Infiltrate IV Therapy Cases with Your CLNC® Expertise
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INFILTRATE IV THERAPY CASES
WITH YOUR CLNC® EXPERTISE

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INfiltrate IV Therapy Cases with Your CLNC® Expertise

I. Introduction

A. Almost All Medical-Related Cases Have an IV Therapy Component
   1. IV therapy issues may not prove to be relevant to the case, but it is important to have a heightened awareness of them. (Exhibit A)

B. Specific IV Therapy Standards Pertain to Access Device Placement, Medication Administration, Patient Monitoring and Documentation
   1. Awareness of these standards will provide the background for determining if they were breached.
   2. Breach of documentation standards points to overall nursing performance and can give clues to other aspects of the case.

II. Common IV Therapy Cases

A. Medical Malpractice

B. Product Liability

C. Healthcare Fraud

III. Common Plaintiff Allegations for IV Therapy Cases

A. Failure to Follow the Standard of Care (SOC) Related to Medication Administration Leading to Patient Harm

B. The MD Failed to Use Proper Central Venous Catheter (CVC) Placement Technique Causing Blood Clots to Form Leading to Stroke and Permanent Disability
C. The Hospital Staff Failed to Use Sterile and/or Clean Technique Leading to the CVC Infection Causing Sepsis and Death

D. The MD Failed to Recognize or Acknowledge the CVC Was Malfunctioning Upon Placement Contributing to a Code Situation Causing Patient Death (Exhibits B and C)

E. The Infusion Company Provided Unneeded Nurse Visit and Delivered Unusually Large Amounts of Infusion Supplies Not Ordered by the Patient’s Physician More Often Than Expected Leading to More Expense for the Patient and Insurance Company

F. The Nurse Failed to Properly Place a Peripheral IV Line and Ignored Immediate Complaints of Pain and Discomfort Leading to Vesicant Extravasation and Tissue Death

G. The Nurse Failed to Properly Insert a Peripheral IV Line Causing Irreversible Nerve Damage

H. The Implanted Portacath Fractured Causing a Pulmonary Embolism Which Led to Patient Death

I. An RN Improperly Performed a PICC Placement Without Proper Training Which Led to Patient Injury and Delay of Treatment

J. The Nurse Failed to Identify an Infiltrated Peripheral IV Line Which Lead to Compartment Syndrome and Permanent Tissue and Nerve Damage

K. The Hospital Staff Failed to Notice the Chemotherapy Extravasation from the Newly Placed, Malfunctioning Mediport Causing Third Degree Burns on the Patient’s Chest and Need for Antidote Delivery Which Resulted in a Longer Hospital Stay, Additional Surgical Procedures, and Emotional Pain and Suffering (Exhibit D)
L. The Blood Bank, Medical and Nursing Staff Failed to Communicate Properly Which Led to the Wrong Blood Type Being Transfused and Ultimate Patient Death

M. The Hospital Staff Failed to Assess the Patient’s Allergies Before Infusing a Medication the Patient Was Allergic to and Failed to Monitor the Patient for Complications, Leading to Patient Death

N. The Huber Needle Used to Access the Patient’s Mediport Was Defective and Led to Leakage of a Vesicant on the Patient’s Chest Which Caused Third Degree Burns and Led to Patient’s Death

O. The Hospital Failed to Use Electronically Secure Intravenous Medication Administration Pumps Allowing Them to Be Hacked Which Led to Patient Injury and Death

P. The Physician Failed to Double Check the Infusion Pump Flow Rate Set by the Nursing Staff Prior to Allowing the Patient to Leave the Office Which Caused Delay in Noticing the Improperly Set Rate and Ultimately Led to Chemotherapy Overdose and Patient Injury (Exhibit E)

IV. COMMON DEFENSES FOR IV THERAPY CASES

A. The MD Was Not Notified That the CVC Was Not Functioning Properly

B. The RN Did Not Cause the Injury. The IV Access Device Malfunction Was the Cause and the Nurse Had to Handle the Situation Resulting from the Device’s Malfunction (Exhibit D)

C. The Appropriately Trained RN Placed This Vascular Access Device (PICC Line) Using Sterile Technique and Followed All Current Manufacturer Recommendations
D. The Integrity Breach Between the Needle and Tubing of the Huber Needle Which Led to the Leakage of Chemotherapeutic Medicines on the Skin of the Patient Causing Burns to the Patient’s Chest Was Appropriately Managed by the Nurses (Exhibit E)

E. The Patient Removed the One-Way Valve on the Central Line Which Caused the Air Embolism That Led to His Death

F. The Nursing Staff Immediately and Appropriately Responded to the Inadvertent Removal of the Central Line

G. The Medication Overdose Antidote, Totect, Was Effectively and Immediately Administered Upon Recognition of the Anthracycline Chemotherapy Overdose by a Provider from a Different Hospital (Exhibit D)

V. THE ROLE OF THE CERTIFIED LEGAL NURSE CONSULTANTCM IN IV THERAPY CASES

A. Review the Records and Determine if There Was a Breach in SOC Related to IV Therapy Management

1. IV therapy issues may not be the reason the attorney requests your case review, however you may discover they are relevant.
   a. Example: Poor nursing care related to NG tubes is now seen in the area of IV therapy. This possibly creates a theme of either poor nursing skills or poor nursing supervision. (Exhibit A)

B. Determine if the Breach Caused Patient Injury or Harm

1. Review the medical records to find evidence of line placement and maintenance of the IV access device.

2. Review the medical records for evidence of any injuries related to an adverse reaction to IV therapy.
   a. Locate photographs of injuries that may have been taken to document the injury and need for treatment.
3. Review the medical records to determine response to treatment after discovery of an adverse outcome to IV therapy.

4. Determine if the patient or family member kept a diary or journal regarding the IV therapy injury.

5. Review the medical records to determine whether additional care was provided to the patient that would not have been provided in the absence of complications related to medication administration through an IV device.
   a. Consider costs of additional treatment.
   b. Consider whether additional treatment of an adverse reaction caused a delay in the delivery of the originally prescribed therapy.
   c. Identify which care providers were involved in recognizing and managing an IV therapy adverse reaction.
   d. Identify the physicians who gave IV therapy orders.

