 Other (Specify) _____
23 Enforcement Action

13. Date of Proposed Action
0 4 0 3 1 4
M MD D Y Y

14. Parties Notified and Dates

	Party	Date
1 Facility	1. [1]	0 4 0 3 1 4
2 Complainant	2. [ ]	
3 Representative	3. [ ]	
4 Other (Specify) _____		M M D D Y Y

15. Date Forwarded to CMS RO or Medicaid SA (MSA) (Attach HCFA-2567)
M MD DY Y

Part III - To Be Completed By Component Taking Final Close-Out Action (RO/MSA)

16. Date of CMS/MSA Receipt
M M D D Y Y

17. CMS RO/MSA Action
[ ]
1 None
2 Termination (23-day)
3 Termination (90-day)
4 Intermediate Sanction
5 Move Routine Survey Date Forward
6 Limitation of Certificate
7 Suspension of Certification
8 Revocation of Certificate
9 Injunction
10 Civil Monetary Penalty
11 TA & Training For Unsuccessful PT
12 Cancellation of Medicare Approval
13 Other (Specify) _____
14 Enforcement Action

18. Date of Final Action Sign-off
M M D D Y Y

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	0288AS	A. BUILDING: _____ B. WING _____	04/03/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PRETERM	12000 SHAKER BOULEVARD CLEVELAND, OH 44120

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
C 000	Initial Comments Complaint Inspection Complaint Numbers OH00074225, OH00074228, OH74193, OH00074159, OH00074154, OH00074144, OH00074148, and OH00074116 Administrator: Chrisse France, Executive Director County: Cuyahoga Number of ORs: 5 Preterm is in compliance with the rules for Ambulatory Surgical Facility at O.A.C. 3701-83 at the time of the complaint inspection completed on 04/03/14.	C 000		

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PATIENT TRANSFER AGREEMENT

This patient Transfer Agreement ("Agreement") is made and entered into as of **September 15, 2013** (the "Effective Date"), by and between University Hospitals Cleveland Medical Center ("Hospital"), located at 11100 Euclid Avenue, Cleveland, Ohio 44106, and Preterm-Cleveland, located at located at 12000 Shaker Boulevard, Cleveland, Ohio 44120 ("Transferring Institution").

RECITALS

WHEREAS, Hospital and Transferring Institution operate health care institutions that provide health care services for the patients of their respective facilities;

WHEREAS, Transferring Institution operates a health care facility, and desires to have a hospital capable of receiving transfers of patients from Transferring Institution, so as to ensure the quality of care for its patients; and

WHEREAS, Hospital is willing to accept transfers of patients from Transferring Institution pursuant to this Agreement;

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained, and for other valuable consideration, the sufficiency of which is hereby acknowledged, Hospital and Transferring Institution agree as follows:

1. Transferring Institution's Responsibilities. In initiating a transfer, Transferring Institution shall have the following responsibilities:

(a) Choice of Receiving Institution. If a Transferring Institution patient requires transfer, Transferring Institution shall determine to which facility the patient will be transferred. Transferring Institution is under no obligation to transfer a specific number of patients, or any patients, to Hospital. The existence of transfers (or the existence of no transfers) between Transferring Institution and Hospital shall not, and is not intended to, constitute, affect or be the basis of any remuneration between Transferring Institution, Hospital and/or any of their respective affiliates.

(b) Patient Transfer. The patient's attending physician shall determine the need for transfer of a patient. When such a determination has been made, Transferring Institution shall determine the patient's medical status, acuity, and risk assessment and if transferring patient to Hospital, shall immediately notify the Hospital of the impending transfer and provide medical and administrative information necessary to determine the appropriateness of the placement and to enable continuing care of the patient.

(b) Medical Screening and Stabilization. Transferring Institution is responsible for ensuring that all transfers are in compliance with the Emergency Treatment and Active Labor Act (commonly referred to as the "COBRA anti-dumping law"), 42 U.S.C. § 1395dd, et seq.

(c) Patient Authorization. The attending physician and Transferring Institution will be responsible for obtaining any necessary patient authorization and consent for transfer prior to the transfer.

(d) Transfer of Information. Transferring Institution shall assure that the Hospital

receives, upon transfer, appropriate information with regard to current medical findings, diagnosis, rehabilitation potential, and a summary of the course of treatment followed in Transferring Institution, nursing and dietary information, ambulation status, pertinent administrative and social information, and documented consent for treatment. In addition, Transferring Institution shall include the name, address and phone number of the individual designated by patient to notify in case of medical emergency, or a statement that there is no known individual to be informed in such case. With the patient's consent, Transferring Institution shall notify that individual of such transfer.

(e) Mode of Transport. Transferring Institution shall have the responsibility for arranging for and effecting the transportation of the patient to the Hospital, including the selection of the mode of transportation and, where indicated, the provision of appropriate health care personnel and equipment to accompany the patient.

(f) Coordination with Hospital. Transferring Institution shall be responsible for contacting and confirming prior to transfer that the Hospital is willing to and can accept the transfer of the patient and provide the appropriate treatment. The attending physician at Transferring Institution shall be responsible for communicating directly with the physician at the Hospital to ensure that adequate space and personnel are available for the patient and to resolve any questions concerning the transfer. If the Hospital has fully committed its resources and is therefore temporarily unable to provide safe, appropriate, and timely medical care to patient; or, if the Hospital cannot provide such care because of a physical breakdown (e.g., fire, bomb threat, power outage, safety concern, etc.), the parties to this Agreement will cooperate to find another medically appropriate facility for the patient.

(g) Personal Effects and Valuables. Transferring Institution will be responsible for the transfer or other appropriate disposition of personal effects, particularly money and valuables, and information relating to these items. The status of such disposition shall be made in writing and forwarded to the Hospital.

(h) Death of Patient after Transfer. In the event a patient dies after transfer, the parties agree to cooperate in determining the patient's next-of-kin or such other persons as may be required to be notified of the patient's death.

5. Hospital's Responsibilities. The Hospital shall have the following responsibilities:

(a) Admission. If the patient transfer is accepted, the Hospital agrees to admit the patient and provide medical care for the patient's condition. The Hospital's responsibility for the patient's care shall begin when the patient arrives at the Hospital.

(b) Consultation. Upon request by Transferring Institution and/or attending physician, the Hospital will provide consultation prior to, during or following transfer.

6. Patient Records. Transferring Institution shall provide all pertinent and necessary medical information and records, which shall accompany the patient, including current medical and social history, diagnosis, treatment summary, prognosis and other pertinent information. Transferring Institution agrees to supplement the above information as necessary for the maintenance of the patient during transport and treatment upon arrival at the Hospital. Once the patient is admitted to the Hospital ongoing oral or written protected health information may be exchanged between Transferring Institution and Hospital for the purpose of providing or coordinating medical care for the patient. Other uses of the patient's medical information may require the patient's authorization to the extent so specified in the Health Insurance

Portability and Accountability Act of 1996 ("HIPAA"), and each party agrees to abide by HIPAA and its regulations to the extent applicable to a given situation.

7. Payment for Services. The patient is primarily responsible for payment for care received at either institution and for payment of transport costs. Each institution shall be responsible for collecting payment for services rendered in accordance with its usual billing practices. Nothing in this Agreement shall be interpreted to authorize either institution to look to the other institution to pay for services rendered to a patient transferred by virtue of this Agreement, except to the extent that such liability may exist separate and apart from this Agreement. Notwithstanding any other provision of this Agreement, in the event the patient fails to accept responsibility for the transfer costs, the parties agree that Hospital shall not be liable for these expenses. Prior to any transfer of a patient, Transferring Institution agrees to provide such treatment as is within Transferring Institution' capabilities, without regard to the patient's ability to pay. Upon receiving a patient transferred from Transferring Institution, Hospital shall provide such treatment as is within Hospital's capabilities, without regard to the patient's ability to pay.

8. Independent Contractor Status. The parties are independent contractors. Neither institution is authorized or permitted to act as an agent or employee of the other. Nothing in this Agreement is intended to or shall be construed to create any relationship between the institutions other than that of independent contractors. Nothing in this Agreement shall be construed as limiting the right of either party to affiliate or contract with any other medical center or extended care facility on any basis whatsoever. Neither party, by virtue of this Agreement, assumes any liability for any debts or obligations of either a financial or a legal nature incurred by the other party to this Agreement.

9. Liability. Each party shall be responsible for any and all damages, claims, liabilities or judgments expenses and costs (including but not limited to, court costs and attorneys' fees) of every kind arising out of or in consequence of the party's breach of this Agreement, and/or of the negligent errors and omissions or willful misconduct of its officers, directors, shareholders, servants, agents, employees, students or independent contractors in the performance of or conduct related to this Agreement.