6. Compare these findings with the known SOC to determine if steps taken after an IV therapy failure were appropriate.

C. **Communicate the Information to the Attorney-Client Either Verbally or in Writing**

D. **Develop a Chronology Showing the Management of a Specific Vascular Access Device**

1. Include comments related to breaches or adherences to the SOC.

2. Consider highlighting areas of additional treatments required to treat an IV therapy adverse reaction.

3. Consider highlighting any independent actions taken by nursing staff without a physician order.

E. **Write a Report to Help Educate the Attorney-Client**

F. **Interview the Patient and Bystanders to Help Your Attorney-Client Develop the Case**
G. Assist the Attorney-Client by Attending an Independent Medical Exam (IME) Where the Injury from an Infiltrated IV Line Is Examined by an Independent Physician

H. Help Develop Demonstrative Evidence with a Comparison of a Right Arm/Left Arm Diagram and a Posterior Arm View/Anterior Arm View Diagram to Effectively Explain Why the Two Are Distinctly Different Diagrams (Exhibit F)

I. Prepare Reports for the Attorney-Client Which Include IV Therapy Standards Which Can Be Used as Demonstrative Evidence to Help Keep Expert Witnesses on Track During Trial (Exhibit D)

J. Assist Your Attorney-Client by Identifying Specific Authoritative IV Therapy Articles, Journals and Textbooks Which Can Be Used to Bolster Testimony of Experts and to Determine if the Breach Caused Patient Injury or Harm

VI. INTERROGATORIES AND REQUESTS FOR PRODUCTION

A. Interrogatories Directed to the Defense

1. Please list the name, telephone number, mailing address and email address of those who have knowledge of (Plaintiff) __________’s alleged injuries at (Facility) __________ caused by (Nurse) __________ from (Date) __________ to (Date) __________.

2. Please list the name, brand and model of infusion pumps used on the (Type of Care) __________ unit where (Plaintiff) __________ was treated at the time of alleged injury on (Date) __________.

3. Please list the name, brand and exact IV therapy equipment stocked on the (Type of Care) __________ unit at (Hospital) __________ from (Date) __________ to (Date) __________ where the plaintiff was treated.

4. Please identify the exact training required to be provided to all staff members who work on the (Type of Care) __________ unit during the time that (Plaintiff) __________ was treated at (Hospital) __________.
5. Please identify the exact training that the RNs who treated (Plaintiff) __________ on (Date) __________ received from (Date) __________ to (Date) __________ before treating her on the date of the alleged injury.

6. Please identify the supplies listed in the infusion therapy homecare order by (Physician) __________ for (Plaintiff) __________.

7. Please identify the specific supplies and amount of each supply included in each delivery for (Plaintiff) __________ from (Date) __________ to (Date) __________.

8. Please provide the name, address, telephone number and fax number of the infusion company that was ordered to provide care and/or infusion therapy supplies to (Plaintiff) __________.

9. Please provide the names of all intravenous medications ordered to be provided to (Plaintiff) __________ on (Date) __________ by (Physician) __________.

10. Please provide the name of all intravenous medications provided to (Plaintiff) __________ on (Date) __________ as ordered by (Physician) __________.

11. Please identify the name of all policies and procedures used at any time while treating (Plaintiff) __________ from (Date) __________ to (Date) __________ at (Hospital) __________.

B. Interrogatories Directed to the Plaintiff

1. Please list your name, address, telephone number and email address.

2. Please list the name, address, telephone number and email address that you were using at the time of the alleged injury on (Date) __________.

3. Please identify the name of any social media you have ever used from (Year) __________ to (Year) __________ and list associated usernames.

4. Please identify the exact dates that you were treated at (Hospital) __________ from (Date) __________ to (Date) __________.
5. Please list the names, address, telephone numbers, fax numbers and email addresses of all physicians, infusion companies and healthcare providers who assisted or treated you from (Date) __________ to (Date) __________.

6. Please describe the care given to you by (Defendant Nurse) __________ on (Date) __________ on the (Unit) __________ at (Hospital) __________.

7. Please describe the care given to you by (Defendant Physician) __________ on (Date) __________ on the (Unit) __________ at (Hospital) __________.

8. Please provide the names of all nurses who treated you on (Date) __________ on the (Unit) __________ at (Hospital) __________ to the best of your recollection.

9. Please provide the names of all physicians who treated you on (Date) __________ on the (Unit) __________ at (Hospital) __________ to the best of your recollection.

10. Please provide all documents given to you by any and all hospital staff during your stay at (Hospital) __________ from (Date) __________ to (Date) __________ and to the best of your ability, identify the staff member who provided you with each document.

C. Requests for Production Directed to the Defense

1. Please provide a copy of all reports and demonstrative evidence to be used by any and all testifying experts who may be called as witnessed in the case involving (Plaintiff) __________.

2. Please provide a copy of all reports and demonstrative evidence to be used by any and all testifying experts who may be called as witnessed in the case involving (Plaintiff) __________.

3. Please produce the brand and names with photographs of all IV therapy equipment stored in the supply room and equipment room on the (Unit) __________ at (Hospital) __________.

4. Please produce the policy and procedure for medical record documentation at (Hospital) __________ for (Year) __________.
5. Please produce the business card(s) of the representative(s) of the electronic medical documentation (EMR) system who in-serviced the staff on (Unit) __________ at (Hospital) __________ on (Date) __________, when (Plaintiff) __________ was a patient.

6. Please provide copies of the medical record for (Plaintiff) __________ from (Date) __________ to (Date) __________ while a patient at (Hospital) __________.

7. Please provide the human resources employee file for (Nurse) __________ who treated (Plaintiff) __________ on the date of the alleged injury.

8. Please provide any management files maintained on (Nurse) __________ who treated (Plaintiff) __________ on the date of the alleged injury.

9. Please provide descriptions of the training required of and provided to all nurses on (Unit) __________ at (Hospital) __________ in (Year) __________.

10. Please provide all education files for all nurses who treated (Plaintiff) __________ from (Date) __________ to (Date) __________ at (Hospital) __________.

11. Please provide the minimum education and training for all nurses who provide and monitor patients receiving chemotherapy at (Hospital) __________ from (Date) __________ to (Date) __________.

12. Please provide the names and dates of any medication errors made by (Defendant) __________ while he was an employee at (Hospital) __________.

D. Requests for Production Directed to the Plaintiff

1. Please provide a copy of all reports and demonstrative evidence to be used by any and all testifying experts who may be called as witnesses in the case involving (Plaintiff) __________.

2. Please provide copies of all documents given to (Plaintiff) __________ while treated as an inpatient at (Hospital) __________ from (Date) __________ to (Date) __________.
3. Please provide copies of all documents signed by (Plaintiff) __________ related to any deliveries of supplies by (Company) __________.

4. Please provide any photographs of supplies or documents which may be used as demonstrative evidence by any of the witnesses during the trial involving (Plaintiff) __________.

5. Please provide any teaching or instructional documents given to (Plaintiff) __________ regarding care of his IV access device and give the name of the person who provided the documents to him from (Date) __________ to (Date) __________.

6. Please provide any medication informational documents provided to (Plaintiff) __________ during (Date) __________ to (Date) __________.

7. Please provide any photographs of the injuries caused by the defective IV therapy device taken on the date of injury and throughout the treatment and recovery of the injuries sustained from (Date) __________ to (Date) __________.

8. Please provide copies of all consent forms signed by __________ (Plaintiff) related to placement of central vascular access devices.

9. Please provide any diaries or journals written by the plaintiff or family members of the plaintiff discussing the events of the hospital stay from (Date) __________ to (Date) __________.

10. Please provide all medical bills related to the home infusion therapy from (Date) __________ to (Date) __________.

VII. RECOMMENDED QUALIFICATIONS FOR CLNC® SUBCONTRACTORS FOR IV THERAPY CASES

A. Certified Registered Nurse Infusion (CRNI) Certification

1. The CRNI certification includes the chemotherapy and biotherapy administration information.
B. Oncology Nursing Society (ONS) Chemotherapy and Biotherapy Administration Certifications

1. The ONS certification does not include all infusion therapy information covered in the CRNI.

C. Association of Pediatric Hematology/Oncology Nurses (APHON) Certifications

1. Pediatric chemotherapy and biotherapy provider course completion.

D. Certified Legal Nurse Consultants (CLNC®) in the NACLNC® Directory

1. CLNC® consultants who specialize in IV therapy or who consider IV therapy to be one of their top two areas of experience.

VIII. CASE STUDIES

A. 45-Year-Old Male with a Chemotherapy Overdose That Occurred When the RN Improperly Set the CADD Infusion Pump (Exhibit E)

1. Male patient had a port placed to facilitate chemotherapy administration.

2. Following port placement, the patient was seen in the oncology office where the staff RN placed a 5-FU infusion that would be running continuously for seven days.

3. The next morning, the patient realized the medication reservoir of the CADD pump was almost empty.

4. The physician was called and told the patient to stop the infusion and come in for evaluation.

5. The patient’s overdose required admission to the hospital and immediate antidote administration.

6. The medical records showed three things:
   a. The infusion pump was not set at the correct rate. The incorrect rate was documented in the patient’s chart.
   b. There was no documentation of any two-person checks before or after starting the infusion.
c. The infusion pump was not locked to prevent changes in the rate.

7. The nurse admitted to making the mistake when she set the rate.

8. Disciplinary measures that were taken were discussed in the medical record written by the physician.

B. 6-Month-Old Female Suffered from a Nasoduodenal (ND) Tube Displacement That Perforated Her Intestines with Associated Injury from a Central Line That Was Malfunctioning Immediately Upon Placement But the CVC Was Left in Place, Causing a Code Situation

1. PICU RNs charted on all invasive devices in the electronic medical record. (Exhibits G and H)

2. Central venous access was required in this patient. Multiple attempts to place a right double lumen femoral line were unsuccessful.

3. The attending placed a double lumen femoral line in the left femoral vein.

4. Documentation of placement found in two sections of the electronic medical records indicating that one of the two lumens did not have a blood return. The line was left in place. (Exhibits B and C)

5. 24 hours later, the bedside RN indicated that the vasopressor drips were running but the infusion pump continued to beep an occlusion alarm.

6. The RN documented, “The third time the line became occluded, a code situation occurred. This was due to the interruption of vasopressors.”

C. Infusion Company That Received a Physician’s Order for 12 Huber Needles and 30 Pre-Filled Normal Saline Syringes, a 12-Month Supply for a Patient’s Mediport, Improperly Billed the Patient and Insurance Company

1. A patient with a Mediport required additional supplies to access and flush the line.
2. Her physician faxed an order for 30 individually wrapped 0.9% normal saline pre-filled flushes, 12 non-safety 22 gauge ¾” Huber needles, and 12 one-way valves.
   a. The infusion company called the physician and asked for a nurse visit order based on their protocol.

3. Later that evening, the ordered supplies were delivered to the patient in a large box.
   a. Extra supplies that were not ordered were provided.
   b. An order for 12 months of supplies to be given to the patient in bulk was split into 12 pieces in order to allow the infusion company to bill the insurance company each month.
   c. The patient refused to accept the supplies because the wrong type of Huber needle and one-way valve was sent.

4. The infusion nurse contacted the patient and acknowledged the fact that the infusion company makes more money when extra supplies are provided to a patient.
   a. The nurse also told the patient that the infusion company has patients who receive infusion supplies without a need for nurse visits.

5. The paperwork that accompanied the large box of supplies supported the availability of “supplies only” as one of the available services.
   a. The paperwork indicated that the order was for port care and included nursing visits.

6. The cost to the patient when the order was split was more than the price of the ordered supplies in bulk.

7. The infusion company advised the patient that they have a contract with the insurance company and could charge them up to $75/day.
   a. Splitting one order into multiple orders with the intent to obtain higher reimbursements is: Unbundling. (Exhibit A)
   b. Unbundling is one of the most common healthcare fraud schemes.