10. Insurance. Each institution, either through insurance contracts or by self-insurance, shall secure and maintain with respect to itself, its agents and employees, during the term of this Agreement, comprehensive general liability insurance coverage with primary limits of not less than one million dollars per occurrence and two million dollars aggregate, and professional liability insurance with primary aggregate limits of not less than three million dollars. Each party hereto shall provide proof of such insurance and/or on the adequacy of its self-insurance upon request. Each party shall immediately notify the other of any notice from its insurance carrier of intent to modify or cancel such insurance coverage.

11. Term, Modification and Termination.

(a) This agreement shall commence on the day and year first above written and shall continue for a period of two years. Thereafter this agreement shall be renewed automatically for successive periods of one (1) year each, unless superseded or sooner terminated as provided in this Section.

(b) This Agreement may be modified or amended from time to time by a prior written agreement signed by the parties hereto, which shall be effective only upon being approval stamped by counsel for University Hospitals Health System.

(c) Any modification or amendments shall be in writing and shall become a part of this Agreement.

(d) Either party may terminate this Agreement without cause by giving thirty (30) days' notice in writing to the other party of its intent to terminate.

(e) During the 30-day notice period, each of the parties will be required to meet its commitments under this Agreement.

(f) Either party may terminate this Agreement immediately if the other party (1) fails to maintain its state licensure or registration, if any; or (2) is the subject of a permissive or mandatory exclusion from the Medicare or Medicaid programs.

(g) If practical, disputes arising under the Agreement shall first be discussed directly by the designated authorities of the Hospital and the Transferring Institution prior to termination.

12. Notice. Any notice required or permitted by this Agreement shall be sent by certified or registered overnight mail, signature and return receipt required, and shall be deemed given upon receipt thereof.

(a) All notices to Hospital shall be addressed to:

University Hospitals Cleveland Medical Center
11100 Euclid Avenue
Cleveland, Ohio 44106
Attn: President

With a copy to:

General Counsel
University Hospitals Health System
3605 Warrensville Center Road
Shaker Heights, Ohio 44122

(b) All notices to Transferring Institution shall be addressed to:

Preterm-Cleveland
12000 Shaker Boulevard
Shaker Heights, Ohio 44120
Attn: Executive Director

13. Legal Compliance. During the term of this Agreement, the parties shall take such actions and revise this Agreement as is necessary or advisable to comply fully with all federal, state, and local laws, rules and regulations applicable to the performance and discharge of such services, including and without limitation:

(a) Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191) ("HIPAA") and the rules and regulations promulgated thereunder, as well as guidance issued by the United States Department of Health and Human Services (the "HIPAA Regulations");

(b) Emergency Treatment and Active Labor Act ("EMTALA"), commonly referred to as the "COBRA anti-dumping law," 42 U.S.C. § 1395dd, *et seq*;

(c) Section 1861 (1) of Public Law 89-97, commonly referred to as the "Social Security Amendments of 1965".

14. Use of Name. Neither party shall use the name of the other party in any promotional or advertising media without prior written approval of the other party. In the case of Hospital such approval must be issued in writing by the Chief Marketing Officer of University Hospitals Health System.

15. Entire Agreement. This Agreement constitutes the entire agreement between the parties and contains all of the agreements between them with respect to the subject matter hereof and supersedes all other agreements, either oral or in writing, between the parties hereto with respect to the subject matter hereof. This Agreement may not be assigned by a party without the other party's written consent. This Agreement may only be amended by a written instrument signed by both parties. This Agreement is governed by the laws of the State of Ohio, and any venue for any dispute hereunder shall lie only in the courts of Cuyahoga County, Ohio. Any waiver under this Agreement shall apply only to the specific instance to which the waiver applies, and not to subsequent instances of the same nature.

IN WITNESS WHEREOF, the authorized representatives of the parties hereto have caused this Agreement to be executed on the day and year first above written.

UNIVERSITY CLEVELAND MEDICAL CENTER

By: Patricia DiPongio

Its: President, UH MacDonald Women's

PRETERM-CLEVELAND

By:

Its: Executive Director

Approval As To Form:
Attorney Signature:
Printed Name: Ryan Hooper
Date: August 1, 2013

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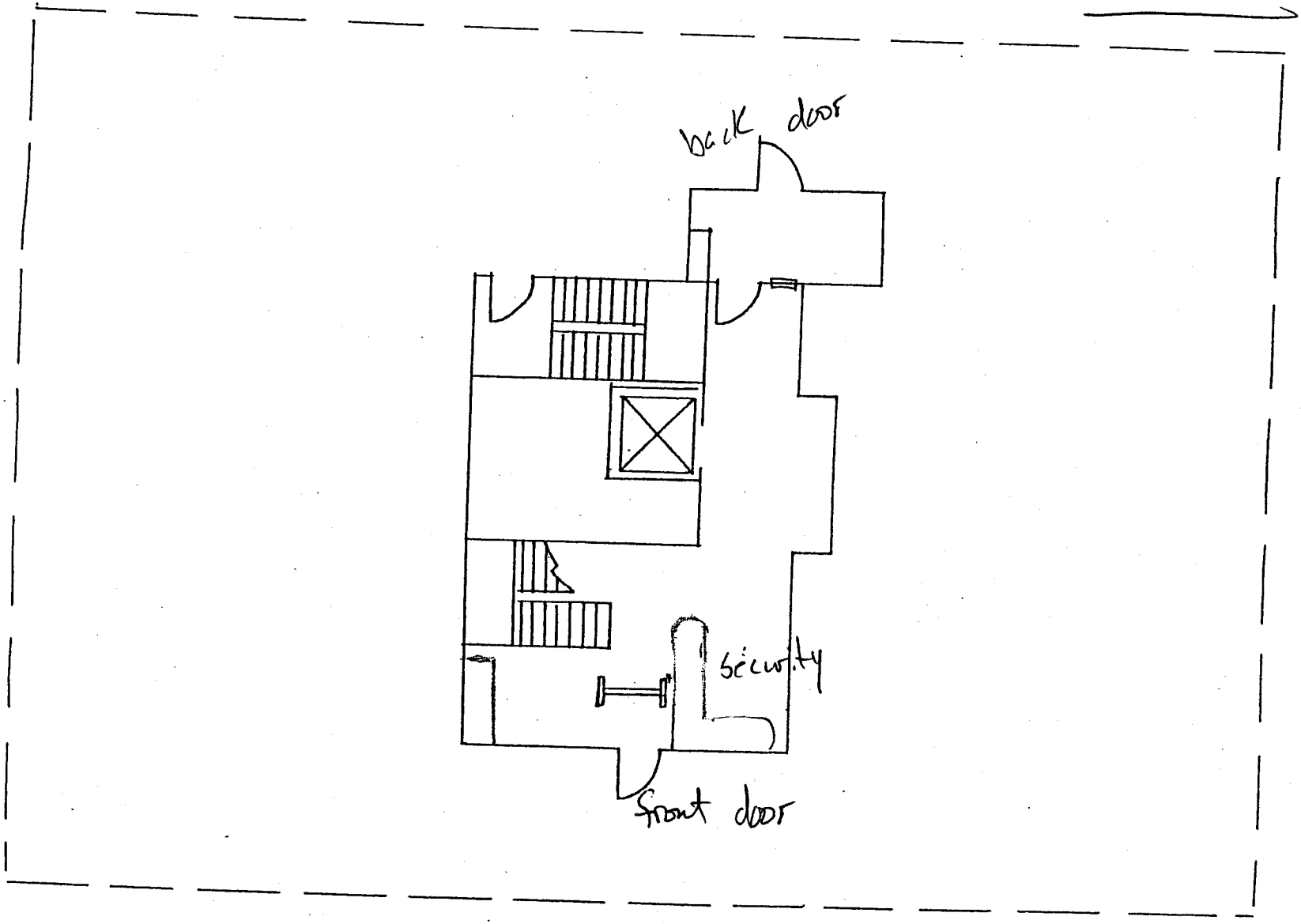