D. The Third Party Biller Appeared to Have Fabricated Nursing Records Related to IV Medications and IV Access Devices to Obtain Payment for Services Rendered in an ED (Exhibits I-M)

1. An overseas provider with a third party biller in the U.S. was asked to submit additional medical records to support the ED charges included in the insurance claim.
2. When the request was made, the RN, CLNC specified standard components of the IV therapy record and medication administration record.
   a. The RN, CLNC purposely left out specific details that would have been standard to document.

3. Medical records were sent in with the resubmitted claim.
   a. The IV therapy record was missing basic details: Catheter length, fluid it was flushed with, presence of a blood return and in which arm the PIV was placed. (Exhibit M)
      (1) All of the details mentioned appeared in the record in the order mentioned in the record request.
      (2) Anything not mentioned was not included on the document.
   b. It appeared that the person who created the records was unaware that the diagram used to denote PIV location was an anterior/posterior arm view and not a right arm/left arm view. (Exhibit F)
      (1) Only one of the arms in the diagram had hand veins labeled.

4. The medication administration record (MAR) was not used properly. (Exhibit L)
   a. In some cases, IV meds were documented as being administered but the IV had not yet been placed according to the IV therapy record.
   b. Incompatible drugs were ordered to be administered together.
   c. Multiple physician orders were lacking drug dosages.
   d. IV push medications and PO medications were listed as having start and stop times.

5. The medication orders in many of the SOAP (subjective, objective, assessment and plan) notes included improper dosing of medications for the adult patient and improper drugs for the condition supposedly being treated. (Exhibit I)
   a. This caused the RN, CLNC investigator to consider whether there could be a safety problem if the medications were actually provided to a patient as ordered.
   b. Identification of the same SOAP notes being used on different dates of service for different members of the family led to the determination that these records had been fabricated with the intent of defrauding an insurance company.
   c. The investigator questioned whether the provider was an actual physician because of the unusual medication orders,
and the improper documentation on the MAR and IV therapy record. (Exhibit L)

d. The red flag that caused further scrutiny of the claims for this family of three was the order for Zelnorm, a drug taken off the market in 2007 due to cardiac side effects.

   1. The drug was ordered for a high-risk patient years after the drug was removed from the market.

   2. The claim form indicated that the physician had signed the claim form in 2010 for a claim that occurred in 2015.

6. This case is being referred to the FBI.

IX. CHECKLISTS AND FORMS

A. Examples of Infusion Therapy Access Device Flow Sheets (Exhibits G, M and N)

1. Review for basic standard contents. If missing, keep your ‘FWA’ glasses on.
   a. FWA glasses – Your high index of suspicion for fraud, waste and abuse in healthcare.

2. It is unusual to have different nursing and IV access documentation forms in a company that has multiple practice locations.

B. Example of a MAR (Exhibit L)

1. Necessary components.
   a. Patient identifiers.
   b. Medication/drug.
   c. Dose.
   d. Route.
   e. Rate.
   f. Infusion start time/time of administration.
   g. Time the infusion completed.
   h. Provider who administered the medication.
C. Example of a Chemotherapy Order Form

1. Necessary components.
   a. Patient identifiers.
   b. Chemotherapy cycle.
   c. Clinical trial/chemotherapy protocol information.
   d. Drug name.
   e. Drug dosage calculations.
   f. Patient weight.
   g. Patient body surface area (BSA).
   h. Lab values to be checked before administration.
   i. Premedication with appropriate dosages.
   j. Drug.
   k. Dosage.
   l. Route.
   m. Rate.
   n. Titration.
   o. Post hydration.
   p. Post administration labs.
   q. Provider who administered and provider who double checked with their signatures.

D. Basic IV Therapy Documentation Should Include the Following Details (Exhibits M and N)

1. Peripheral v central intravenous access device.
   a. PIV: Length and gauge.
   b. CVC: Type, number of lumens, internal length, external length, catheter tip position.
      (1) The ideal position for the tip of a central line is in the cavoatrial junction.
      (2) All patients with a CVC should have information on their line. A duplicate copy should be maintained in the medical record.

2. IV placement information.
   a. Date and time of placement.
   b. Name and initials of person(s) responsible for placing IV.
   c. Number of attempts and their location.

3. Location of the venous access device (VAD): Specific vein.
   a. By name or by using a diagram to denote the vein used.
      (1) There is a difference between anterior/posterior and right arm/left arm diagrams that can be determined because in anterior/posterior views, only one of the
arms will have veins identified on the hand (anterior view). *(Exhibit F)*

   a. PIV: Blood return and ease of flushing.
   b. PICC line: EKG method, or under indirect visualization via fluoroscopy or CXR.
   c. CVC: CXR or under indirect visualization via fluoroscopy.

5. Type of dressing used and date last changed.
   a. Dressing types include transparent v gauze.

6. Method of maintaining an infection-free line.
   a. Biopach.
   b. Chlorhexidine gluconate (CHG) dressings.
   c. CUROS™ caps.
   d. CHG preps v alcohol preps.

7. Method of maintaining patency.
   a. This may be noted in nursing notes or the MAR especially if heparin is used.
      (1) Type of one-way valve used.
          (a) Positive pressure v neutral v negative.
      (2) Flushing standards.
          (a) Heparin v saline.
      (3) Mediport flushing standards.
          (a) Requires a doctor's order because heparin is a medication.
          (b) Different heparin concentrations 10 unit/cc v 100 unit/cc.
              i) 10 units/cc – Peripheral line or intermittent flushing of a Mediport when the needle is not being removed.
              ii) 100 units/cc – Use only when re-accessing a Mediport.
          (c) If heparin is used, the concentration must be documented.
          (d) It is not appropriate to document the color of the syringe holding the heparin.
              i) Blue = 10 units/cc.
              ii) Yellow = 100 units/cc.
          (e) There is incidence of manufacturer error of putting the higher concentration heparin in the blue syringe and the 10 unit/cc in the yellow syringe.
8. Routine site assessments. *(Exhibit G)*
   a. Some hospitals continue to have routine site changes even if
      the line appears to be okay when assessed.
      (1) Typically three to four day site rotation in adults.
      (2) Site rotation is often not done for pediatric patients.
      (3) Documentation of clean, dry, intact dressing should
          be indicated in the patient’s chart.

9. Arm circumference measurements for PICC and midlines.
   a. Notation of the exact spot the measurement was taken must
      be documented to truly identify changes.

10. Removal date, time, reason for removal, condition of catheter and
    appearance of the old IV site.

**X. RESOURCES**

**A. Associations and Organizations**

   [avainfo.org](http://avainfo.org)

2. Association of Pediatric Hematology/Oncology Nurses.
   [aphon.org](http://aphon.org)

3. Food and Drug Administration (FDA).
   [fda.gov](http://fda.gov)

4. Infusion Nurses Society.
   [ins1.org](http://ins1.org)

   [nhcaa.org](http://nhcaa.org)

   [nhia.org](http://nhia.org)

7. Oncology Nurses Society.
   [ons.org](http://ons.org)
B. Authoritative Textbooks


C. Journal Articles


8. Infusion Therapy Standards of Practice 2016: *Journal of Infusion Nursing.* Supplement to January/February 2016, Volume 39, Number 1S.


D. Websites

   cathmatters.com  
   cathmatters.com/education

2. Institute of Medicine (IOM) Guideline Clearinghouse.  
   guideline.gov

3. Intravenous Nursing Society Learning Center.  
   learningcenter.ins1.org

4. IV Access.  
   ivaccess.com

5. IVTEAM.com.  
   ivteam.com/vascular-access-and-infusion-therapy-resources
## Exhibit A
### Medical Terms or Abbreviations and Definitions

<table>
<thead>
<tr>
<th>Medical Term or Abbreviation</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>APHON</td>
<td>Association of Pediatric Hematology Oncology Nurses.</td>
</tr>
<tr>
<td>ASC</td>
<td>Ambulatory surgery center.</td>
</tr>
<tr>
<td>CA Junction</td>
<td>CavoAtrial junction (where the superior vena cava and right atrium meet).</td>
</tr>
<tr>
<td>CHG</td>
<td>Chlorhexidine.</td>
</tr>
<tr>
<td>CLABSI</td>
<td>Central line associated blood stream infection.</td>
</tr>
<tr>
<td>Compatibility Chart</td>
<td>Chart used by healthcare professionals to look up specific IV fluids and medications in order to determine whether they can be safely mixed together.</td>
</tr>
<tr>
<td>CXR</td>
<td>Chest X-ray.</td>
</tr>
<tr>
<td>CRNI</td>
<td>Certified registered nurse of infusion.</td>
</tr>
<tr>
<td>CVC</td>
<td>Central venous catheter.</td>
</tr>
<tr>
<td>DX</td>
<td>Diagnosis.</td>
</tr>
<tr>
<td>Extravasation</td>
<td>The inadvertent administration of a vesicant into the tissues; the intensity of the irritating action is so severe that plasma escapes from the extracellular space and blisters are formed. Large extravasations of some medications may lead to contractures, with the need for debridement and grafting. Severe cases may require amputation.</td>
</tr>
<tr>
<td>FLARE</td>
<td>A red streak or patchy urticaria along a vein, usually associated with the intravenous infusion of a hypotonic solution or of certain medications. It normally disappears within one to two hours, and almost never lasts longer than 12 to 24 hours.</td>
</tr>
<tr>
<td>FWA</td>
<td>Fraud, waste and abuse.</td>
</tr>
<tr>
<td>Gauge</td>
<td>Referring to the size of an IV catheter's lumen.</td>
</tr>
<tr>
<td>IO</td>
<td>Intraosseous.</td>
</tr>
<tr>
<td>Infiltration</td>
<td>Inadvertent pooling of fluid outside of the vein.</td>
</tr>
<tr>
<td>IV</td>
<td>Intravenous.</td>
</tr>
<tr>
<td>MAR</td>
<td>Medication administration record.</td>
</tr>
<tr>
<td>NDT</td>
<td>Nasoduodenal tube.</td>
</tr>
<tr>
<td>Medical Term or Abbreviation</td>
<td>Definition</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>------------</td>
</tr>
<tr>
<td>NGT</td>
<td>Nasogastric tube.</td>
</tr>
<tr>
<td>ONS</td>
<td>Oncology Nursing Society.</td>
</tr>
<tr>
<td>PICC</td>
<td>Peripherally inserted central catheter.</td>
</tr>
<tr>
<td>PIV</td>
<td>Peripheral intravenous (line).</td>
</tr>
<tr>
<td>Powerline</td>
<td>A central venous access device strong enough to handle the pressure of a rapid infusion. (BARD makes all of these lines in PURPLE to minimize confusion).</td>
</tr>
<tr>
<td>PN</td>
<td>Parenteral nutrition.</td>
</tr>
<tr>
<td>PPN</td>
<td>Peripheral parenteral nutrition.</td>
</tr>
<tr>
<td>SBAR</td>
<td>Situation, background, assessment and recommendation. This is a method of documentation and communication used by many healthcare professionals.</td>
</tr>
<tr>
<td>SOAP</td>
<td>Subjective, objective, assessment and plan. This is a method of documentation used by many medical professionals.</td>
</tr>
<tr>
<td>TPN</td>
<td>Total parenteral nutrition including lipids.</td>
</tr>
<tr>
<td>TX</td>
<td>Treatment.</td>
</tr>
<tr>
<td>Unbundling</td>
<td>A fraudulent practice in which provider services are broken down to their individual components, resulting in a higher payment from the insurance company or the patient. Examples: Blood or chemistry panels.</td>
</tr>
<tr>
<td>VAT</td>
<td>Vascular access team.</td>
</tr>
<tr>
<td>Vesicant</td>
<td>A chemical agent that causes burns and destruction of tissue both internally and externally. (often related to the pH of the infusate).</td>
</tr>
</tbody>
</table>
Exhibit B
Narrative Procedure Report for CVC Placement

EMR section: “other results.”
Exhibit C
Additional CVC Narrative Procedure Note

Procedure Notes (continued)

SpO2 99.00%.