FIRST FLOOR

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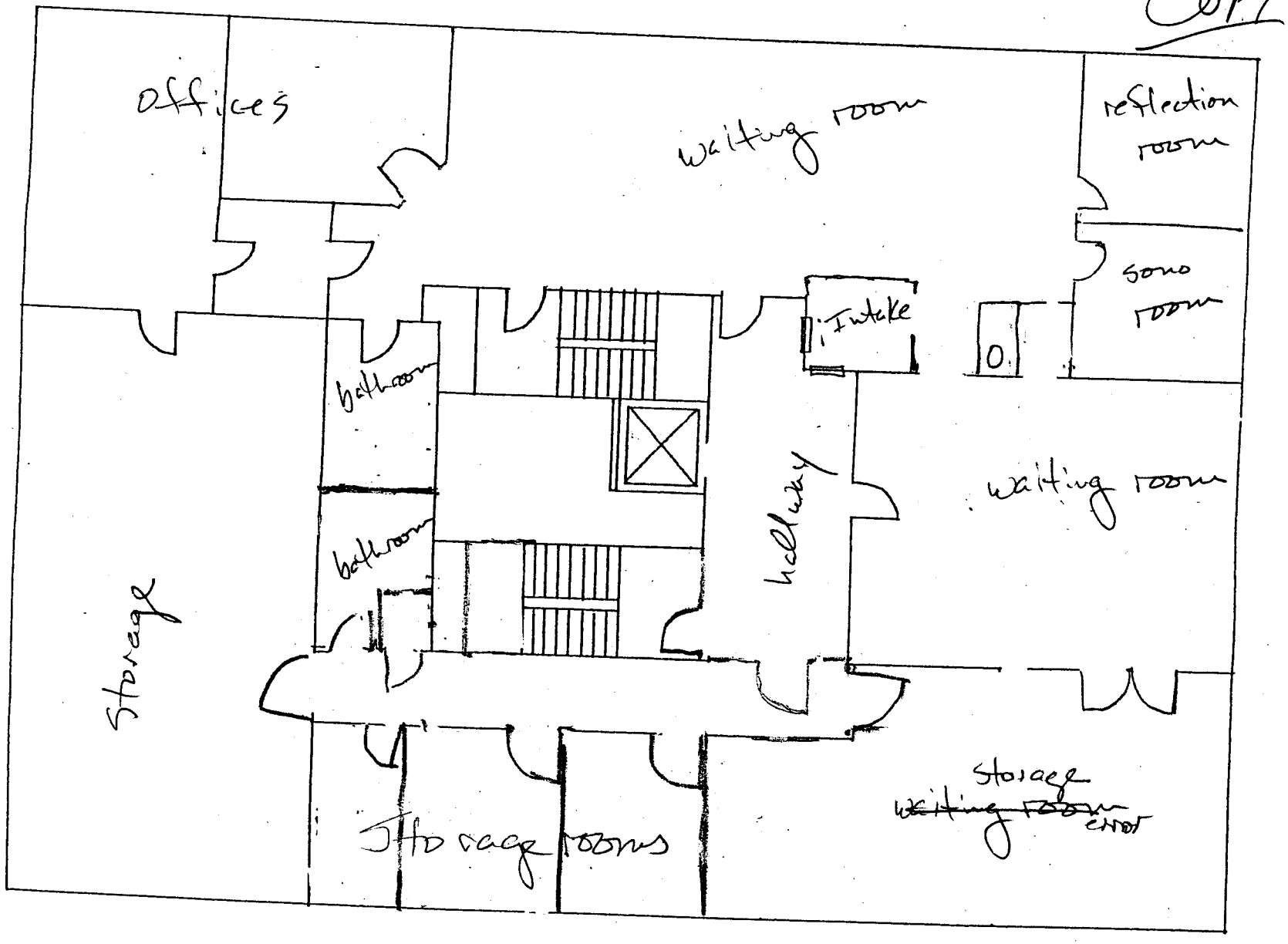

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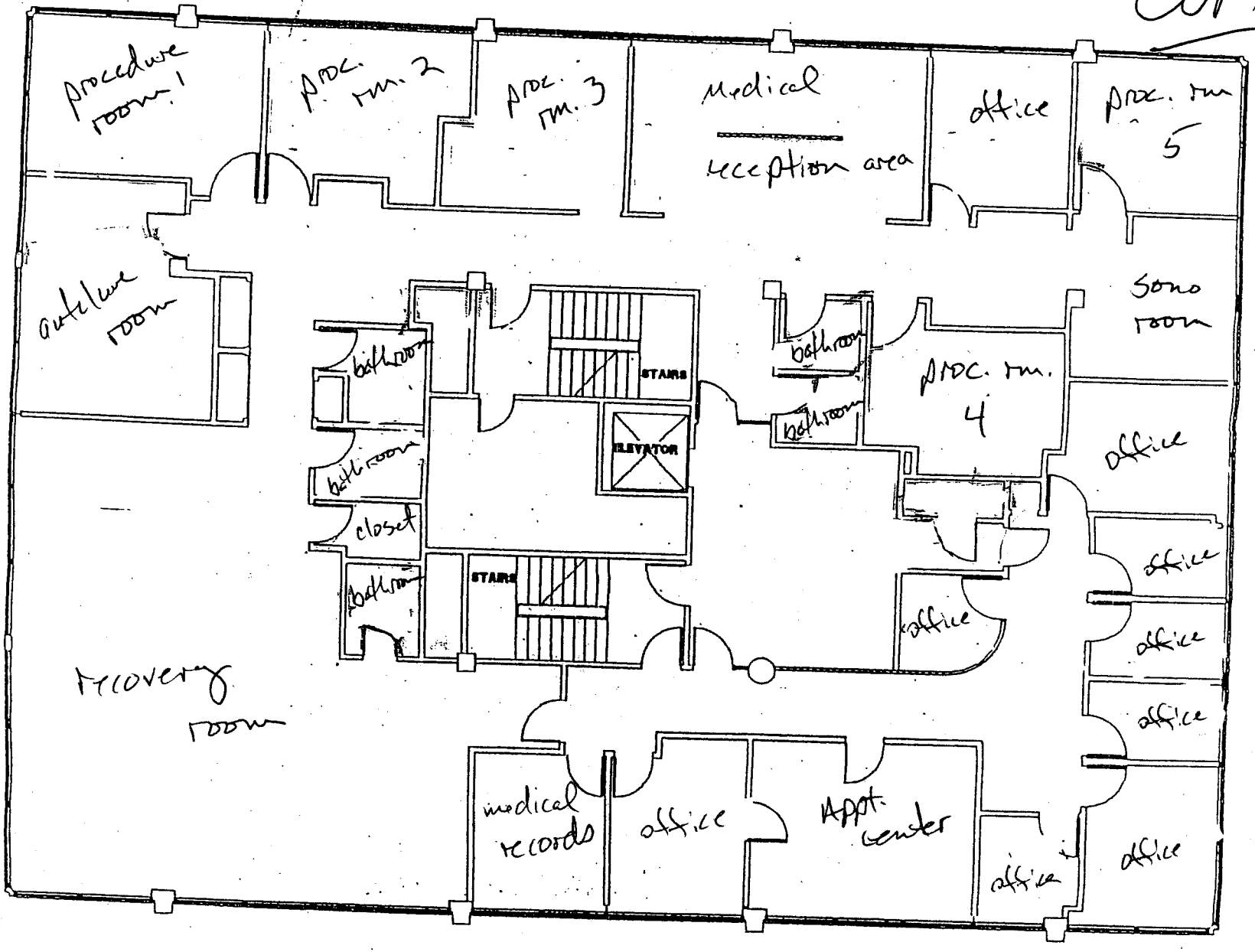

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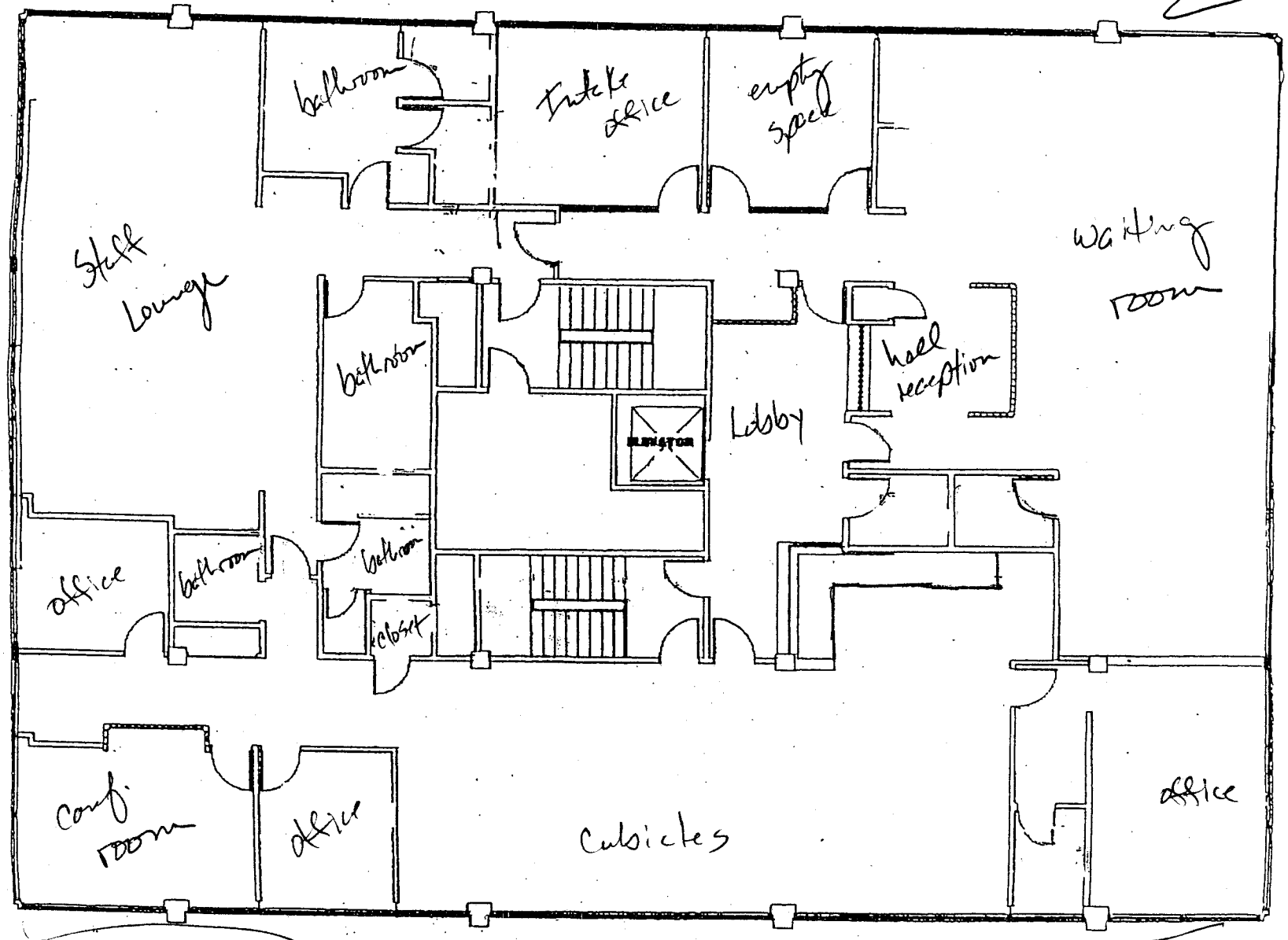