Central line
Date/Time: 06/06/0000 9:10 AM
Attending present during the procedure.
The procedure was discussed with the attending.
Performed by:
Authorized by:
Consent: Verbal consent obtained. The procedure was performed in an emergent situation.
Risks and benefits: risks, benefits, and alternatives were discussed
Consent given by: parent
Patient status understanding of procedure being performed: parent states understanding of the procedure
being performed.
Patient's understanding of procedure matches consent: Parent's understanding of procedure matches consent.
Procedure consent: procedure consent matches procedure scheduled
Relevant documents: relevant documents present and verified
Test results: test results available and properly labeled
Site marked: the operative site was marked
Imaging studies: imaging studies available
Required items: required blood products, implants, devices, and special equipment available
Patient identity confirmed: hospital-assigned identification number and arm band
Time out: Immediately prior to procedure a "time out" was called to verify the correct patient, procedure,
equipment, support staff and site/side marked as required.
Indications: vascular access
Anesthesia: see MAR for details
Preparation: skin prepped with Chloraprep
Skin prep agent dried: skin prep agent completely dried prior to procedure
Sterile barriers: all five maximum sterile barriers used - cap, mask, sterile gown, sterile gloves, and large sterile
sheet
Hand hygiene: hand hygiene performed prior to central venous catheter insertion
Location details: left femoral
Patient position: flat
Catheter type: double lumen
Catheter size: 4 Fr (x 8cm)
Pre-procedure: landmarks identified
Ultrasound guidance: no
Number of attempts: 1 (There were 5 or more previous unsuccessful attempts in the right groin under
ultrasound guidance)
Successful placement: yes
Permanent recorded image of site in record: Yes
Patency: Open
Post-procedure: line sutured and dressing applied
Assessment: placement verified by x-ray (Blood return from lumen 1 but not lumen 2. Both lumen flush well)
Patient tolerance: Patient tolerated the procedure well with no immediate complications.
Exhibit D
Long Testifying Expert Report (Totect)

RN, CLNC
51 Goebel Road Suite 211
Columbia, Maryland 20145

January 24, 0000

Attorney, Esq
25 Prospect Street
Morristown, New Jersey 07960

RE: Jason Miller v Melissa Dixon, RN and Laura Thomas, RN et al.
Docket no: MRS-L-2408-12

Dear Attorney,

Thank you for requesting my expert review of medical records surrounding the care of Mr. Jason Miller regarding the December 22, 0000 episode of the chemotherapy extravasation on behalf of your clients Melissa Dixon, RN and Laura Thomas, RN.

I have reviewed the following medical records and documents provided to me by your office.

1. Deposition transcript of Melissa Dixon, RN.
2. Deposition transcript of Laura Thomas, RN.
3. Deposition transcript of Lisa Katz, RN.
4. Expert report of Mary Sweat, RN.
5. Deposition transcript of Mark Lewis, MD.
6. Deposition transcript of George Santini, DO.
7. Deposition transcript of Jason Miller (Plaintiff).
8. Deposition transcript of Debbie Jamison.
9. Answers to interrogatories of Melissa Dixon, RN.
10. Answers to interrogatories of Laura Thomas, RN.
11. Plaintiff’s answers to interrogatories.
12. Medical records from Allison Minky, MD.
13. Medical records from Jeffrey Picard, MD.
14. Medical records from George Santini, DO.
15. Medical records from Aaron Short, MD.
16. Records from plaintiff’s December 22, 0000 admission at Middleburg Medical Center.

In addition, I have reviewed the following articles and texts to help formulate my expert opinion. A complete bibliography of these resources accompany this letter.
2. Vesicant extravasation from an implanted venous access port.
4. Oncology Nursing Society releases updated guidelines on management of extravasations.
10. Preventing and managing vesicant chemotherapy extravasations (Journal of Community and Supportive Oncology).
12. Infusion nursing standards of practice (0000).
13. Chemotherapy and biotherapy guidelines and recommendations for practice (0000).

Based on my review of the medical records listed, I have determined that the following timeline of events occurred.

Mr. Miller was admitted to Middleburg Medical Center from a rehabilitation facility on December 22, 0000 for the purpose of Mediport placement and initiation of chemotherapy treatment for osteosarcoma of his thoracic spine. Dr. Lewis placed his Mediport under fluoroscopic guidance without problem. A 1″ Huber needle was left in place by the surgeon for the expected immediate chemotherapy administration upon patient’s return to the oncology unit. Prior to leaving the operating room, Dr. Lewis noted positive blood return in the central line. A portable chest X-ray (CXR) was performed and he later gave the order to use the Mediport/port-a-cath after noting that the central line’s tip was in the proper location at the edge of the superior vena cava/right atrial junction (cavoatrial junction).

Upon reviewing the order in the chart, the oncology unit nurses properly prepared his Adriamycin (Doxorubicin) infusion for administration using the hospital’s protocol and the two-nurse double check. The nurses were both in the room when they double checked blood return from Mr. Miller’s port, giving them the indication that it was in the proper place and safe for chemotherapeutic medication administration. This was done at 2:30pm. (Blood return from Mr. Miller’s port was also checked about an hour earlier with positive results per documentation in the medical record.)

As would be expected, the checks before starting the infusion took 10-15 minutes. Upon starting the medications, they noted the approximate time that the carrier fluid would be

Contents
out of the primary line and the actual chemo dose would reach the patient. They then planned to return to his room when the infusion was expected to be complete. Before leaving his room, both nurses advised Mr. Miller to use his call bell if anything felt “different” or if he needed anything per their reported usual practice.

Upon returning to the room shortly after the change of shift, L. Thomas, RN noted approx. 5ml of the red-orange fluid pooled under the Tegaderm dressing around the Huber needle. She stopped the infusion, appropriately tried to get a blood return from the Huber needle and was not able to. She notified the physician and initiated the hospital extravasation protocol. She also notified her charge nurse and the educator on the unit. At 4:08pm, she obtained the phone order from Mr. Miller’s attending physician, Dr. Santini: “Totect per protocol STAT,” M. Dixon, RN whose shift had ended at 3:00pm, personally went to the pharmacy to hand carry the antidote to the patient’s bedside. Dr. Santini called back about 15 minutes later with the exact dosage he wanted the nurse to administer. By doing this, he got the pharmacy alerted to the need for the medication and gave them time to start preparation of this medication. By giving the order in a two-step manner, he cut down on the time it would normally take to decide the dosage before ordering the medication from the pharmacy. Accepting the first order without a dose, knowing a dose would follow before administration was prudent on L. Thomas’s part.