FOURTH FLOOR

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EMERGENCY TRANSFER TO UNIVERSITY HOSPITALS

The Director of Clinical Services (or charge nurse in her absence) will:

1) Inform the MR that there is an emergency and a possible patient transfer.
2) Consult the physician and assess the patient's need for immediate care.
3) Act as liaison between the MR, physician, patient and Director managing the situation.
4) Ensure that the medical record is complete, containing the physician's reason for transfer, patient's status prior to and at the time of transfer, how she is being transported and who is accompanying her, and that a copy of the record is accompanying the patient.
5) Direct the MR to call 911. The DCS should be prepared to give information to the 911 dispatcher.
6) Direct the MR to notify staff (overhead page: "attention all staff: disposition TR") and initiate transfer checklist.
7) Call the emergency room triage nurse of the admitting hospital and give report.
    a. UH Adult ED Nurses Station: 844-7007
8) Control the chart flow to:
    a. MR for transfer information
    b. Physician for charting
    c. Administrator for copying of chart (facesheet, labs, screening, sedation/anesthesia, procedure/recovery are to be copied)
    d. Nurse for charting (meds, vitals, times, etc.)
9) Tell the MR to page "Attention all staff: all clear disposition", and begin procedures again.

The Emergency Team will:

1) Report to the Director of Clinical Services (or charge nurse in her absence) in the room where the event is occurring as soon as possible upon hearing the "disposition TR" page.
2) Perform any duties as assigned by the DCS or physician.
3) Leave the area and resume her normal duties as soon as directed to do so by the DCS.

The Medical Receptionist will:

1) Inform the Director of Clinical Services, Director of Clinic Operations, Director of Counseling Services, or other Administrator, of the possibility of a patient transfer to the hospital.
2) For emergency transfers where the MD or CRNA need to be at bedside continually, stop all procedures and traffic in the procedure area until the DCS says it is okay to start procedures again. For non-emergent transfers, procedures do not need to be suspended, as long the MD or CRNA do not need to be at bedside. This should be determined by the MD/DCS. Stop flow to the third floor until patient has been transferred.
3) After the DCS has notified the MR of the transfer, she will call 911 and initiate transfer checklist. Overhead page: "Attention all staff- disposition TR".
4) Using the handset, inform each Patient Support staff in other procedure rooms with patients that the physician will be delayed. It is important that the Patient Support staff remain in the room with her patient.
5) Facilitate the physician calling the UH transfer center to give report to the attending OB/GYN.
    a. UH Transfer Center: 844-1111
6) Notify all areas when procedures may begin again by paging: "Attention all staff: all clear disposition".

The Director of Clinic Operations (or Director of Counseling Services in her absence) will:

1) Be present, convey a sense of calmness and safety throughout the transfer event.
2) Use the transfer checklist to manage the overall transfer process.
3) Ensure proper charting and documentation in the medical record is complete and accompanies the patient to the hospital in the absence of the Director of Clinical Services.
4) Check in/debrief with the staff involved about how they are reacting to the event and for feedback about the process itself.
5) Ensure that process is in place for picking up Patient Support staff at hospital.

The Patient Support person will:

1) Accompany her patient to the hospital in the ambulance. The purpose of this is to:
   a. Provide support to her patient.
   b. Advocate for the patient.
   c. Represent Preterm in a favorable light to the patient and the hospital.

The Financial Aid Manager (or Hall Receptionist in her absence) will:

1) Call MR to determine patient identity.
2) Locate the person accompanying the patient and remove that person to a private area.
3) Let Appointment Center know that she has the person secluded.
4) Inform the person that our physician has decided to transfer the patient to the hospital for further evaluation.
5) Remain with the person until the transfer is complete and facilitate him/her getting to the hospital.

The Appointment Center Manager (or senior staff in AC in her absence) will:

1) Inform visitors in the 3rd floor waiting room that a patient is being transferred to the hospital for further evaluation and that we need them to move to the 4th floor waiting area. Do not convey alarm.
2) Alert the Patient Advocates that a transfer is taking place and to escort their patients back to the 2nd floor waiting area when their sessions are finished.
3) Hold completed Day One charts that need consenting until the "clear disposition" is paged, then take them to MR.

The sono-in-the-room staff will:

1) Go to the first floor and hold the elevator for EMS.

All staff will:

1) Stop the flow of patients and visitors to the 3rd floor.
2) Convey a sense of calm, safety and confidence.

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Patient Complaints and Grievances

Staff should attempt to resolve situations that patients or significant others bring to their attention, whenever possible.
If the patient is currently experiencing a medical problem, a nurse should speak with the patient and recommend a course of action. If patient is dissatisfied with medical care, notify Director of Nursing or Director of Clinic Operations (in DON absence).

When patients seek reimbursement or compensation due to dissatisfaction with services, the Director of Clinic Operations should be notified. In her absence notify Director of Counseling Services or Director of Nursing.

The Director of Clinic Operations will keep a file of all information pertaining to the complaint including:

The date the complaint was received
The identity of the complainant
Patient's demographic information
Date of service, name of physician when applicable
A detailed description of the complaint.
Resolution of the complaint
If the patient sought medical attention following the abortion, the Director of Clinic Operations should be informed. She will seek to obtain all medical records from physician visits or hospitalizations related to post abortion care. The complainant will be informed about the necessity of receiving these records prior to resolving the complaint.

After reviewing medical records, the Director of Clinic Operations and/or Medical Director will advise the Executive Director regarding Preterm's responsibility.

If the complaint is not related to medical care, the Director of Clinic Operations will consult with staff who were involved to gather information relating to the complaint. She will consult with Executive Director to advise regarding resolution. If the complaint is related to staff behavior, it should be directed to that staff member's supervisor.

The Director of Clinic Operations will inform the patient of the decision regarding reimbursement or compensation.

05/29/02
01/12/04 updated
01/12/05 updated
05/12/06 reviewed
04/12/07 reviewed
04/17/08 reveiwed
4/16/09, reviewed
9/2/10, updated

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GUIDELINES FOR NURSE ADMINISTERED CONSCIOUS SEDATION

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1. Policy for Patient Selection

A. Patient selection

The physician is responsible for determining patient appropriateness for nurse monitored sedation. This must be recorded on the conscious sedation page.

B. Patient selection criteria for nurse monitored sedation

1. Medical history and physical examination must be performed and documented in the medical record.

2. Evidence of documented pre-procedure nursing assessment prior to the administration of conscious sedation medications.

3. No solids eight (8) hours prior to procedure. May have clear liquids four (4) hours prior to appointment time.

4. Established venous access.

5. Oxygen tanks and masks in the procedure room.

6. All patients will be monitored with automatic blood pressure cuff, and pulse oximeter.

C. Pre-procedure Nursing Assessment

1. Patient's full name

2. Verify signed informed consent.

3. Physical assessment (i.e., skin integrity, auscultation of the heart and lungs, and evaluation of the airway).

4. Current medications.

5. Drug allergies/sensitivities.

6. Concurrent medical problems (e.g., diabetic, hypo/hypertension, asthma, substance abuse),

7. Baseline vital signs, including ht, wt and age.

8. Level of consciousness.

9. Emotional state.

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10. Patient's ability to communicate and respond to verbal commands.

11. Perceptions regarding procedure and sedation.

2. IV Conscious Sedation Medication

The following guidelines will be followed for administration of IV conscious sedation medications by the RN.

A. Purpose

To provide optimal care for the patient receiving IV conscious sedation administered by the RN.

B. Policy Statement

1. Medications ordered by the physician will be documented on the patient record.

2. One nurse will be assigned to monitor and administer medications to the patient. This individual may assist with minor interruptible tasks that do not interfere with monitoring responsibilities.

3. The medications administered by the RN may not be combined or mixed with other medications for the purposes of achieving conscious sedation.

4. The medications are administered under the direction of a physician.

5. The physician must be in the procedure room prior to the administration of medications for IV conscious sedation.

6. The RN is authorized to administer the following medications according to established guidelines.

   a. Midazolam (Versed)
   b. Fentanyl Citrate (Sublimaze)
   c. Naloxone HCL (Narcan)
   d. Flumazenil (Romazicon)

7. Physician orders exceeding the medication dosage guideline for nurse administration will be administered by anesthesia personnel.

8. The physician will sign all medication orders before the patient leaves the room.

3. IV Medication Guidelines

Medications

A. Midazolam (Versed)

Initial Dose: 1 - 2 mg (per MD order)
Technique: Titrate slowly over 1 - 2 minutes to patient's response, inject into an

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infusing line.
Maximum Dose: 4 mg
Potential Adverse Reactions: Drowsiness, thrombosis and phlebitis at the site of the injection, slurred speech, nausea, bradycardia, hypotension, respiratory depression, skin rash, blurred vision, nystagmus, fluctuations in vital sign, apnea, hiccough, nausea, vomiting, coughing, over sedation, and headache.

B. Sublimaze(Fentanyl)
Initial Dose: 2 mcg/kilogram
Technique: Administer slowly over 1 -2 minutes, inject into an infusing line.
Maximum Dose: 200 mcg
Potential Adverse Reactions: Respiratory depression, apnea, rigidity, bradycardia, hypertension, dizziness, blurred vision, nausea, emesis, laryngospasm, diaphoresis, hypersensitivity, sedation, drowsiness, convulsions, respiratory depression, hypotension, peripheral circulatory collapse, cardiac arrest, allergic reactions, suppression of cough reflexes.

C. Flumazenil(Romazicon)
Initial dose: 0.2 mg
Technique: Administration over 15 seconds, inject into infusing line. Wait additional 45 seconds before repeating, if necessary additional doses of 0.2 mg at intervals of 1 minute
Total dose: 1 mg
If desired level of consciousness is not achieved, request assistance.
Potential Adverse Reactions; nausea and vomiting, dizziness, injection site pain, agitation, headache, sweating, flushing, hot flashes, paresthesia, emotional lability, inflammation at injection site, abnormal vision, fatigue, convulsions for patients on benzodiazepines for seizure control.

D. Naloxone HCL(Narcan)
Initial dose: 0.1 - 0.2 mg increments
Technique: Dilute 1 ampule (0.4) with normal saline in a 10 ml syringe, Administer .1 to .2 mg increments at 2 to 3 minute intervals, inject into infusing line, titrating to desired effect.
Total dose: .4 mg (10cc): NOTE if .4 mg has been administered with no effects on patient response, the diagnosis of narcotic induced toxicity is questionable.
Potential Adverse Reactions: Excitement, hypotension, hypertension, ventricular tachycardia and fibrillation, pulmonary edema, seizures, nausea, vomiting, sweating, circulatory stress.

4. Intraoperative

A. Minimal monitoring parameters include:
1. blood pressure
2. mental status
3. respirations
4. oxygen saturation
5. pulse rate

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B. The RN will document every 5 minutes on the nursing procedure record:

1. blood pressure, respiration
2. pulse oximetry range
3. medications, dosage, time administered, route, and by whom.
4. heart rate
5. complications, interventions, and patient's response.
6. mental status

C. If a deeper level than intended level of sedation occurs (oxygen saturation <93%), the following steps should take place by RN/LPN, CRNA, and/or physician:

1. initiate tactile stimuli, including but not limited to sterna chest rub
2. increase oxygen level for desired effect; apply bag mask if needed
3. insure IV access is maintained
4. have reversal agents on hand (Narcan/Romazicon); give if necessary

5. Nurse's Procedure

A. An infusing IV line is started by the RN with a 20 or 22 gauge catheter and 150cc N.S., unless ordered differently by the physician.

B. Blood pressure cuff and pulse oximeter are applied to the patient. Oxygen by mask is available.

C. Baseline vital signs are taken and recorded on the nursing care record every 5 minutes.

D. The physician must be present in the room to order a medication.

E. The verbal order is recorded on the medication section of the nursing care record. Date, time, medication, dose, route per verbal order physician's name. Orders will be signed by the physician before leaving the room.

F. The patient is monitored for potential adverse reaction to the medication(s) being administered. Any untoward signs and symptoms are reported immediately to the physician.

G. Documentation for post procedure includes: vital signs and mental status.

6. Management of Emergency Complications

A. The Physician is responsible for the diagnosis and treatment of complications related to the procedure and/IV conscious sedation.

B. The physician is responsible for obtaining medical consultation as appropriate.

C. Nurse Procedure

The nurse is responsible for monitoring and reporting to the physician signs and symptoms related to:

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Possible allergic reactions:

Rash, redness, itching, hives, edema, hypotension, syncope, bronchoconstriction, respiratory distress, apnea.

Possible toxic responses:

Uneasy feeling, tinnitis, numbness of tongue, blurred vision, dizziness, confusion, temporary loss of consciousness, tonic-clonic convulsions, CNS depression, respiratory depression, apnea.

Possible adverse reactions to medications:

Nystagmus, agitation, combativeness, severely slurred speech, unarousable sleep, respiratory depression, apnea, significant tachycardia or bradycardia, significant hypertension, significant hypotension, dizziness, flushing, light headedness, nausea/vomiting, rash, restlessness, sweating.

During an emergency, the nurse will administer medications under the supervision and direction of the physician.

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Policy: Termination of pregnancy greater than 19.6 weeks gestation

Pursuant to sections 2305.11, 2307.52, 2919.16, 2919.17, 2919.18, 2919.171 and 4731.22 of the Ohio Revised Code, no abortions shall be performed at Preterm beyond 19.6 weeks gestation, as determined by ultrasound, unless the following conditions are met:

- The gestational age of the pregnancy will not exceed 23.5 weeks gestation when the abortion is performed.
- The estimated fetal weight does not exceed 500 grams when the abortion is performed.

Accurate pregnancy dating by ultrasound and estimation of fetal weight are widely accepted scientific means of determining fetal viability(2,3,4,5). It is the determination of Preterm's physicians, in light of current medical technology and information reasonably available to them, that there is not a realistic possibility of maintaining and nourishing life outside the womb with or without temporary artificial life-sustaining support, prior to 24 weeks gestation and/or fetal weight of less than 500 grams(1,2,3,4).

Pursuant to section 3701.47.03 of the Ohio Revised Code, Preterm will submit the required reporting form to the Ohio Dept. of Health for all abortions performed beyond 19.6 weeks gestation. This form will be submitted within fifteen days after the completion of the abortion.

1. Moore K, Persaud T. The Developing Human, Clinically Oriented Embryology, 7th edition. 103-107 (2003)
2. Perinatal Care at the Threshold of Viability. ACOG Practice Bulletin, Clinical Management Guidelines for Obstetrician-Gynecologists, Number 38, September 2002
3. Luke B, Brown M. The Changing Risk of Infant Mortality by Gestation, Plurality and Race: 1989-1991 vs. 1999-2001. Pediatrics. 2006;118;2488
4. Tyson J, Parikh N, Langer, J, Green C, Higgins R. Intensive Care for Extreme Prematurity-Moving Beyond Gestational Age. New England Journal of Medicine 358.16, 2008.
5. Hadlock FP, Harrist RD, Sharman RS, Deter RL, Park SK. Estimation of fetal weight with the use of head, body, and femur measurements-a prospective study. AM J Obstet Gyneco. 1985 Feb 1; 151(3):337-7

Policy approved by the Preterm Executive Committee on November 1, 2011

P&P

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ULTRASOUND GUIDELINES

An ultrasound will be performed on every patient to determine gestational age. She will have a repeat ultrasound prior to her abortion if: she reports vaginal bleeding since the first ultrasound, or an intrauterine pregnancy with a measurable CRL was not located on her first ultrasound, or it has been more than 28 days since her first ultrasound.

All patients will be given the opportunity to view their ultrasound and receive an ultrasound picture if they so choose. All patients must be informed of the gestational age of their pregnancy.