The Totect was administered through a new PIV placed in Mr. Miller’s left forearm at 5:00pm, less than two hours after the extravasation had occurred. Based on documentation in the medical record, it was evident that multiple nurses and physicians assessed Mr. Miller’s chest. It is also evident that psychological care was given to Mr. Miller and his family surrounding this incident. Definitive assessment of Mr. Miller’s port was made the following day with a dye flow study through a newly inserted 1” Huber needle. The port was found to be intact without deficit. His chemotherapy was restarted through the Mediport the following day and the remaining two Totect doses were administered peripherally as ordered.

Continued assessments on Mr. Miller’s skin were made throughout his stay at Middleburg Medical Center. Based on the depositions of both L. Thomas, RN and M. Dixon, RN neither of these nurses cared for Mr. Miller again during this hospital admission.

Expert Opinion
Based on the information I’ve been provided and reviewed, and research I have done, my expert opinion in the matter of the immediate treatment and nursing care of the Adriamycin extravasation of Jason Miller, there was no deviation from the standards of care at the time of the incident. I believe that both nurses, Laura Thomas and Melissa Dixon, followed the accepted standard of care in administering a vesicant, like doxorubicin, through an implanted port. They also adhered to these standards when noticing the potential extravasation by immediately discontinuing the infusion and removing the Huber needle from the port-a-cath. They properly prioritized their interventions and made immediate actions to obtain the antidote that was delivered to
the patient properly within the six-hour time frame suggested by guidelines and Totect manufacturer recommendations.

The plaintiff’s expert, Mary Sweat, RN, MS suggested that L. Thomas, RN and M. Dixon, RN did not continuously check for proper port placement during the chemotherapy infusion. Proper placement of the Huber needle cannot be checked by visualization. The only way to check for proper placement is by assessing for blood return. Both the nurses and the surgeon checked twice before the infusion began, as documented in the medical records.

Interruption of an IV push vesicant through a peripheral IV line (PIV) is typically double checked for blood return every few minutes because of the more frequent incidence of infiltration in these smaller and shorter IV lines placed in smaller peripheral veins of the forearms, hands, legs and feet. With IV push medications given via syringe, checking for blood return frequently does not involve opening the line which causes infection risk to the patient and chemotherapy risks to the provider. The system remains closed during this check.

In an IV drip vesicant infusion via central line, any blood return check requires both of these risks to be present. The risk is greater for infection as the tip of the line ends in the patient’s heart and delivers the resulting bacteria directly into the heart. Treatment of patients with central lines follow strict standards of care to prevent infection making this recommendation questionable. I believe that the suggestion of it being appropriate to double check blood return through an IV drip administration of a vesicant through a central vascular device like Mr. Miller’s Mediport to be a misinterpretation of the suggested guidelines. I also believe that is suggests a gross misunderstanding of the mechanics and principles behind infection prevention in immunocompromised patients or those with central vascular access.

It is possible for extravasation to occur even in a properly positioned Huber needle if an integrity problem occurs in the properly placed needle and the tubing attached to it. It is my belief that this was the encountered problem.

The plaintiff’s expert, Mary Sweat, RN, MS suggested that neither education nor emotional support was provided to the patient post extravasation. I will address each of these areas separately but feel that both were delivered to the patient properly and likely promptly.

The medical records stated that approx. 5ml of the Adriamycin was “pooled” under the Tegaderm dressing. This dressing is a thin, clear, completely adhesive covering. It is not permeable and does not have the ability to wick fluids away from the skin. If completely adhered to the skin, pooling of medication, perspiration or fluids would not be possible.

During Mr. Miller’s initial port placement and accessing with the initial Huber needle by the surgeon, a 1″ long Huber needle was used. Since a ¾″ Huber needle was used later
on in Mr. Miller’s treatment, it can be noted that the 1” Huber needle would be positioned so it had a space between the skin covered port and the wings of the Huber needle. It would be expected that the plastic wings of the Huber needle would have been pushed down leaving space for medication to pool under the dressing and Huber’s wings but without affecting the integrity of the Tegaderm. This space allow for areas of Tegaderm to be raised off of the patient’s skin. This is why the dressing did not peel off when the medication leaked from the Huber needle tubing onto his chest. Tegaderm does not have the ability stretch.

For a medication to pool under a Tegaderm, the Tegaderm still needs to be intact. Pooling would not occur under a dressing that has peeled off. Based on the description of the initial reddened areas, it is my belief that the dressing remained intact until removal by the nurses who noticed the Adriamycin pooling underneath. The removal of the dressing likely caused initial reddening of the surrounding skin. (Many central line dressings are 8x8 to 12x12 in size.) Based on multiple documents in the medical records by nurses and doctors, the patient’s initial response to the Totect administration was favorable and symptoms of redness and skin irritation were favorable. Redness from removal of Tegaderm or other dressings typically resolves quickly in most patients.

Since the 1” Huber needle was used, approximately ½” to ¾” or the entire Huber needle would have had to be pulled from his chest to allow for medication to leak from the distal part, or tip, of the needle onto Mr. Miller’s chest. Had that happened, the dressing would not have stayed intact and pooling could not have occurred. If the needle dislodged and pooling could not have occurred, gravity would ensure the medication dripped either laterally or distally ensuring that the Tegaderm was completely saturated in the medication.

For the fluid to leak from the tip of the needle, the entire inch would have had to dislodge from Mr. Miller’s chest. A port has a silicone septum that does not fill with medication, nor does it allow for medication to push into it. That septum helps to grip and stabilize the Huber needle in an accessed port. RNs skilled in accessing ports will tell you that they won’t be able to push fluids into the port if the needle is not positioned flush with the back of the port. The fact that the 1” Huber needle was used for this infusion and the Tegaderm remained intact upon discovery of the extravasation strengthens my opinion that there was an integrity problem of the Huber needle tubing that developed towards the completion of the Adriamycin infusion.