Sonographers will use best judgment in determining the most appropriate means of measuring gestational age; i.e. abdominal or transvaginal ultrasound, gestational sac, CRL or BPD. When BPD measurement is possible, this is the measurement to be used; CRL measurement is preferable to gestational sac measurement in early pregnancy.

Patients <7.0 weeks gestation, no uterine pregnancy is located by ultrasound, or a gestation of >7.0 weeks with no cardiac motion must have a urine pregnancy test with results documented on patient's chart. Patients with a positive pregnancy test and no intrauterine pregnancy located must be given ectopic warnings and have blood drawn for a possible BHCG test; if , when the patient returns and has a repeat ultrasound, an intrauterine pregnancy is again not located, blood will again be drawn and both samples will be sent for BHCG testing. Ectopic warnings must also be given to all patients with no fetal pole.

Sonographers will note on ultrasound report in patient's chart any abnormal uterine findings (bicornate uterus, presence of fibroid tumors, etc.).

If a physician requests measurement of femur length in addition to BPD for second trimester patients, sonographers will measure and note on ultrasound report.

All second trimester (>12 weeks) abortion procedures will be performed under ultrasonic guidance. Physician may request additional ultrasounds at his/her discretion.

All non-surgical abortion patients returning for Day 14 visit will receive a transvaginal ultrasound.

Any patient returning to Preterm after an abortion with a complaint of excessive cramping, clotting or bleeding will receive a transvaginal ultrasound.

TISSUE PROCEDURES

Equipment used:

- 2 oz. specimen boats
- 16 oz. specimen cups
- 32 oz. specimen cups
- scale
- wire strainer
- plastic colander
- glass dish
- light box
- tissue forceps
- ruler
- tube gauze
- biohazard bags
- saline
- Lab Corp. specimen containers 1 oz. & 4 oz
- specimen biohazard bags
- goggles or face mask
- latex and utility gloves
- gown

To Check Tissue:

4-10 weeks

Empty the contents of the specimen cup and the sock into the wire strainer. Rinse away blood and protein with water, then put remaining tissue into the glass tray. Add enough water for the tissue to float. Put it on the light box and examine tissue. When complete, put contents back in strainer to remove water, then put tissue into a specimen container and weigh. (be sure to adjust scale for weight of container—2 grams for the 2-oz. boat, 15 grams for the 16-oz. cup.) Fill out tissue report form and put tissue into the receptacle on the left-hand side of the freezer.

11-23 weeks

Empty the contents of the specimen cup and the sock into the plastic colander. Rinse away blood and protein with water. Use tissue forceps to go through tissue, removing any fetal tissue and putting it back into the specimen cup. Put all tissue into the specimen container and weigh. (be sure to adjust scale for weight of container—2 grams for the 2-oz. boat, 15 grams for the 16-oz. cup, 30 grams for the 32-oz. cup.) Measure fetal foot length, if possible. Fill out tissue report form and put tissue that is 10-19 weeks in the receptacle on the left-hand side of the freezer. Tissue that is 20-23 weeks goes into the receptacle on the right hand side of the freezer.

Observations by Week:

4- 8 weeks - look for sac and villi. Weight must be over 11 grams.
8- 9 weeks - look for fetal parts. (parts of the spine; webbed fingers; white, leaf shaped neural tissue)
9-11 weeks -look for fingers, toes, and spine. Look for eyes to determine if the capit is there.
12 weeks - look for eyes, capit, spine and body parts.
13-23 weeks - look for spine, body parts (arms, legs), placental tissue and the sac. It is imperative that the capit be present.

Special Circumstances:

Early Abortion (less than 7 weeks by ultrasound)

Sock must be taken off the machine prior to procedure to avoid tissue remaining caught in the sock.

Tissue 11 grams or less

See "Small Tissue Guidelines", attached. Put the tissue in a Lab Corp. specimen container with formulin, labeled with the patient's name, LMP and 'Preterm'. Fill out a Lab Corp. requisition form with the patient's name, D.O.B., time of collection and date. Under the 'Clinical Findings' write "TAB for product of conception". Call Lab Corp. at 440-838-0404 and let them know we need a specimen pick up. Be sure to get a confirmation number. Put the specimen in a biohazard specimen bag and send along the first two

sheets of the requisition form. The last sheet should be put into the gray logbook in the tissue room. Take the specimen to the guard for pickup. When Lab Corp.'s exam is complete, they will fax their findings. Note that it was small tissue on the tissue report; also that it was sent out.

Decidua only

If there is decidua only, with no villi or fetal tissue, notify the M.D. and recovery room nurse. The patient will have a vaginal ultrasound to determine if the abortion is complete. If not, she will be re-suctioned, and the tissue obtained will be examined. If no tissue is obtained, she will be given ectopic warnings and decidua only instructions. Fill out a decidua only report and give to the Director of Nursing, or Director of Clinic Operations in her absence. The decidua will be put into tube gauze and placed in a Lab Corp. specimen container filled with formulin. The container will be labeled with the patient's name, LMP, and 'Preterm'. Fill out a Lab Corp. requisition form with the patient's name, D.O.B., time of collection and date. Under the 'clinical findings' write "TAB for product of conception". Call Lab Corp. at 440-838-0404 and let them know we need a specimen pick up. Be sure to get a confirmation number. Put the specimen in a biohazard specimen bag and send along the first two sheets of the requisition form. The last sheet should be put into the gray logbook in the tissue room. Take the specimen to the guard for pickup. When Lab Corp.'s exam is complete, they will fax their findings. Note that it was decidua only on the tissue report under 'gestational age'; also that it was sent out.

Possible Molar Pregnancies

In a molar pregnancy, there will be no fetal tissue, and the villi are very large. The sac has lots of bubbles in it, resembling grapes. Notify the M.D. and recovery room nurse so molar pregnancy instructions can be given to the patient.. The tissue will be put into tube gauze and placed in a Lab Corp. specimen container filled with formulin. The container will be labeled with the patient's name, LMP and 'Preterm'. Fill out a Lab Corp. requisition form with the patient's name, D.O.B., time of collection and date. Under 'clinical findings' write "R/O molar pregnancy". Call Lab Corp. at 440-838-0404 and let them know we need a specimen pickup. Be sure to get a confirmation number. Put the specimen in a biohazard specimen bag and send along the first two sheets of the requisition form. The last sheet should be put into the gray logbook in the tissue room. Take the specimen to the guard for pickup. When Lab Corp.'s exam is complete, they will fax their finding. Note on the tissue report that it was possible molar and that it was sent out.

No capit/fetal parts

If the pregnancy was greater than 9 weeks and there was no capit or fetal parts found, inform the M.D., procedure nurse and recovery room nurse. The patient will be resuctioned and any tissue obtained will be examined.

Fibroid/unusual situations

If M.D. requests tissue to be sent out for examination due to fibroid or other unusual situations, follow usual Lab Corp. procedure. Under 'clinical findings' put "Fibroid" if it is a fibroid; put "Removed from uterus" if it is something unusual.

Tissue out of range

Inform the M.D. If it is more than expected, it may be due to a large number of clots or very thick decidua. Note that on the tissue report under 'gestational age –weeks'. If it is less than expected for the number of weeks of pregnancy, it should be acceptable as long as everything is there (sac, villi, body parts). If this is the case, the M.D. must be notified. S/he will also examine the tissue and will make the final determination.

Resuction

In the event that a patient has to be resuctioned, the tissue examiner must confirm directly with the M.D. whether or not to send the tissue out for pathological evaluation and document on the tissue report as per "Small Tissue Guidelines".

Twins

If the patient is far enough along that body parts are able to be seen, there must be double of everything. If not, notify the M.D..

Genetic Testing

Tissue from fetal anomalies is handled the same as any other tissue unless the patient has requested genetic testing. This should have been arranged ahead of time by the patient and her doctor. When the tissue exam is complete, pack the tissue according to the requesting physician's protocol. The physician will usually only want a thigh or an upper arm, not all the tissue. Be certain to label the specimen with the patient's name, LMP and date. If the lab to which the tissue is being sent has sent us a requisition form, complete it and make a copy of it to include in the patient's chart. The original will accompany the tissue to that lab. Place the specimen in a biohazard bag. The requesting physician will arrange for pickup at Preterm. The tissue examiner will notify the medical receptionist that the tissue is ready for pickup. The medical receptionist will then call whoever has been designated to pick up the tissue to let them know the tissue is ready for pickup. The tissue examiner will give the physician (or his/her agent) the specimen personally.

Cremation/Burial

If the patient requests the tissue for cremation or burial, arrangements must be made in advance with a funeral home. After the tissue has been examined, place it in tube gauze, put it in a 32 oz. cup with a lid, place it in a biohazard bag and place it in a box marked as containing biohazardous material. Take this box to the administrative secretary, who will give it to the funeral home representative.

DNA Testing:

When DNA testing is being done for a criminal case, a detective will remain in the procedure room during the procedure and must accompany the tissue to the autoclave room, where s/he will watch the tissue examiner examine the tissue. When the examination is complete, put the tissue in tube gauze and put it in an appropriate sized container with a lid. Place the specimen container in a red biohazard bag and give it to the detective. Mark on the daily log and on the tissue report that it was picked up by a detective, and be certain to include his/her name.

Preterm will not "hold" tissue for future evidence. A detective MUST be present and follow the above procedure, or tissue will be disposed of as usual.

Tissue Pickup:

This is done only for tissue that is 20 weeks or greater (BPD 46mm or greater). The tissue examiner receives the burial transit permits from the City of Cleveland. When she has an adequate number of permits, usually every 2-3 weeks, she notifies the Building Director that she is in need of a pickup. She finds out from the Building Director when the pickup will occur. The tissue examiner will seal the receptacle and place it in 3 red biohazard bags. She will put these bags in a box and tape a manila envelope containing the burial transit permits to the box. It is then given to the Hillcrest Park Crematory representative.

Tissue that is less than 20 weeks does not get picked up. All tissue that is less than 20 weeks is stored in a separate receptacle. When full, this receptacle is sealed, placed in 3 red biohazard bags and placed upright in the bottom of a biohazard box in the biohazard room.

Patients wishing to view tissue:

MR or the PA lets tissue examiner know ahead of time that the patient wishes to view tissue. The tissue examiner will first examine the tissue, then put it in a clear dish with enough water to make the tissue float. If the patient wishes to view the tissue:

1) In the room – Tissue examiner will take the dish to the room once the patient is dressed. The tissue examiner will ask the patient if she wants to be shown the tissue (along with explanations of what everything is) or if she just wants to look. The tissue examiner then complies with the patient's request. When the patient is done viewing, the tissue examiner returns to the autoclave room and disposes of the tissue in the appropriate receptacle in the freezer. She/he will then enter the patient's name, chart number, and date in the 'patients viewing tissue' book.

2) In recovery – The recovery room personnel inform the tissue examiner that the patient is ready for discharge and will take the patient to the bathroom. The tissue examiner will take the glass dish to the bathroom and ask the patient if she wishes to be shown the tissue (along with explanation of what everything is) or if she just wants to look. The tissue examiner will then comply with the patient's wishes. When the patient is done viewing the tissue, the tissue examiner returns to the autoclave room and disposes of the tissue in the appropriate receptacle in the freezer. She/he will then enter the patient's name, chart number and the date in the 'patient's viewing tissue' book.

   The tissue examiner will also enter on page 9 of the patient's chart that the patient did view her tissue and any comments regarding the patient's reaction to viewing the tissue.

Freezer Cleaning:

This will occur every other Tuesday. The tissue examiner will unplug the freezer and remove the tissue. She will fill a dish basin with hot water, place it in the freezer and close the door so it can defrost. Once it is defrosted, she will clean the freezer with Pine-Sol and water and will note it in the cleaning log.

Tissue Exam Daily Log:

The tissue examiner will enter the date at the top of the page. For each patient, she will enter the chart number, name and observations.

Tissue Report:

The tissue examiner will complete a tissue report for each patient. There can be no error on this form; nothing is to be crossed out. If an error is made, the tissue examiner is to tear up the form, throw it away and begin again.

Lab Corp.:

The tissue examiner is to call Lab Corp. both for tissue pickup and to order supplies. The phone number is 440- 838-0404. Our account number with them is 34107470-4. We order 1-oz. specimen containers with formulin and 4 oz. specimen containers with formalin.

GUIDELINES FOR MIFEPRISTONE AND MISOPROSTOL IN EARLY ABORTION

RU-486
Procedure
✓ complaint
Re - failed ab

ELIGIBILITY:

1. Women considering medical abortion with Mifepristone and Misoprostol:
   a. should not have any of the following:
      1) hemorrhagic disorder, or concurrent anticoagulant therapy
      2) chronic adrenal failure
      3) concurrent long-term systemic corticosteroid therapy
      4) confirmed or suspected ectopic pregnancy or undiagnosed adne
      5) inherited porphyries
      6) IUD in place (must remove before treatment)
      7) history of allergy to Mifepristone, Misoprostol or other prostaglandin
      8) unwillingness to undergo a surgical abortion (if indicated);
      9) use of: anti-coagulants, Rifampin, EES, Ketoconazole, Dilantin, Tegretol, Phenobarbital, anti-inflammatories (excluding analgesics)
   b. should have gestation no more than 49 days LMP, to be determined by ultrasound exam.
   c. should be able to give informed consent, comply with treatment requirements, receive the Mifepristone/Mifeprex™ Medication Guide, and sign the Mifepristone/Mifeprex™ patient agreement; and
   d. should have access to a telephone and transportation to a medical facility equipped to provide emergency treatment of incomplete abortion, blood transfusions and emergency resuscitation.
   e. must be 18 years of age, or 16-17 years of age with parental involvement in abortion; parent must participate in education session at Preterm.
   f. Must provide 2 telephone numbers at which we can say "Preterm".

2. Special considerations:
   a. There are limited data available on the effects of Mifepristone or Misoprostol while breast-feeding. Clinicians may choose to advise patients to refrain from breastfeeding (i.e. pump and discard breast milk) after taking Mifepristone and up to 72 hours after Misoprostol use.
   b. Current severe anemia should be considered when assessing eligibility due to the bleeding involved in the process. Notify the physician for patients with a Hemoglobin under 10g/dL before procedure. Most research studies do not include women with a hemoglobin <10gm/dl.
   c. Concurrent illness with significant diarrhea should be considered when assessing eligibility because of the diarrhea associated with Misoprostol use.
   d. Any patient with serious systemic illness (e.g. severe liver disease, significant cardiac disease, renal failure, uncontrolled seizure disorder) should be evaluated individually to determine the safest method of pregnancy termination.

COUNSELING, EDUCATION and INFORMED CONSENT should include:

1. discussion of the decision to have an abortion and assurance that the decision is patient's own;
2. discussion of abortion methods (e.g. medical abortion, vacuum aspiration) and the risks and benefits of each in relation to alternative options (continuing pregnancy), including the risk of death for all options;
3. discussion of known side effects and possible complications of Mifepristone and Misoprostol. This discussion should include:
   a. information about what symptoms warrant contacting the on-call provider, for example:
      1) soaking 2 or more maxipads in 1 hour, or 1 pad per hour for 3 hours;
      2) sustained fever or onset of fever days after Misoprostol;
      3) abdominal pain or discomfort, or "feeling sick" including weakness, nausea, vomiting, or diarrhea more than 24 hours after taking Misoprostol;
      4) no bleeding within 24 hours after using Misoprostol.
   b. explanation that although ectopic pregnancy is not a result of medical abortion, and that neither the medications nor the route of their administration has been found to be the cause of infection

or toxic shock, it is important to contact a provider who will be familiar with any signs and symptoms of ruptured ectopic pregnancy or atypical infection following medical abortion;
   c. explanation of the importance of a follow-up visit to confirm complete abortion;
   d. explanation that Mifepristone is not known to increase the risk of teratogenesis in humans, but that fetal malformations have been reported after first trimester use of Misoprostol. Therefore, *women must be strongly advised to complete the abortion, either medically or with vacuum aspiration, once the medications have been administered;*
4. discussion of the length of time involved in the medical abortion process and the need for multiple visits. The FDA-approved regimen calls for 3 visits; use of alternative evidence-based regimens can result in fewer visits. In regimens using Mifepristone 600 mg and Misoprostol 400 µg orally up to 49 days' gestation, approximately two-thirds of all women will abort within 4 hours of taking Misoprostol, and about 90% of women will abort within 24 hours.
5. discussion of usual range in the amount of pain experienced by women and the use of pain medications. The patient should have an appropriate supply and instructions for use of oral pain medications once treatment is initiated. Pain is typically described as cramping and is most intense during expulsion, most commonly over a 2-4 hour period, after which the pain usually subsides;
6. discussion of the amount and quality of bleeding associated with the abortion process, including:
   a. bleeding is typically heavier than menses and may depend on the length of the pregnancy;
   b. likelihood of the passage of clots;
   c. an embryo is approximately the size of a grain of rice at the time when medical abortion is most commonly provided, and is typically not seen.
   d. while many women may start bleeding prior to using Misoprostol, Misoprostol is typically needed to complete the process;
   e. using maxi-pads allows the clinician to assess the amount of bleeding;
   f. some women may experience an episode of heavy bleeding 3-5 weeks after initiating a medical abortion with Mifepristone/Misoprostol.
7. a review of the Medication Guide given to the patient, the signed Patient Agreement, and consent form.
8. compliance with additional applicable state and local laws, ordinances, regulations, and common law governing the consent process and standard of care for abortion procedures;
9. discussion of issues of confidentiality;
10. review of aftercare instructions, including 24-hour emergency contact information; and
11. availability of contraception and contraceptive counseling, with initiation of contraception, if desired by the patient, as soon as possible. Clinicians' individual practices in the timing of initiation of contraceptive methods following abortion with Mifepristone/Misoprostol vary.

MEDICAL HISTORY and PHYSICAL EXAMINATION should include:

1. pertinent medical and obstetrical history, including history of allergies and all current patient medications;
2. pertinent physical examination, including vital signs;
3. determination of gestational age by ultrasonography;

ULTRASOUND EXAMINATION:

1. All medical abortion patients receive an ultrasound.
2. Transvaginal probe or abdominal probe ultrasound may be used routinely to confirm gestational age and intrauterine gestation. When ultrasound examination is performed, document findings (gestational sac, yolk sac, embryonic pole, presence of cardiac activity) for the medical record before administering Mifepristone.
3. If an embryonic pole is visible, this measurement will be used instead of gestational sac measurement because it is more accurate for dating.
4. If an intrauterine sac is not present, this could indicate early intrauterine pregnancy, ectopic pregnancy, or an abnormal intrauterine pregnancy. After clinical assessment, further evaluation may be warranted. Mifepristone will not be administered if an intrauterine pregnancy is not located. Patient must be given ectopic warnings and referred to a tertiary care facility if necessary.

LABORATORY EVALUATION:

1. Documentation of Rh factor.
2. Hemoglobin.
3. B-hCG level is not required unless it is being used to monitor the completeness of the abortion or ectopic pregnancy is suspected.
4. Other tests as medically indicated.

MEDICATION and FOLLOW-UP:

Mifepristone 600mg followed in 2 days by 400ug Misoprostol administered orally.

DAY 1:

a. Mifepristone 600mg taken orally.
b. Rhogam administered to Rh-negative patients.

DAY 3:

a. Misoprostol 400mcg taken orally.

DAY 14:

Patient returns for a follow-up visit on approximately day 14 to be assessed for completion of abortion by ultrasonography. Surgical abortion is necessary if a viable pregnancy is detected at this time, because the pregnancy may continue and there is a risk of fetal malformation. If a viable pregnancy is not located, but uterus does not appear to be completely evacuated, patient will either be dispensed repeat Misoprostol and follow-up ultrasound scheduled, or may opt for surgical evacuation. If a patient returns for follow-up ultrasound after repeat Misoprostol, and her uterus is still not completely empty, surgical completion will be performed at that time.

If patient fails to keep follow-up appointment, Preterm will attempt to contact patient twice by telephone. It will be stated that the call is from Preterm. If patient is not reached by telephone, Preterm will mail a letter in a Preterm envelope stressing the importance of follow-up for patient.

FACT SHEET
ABORTION WITH MIFEPREX™ (MIFEPRISTONE) AND MISOPROSTOL

Description

Mifeprex™ is a medication used to end an early pregnancy of up to 49 days (7 weeks). It works by blocking the action of progesterone, a hormone needed to continue a pregnancy. This causes an early pregnancy to detach from the wall of the uterus. It is used in combination with misoprostol, a drug that causes the uterus to contract and expel the pregnancy. This method is known as medical abortion because it allows a pregnant woman to have an abortion without surgery, in other words, without putting instruments in her uterus.

Mifeprex™ has been approved by the U.S. Food and Drug Administration (FDA) for early abortion when combined with misoprostol. It has been used by millions of women in Asia and Europe, where it is also called RU486 and the "French abortion pill." Misoprostol is used in the United States to prevent stomach irritation and ulcers in people using aspirin or aspirin-like pain medicine. Studies have shown that these two medications, when used together, are approximately 92-95% effective in causing an abortion in early pregnancy.

Procedure

The following procedure is the FDA approved regimen. It uses a 600 mg dose of Mifeprex™ and a 400 mcg dose of oral misoprostol 2 days after taking Mifeprex.

On First Visit

A medical history will be taken and an ultrasound exam will also be performed to determine how far along your pregnancy is. The ultrasound may be done by putting an ultrasound probe into your vagina or on your abdomen. A blood sample will be drawn to check blood Rh and to test for anemia.

On Second Visit

You will swallow three Mifeprex™ tablets. If you are experiencing nausea or vomiting, please be advised that if you vomit within 30 minutes of taking Mifeprex, it is unlikely that the medication will work. If this happens, you can purchase a second dose of Mifeprex for an additional fee or you can choose to have a surgical abortion at no additional charge. You will be given an antibiotic and should begin taking them that day. You will be given prescriptions for a narcotic pain reliever and an anti-nausea drug. We recommend that you have them filled before you return for your third visit.

On Third Visit

You will return to the clinic two days after you swallow the Mifeprex™ tablets and will swallow 2 misoprostol tablets.

After Misoprostol Administration

1. You may experience cramping in as little as 20 minutes. Expect some bleeding and clots. Most women pass the pregnancy in 24 hours, but it could take up to 48 hours.
2. If you have cramping in your lower abdomen, you can take Tylenol (acetaminophen) or Motrin (ibuprofen) as needed every 4-6 hours. You will be given a prescription for Vicodin for pain and Phenergan for nausea, if needed.

You must contact Preterm at 216/991-4579 if you experience any of the following:

- You soak 2 or more maxipads per hour for 2 consecutive hours.
- You have a sustained temperature of 100.4°F or higher or you begin to have a fever a few days after misoprostol.
- You have abdominal pain or discomfort, "feeling sick", including weakness, nausea, vomiting, or diarrhea more than 24 hours after taking Misoprostol.
- You have no bleeding within 24 hours after misoprostol. This may indicate that you may need more medication or an evaluation for an ectopic pregnancy.

Follow-up Visit (on around Day 14)

It is very important that you return to Preterm or your physician on or around day 14 for a follow-up visit.

During this visit we will examine you to confirm that you are no longer pregnant and that there are no complications. You will have a vaginal ultrasound and possibly a physical examination or another blood test. If your abortion was complete, then you are done. If the pregnancy is still growing, you will need a surgical abortion. If you do ***not*** return for your follow-up visit as scheduled, or if the follow up letter is not returned from your physician, then Preterm will attempt to contact you at the phone numbers that you gave us to reschedule a follow-up exam. It will be stated that the call is from Preterm. If there is continued non-compliance, a letter in a Preterm envelope will be sent to your home. If the pregnancy is still in your uterus, you may be treated with medication or have a surgical completion of your abortion.

Risks of a Medical Abortion

Incomplete abortion: As with a surgical abortion, some pregnancy tissue may remain in the uterus. If this happens, Preterm will discuss your treatment options. These options include waiting one or more weeks to give the medications more time to take effect, using more misoprostol, or having a surgical abortion. If you decide to wait or use more misoprostol and the abortion still is not complete, you will need a surgical abortion. The risks of a surgical abortion include making a hole in the uterus, tearing the cervix, adverse reaction to sedation if used during the procedure, infection, excessive bleeding, and failure to remove all of the tissue from the uterus.

Vaginal bleeding: As with a surgical abortion, you may have heavy bleeding and blood clots may come out of your vagina. If you have extremely heavy vaginal bleeding or dizziness, you may need a surgical abortion to stop the bleeding. The risks of a surgical abortion are stated above. The risk of having very heavy vaginal bleeding after using Mifeprex™/misoprostol is about 1 per 100 (1%). The risk of needing a blood transfusion after using Mifeprex™/misoprostol is about 1 per 1000 (0.1%).

Continued pregnancy and birth defects: Your pregnancy may not end after receiving the medications. If you continue your pregnancy, it is possible that your child will have birth defects. For this reason, we strongly recommend a surgical abortion to end the pregnancy. The risks of a surgical abortion are stated above.

Side Effects

The following side effects are possible: nausea, vomiting, diarrhea, fever, headaches, and chills. Most of these side effects last less than a day.

Drug/Food Interactions

It is possible that the following medications and food may interfere with the metabolism of Mifiprex and should be avoided: Ketoconazole, Itraconazole, Erythromycin, Rifampin, Dexamethasone, St. John's Wort, certain anticonvulsants such as: Phenytoin, Phenobarbital, Carbamazepine, and grapefruit juice.

Ectopic Pregnancy

Ectopic pregnancy is a pregnancy in the fallopian tube or elsewhere outside of the uterus. It is a rare condition and is a complication of pregnancy rather than of abortion. Neither surgical or nonsurgical abortion will end an ectopic pregnancy. Because of the possible threat of rupturing the fallopian tube, hospitalization and further medical and surgical treatment may be necessary when it is discovered.

Fees

Your fee for a nonsurgical abortion at Preterm includes the cost of a surgical abortion performed at Preterm if needed, and a follow-up ultrasound. If you choose to follow-up elsewhere, there will be an additional fee from your healthcare provider. Please investigate this with your healthcare provider before you make your appointment for a medical abortion. The fee does ***not*** include any charges incurred for an emergency room visit or for care at another facility.