The only way to dislodge a Huber needle from a port is by a forceful pull of the Huber needle wings or tubing in the direct opposite direction of the chest. Incomplete dislodgement of the Huber would cause the IV pump to beep and alarm – Occluded. Simply resetting the pump would not resolve this problem. The infusion pump is designed to discontinue attempts to deliver medication in the face of an occlusion or increased pressure below the infusion device. Therefore it is not likely that continued pressure created by the infusion pump perpetuated an integrity problem in the Huber needle.
For the medication to have leaked out in the first place I believe there was a problem with the Huber needle’s integrity. It was likely a microscopic detachment or tear of the tubing that connected directly to the Huber needle itself. That tear may have been a weakening in the tubing that finally gave way or may have developed from a brisk movement that occurred during Mr. Miller’s semi-sedated sleep that put enough pressure to cause integrity failure. It would have been inappropriate for the nurses to assess the integrity of the removed Huber needle knowing that a vesicant was within it due to potential exposure. They acted appropriately, removed the needle and disposed of it. They had the port re-accessed with a new Huber needle and assured that the patient’s port was assessed definitively by dye flow study to determine if the port was a problematic factor causing the extravasation. Ruling that factor out assures me that my assessments are the most likely to have occurred as I have seen it happen in my practice, though it is a uncommon occurrence.

Mr. Miller’s response to the Totect was favorable as documented by both the RNs and the MDs caring for Mr. Miller. By 5:00pm, it was noted that there was a decrease in the swelling or redness, even before the Totect was administered. I believe, though, that continued use of the port with required dressings covering it, may have irritated the skin beneath causing slower overall healing and exacerbation of the extravasated area. That combined with continued immunosuppression with chemotherapeutic medications may have caused addition issues and are large factors in the pain and redness of the skin near the extravasation that continued throughout his entire treatment.

Mr. Miller and his girlfriend, Ms. Jamison, expressed their belief that his gown and linens were not changed until the morning following the medication extravasation. In her deposition, Ms. Jamison stated that on the day of the extravasation, she was not present until later that evening. Mr. Miller stated that he was “groggy” and doesn’t recall much of what went on that day following the port placement.

Prior to the documented linen and gown change at 10:41am on 12/23/0000, at least four licensed personal assessed Mr. Miller, specifically looking at his chest. Since the Adriamycin is a bright red-orange colored fluid as described by Ms. Jamison in her deposition, I find it hard to believe that none of these providers would have noticed if it was “all over the gown.” I believe that more likely than not, something else like fruit punch may have spilled on Mr. Miller while he was “groggy” and perhaps that’s what was on the gown. I believe that if a fuss was made over it the following morning, it may have just been as a precaution. Under the circumstance that was the prudent thing for the staff to do, not necessarily because it hadn’t already been done.

There was a question of whether ice should have been administered to the patient. Based on my review of information available at the time of the episode, it appears that literature was inconclusive about whether ice and Totect should be delivered to the same patient. The actions of both are unknown, but it is felt that ice vasoconstricts the tissue preventing further absorption of the potentially damaging medication. However, it is my expert opinion based on my knowledge of science, human anatomy and physiology, and infusion therapy, that if the vasoconstriction is enough to prevent
absorption of topical medications then it will also vasoconstrict enough to decrease perfusion of medications intended to reach and saturate the area, medications such as Totect, the only known antidote to prevent the need for surgical intervention after Adriamycin/Doxorubicin extravasation. In my opinion, had the nurses iced the area as had been practice before Totect was developed, they would have potentially minimized the effectiveness of the antidote.

Most standards of care I have reviewed mention that ice should be given distally to the extravasated area. For clarification purposes, I believe this recommendation to refer only to peripheral extravasations, injuries occurring through an IV in the hands, arms, feet or legs. The reason for this is to prevent extravasations from damaging the smaller vessels of the fingers and toes. In addition, you would want to make sure that the antidote flows through all tissues touched by the vesicant. The only way to ensure this with peripheral infusions is to be certain to deliver it below the site affected. In the situation like Mr. Miller’s with the extravasation being on his anterior chest, recommendation of distal application of ice is nonspecific, but also not helpful. It would not prevent any of the issues that the recommendation was designed to prevent. Circumferential issues are not likely with the minimal 5ml amount estimated to have caused this extravasation and the location of that exposure was not an extremity and thus would not have become circumferential.

Totect (Zinecard or Dexrazoxone) (pronounced dex-ray-ZOX-ane) is administered over three days, in three doses 24 hours apart. Therefore, the expectation of a nurse administering this medication would be to take measures to prevent vasoconstriction at the site of the extravasation to assure that as much of the antidote reaches the tissues touched by the vesicant. Since Totect is given in multiple doses 24 hours apart, a prudent nurse would expect the half-life of the drug to remain in the system for the full 24 hours, otherwise administration times would be more frequent. For that reason, reasonably prudent nurses would not consider placing ice on the extravasation in between Totect administrations to prevent minimization of circulation to affected tissues.

I am aware of the expense of this medication being high and its short shelf life. Therefore, I’m also aware that some hospitals do not have the means to obtain the medications. For that reason, it is my belief that the ice has not been removed from the extravasation recommendations for anthracycline chemotherapy agents because it is the only other option when Totect is not available.

It may be said that using ice is a nursing measure and the nurses could have done this independently. I believe that in this instance, since it had the potential to decrease the antidote’s effectiveness due to the known vasoconstriction ice produces, as well as because of the duration of the treatment that would have been required, the nurses would have needed a physician’s order to use this measure as an antidote in this situation. Since they were not given a specific MD order to ice the site of extravasation, I believe they acted prudently in this when treating the extravasation of Mr. Miller’s chest.
Reasonably prudent nurses are aware that providing education to a relatively new cancer patient must be done slowly and over time, using cues of readiness to determine what to teach and when. Having worked in oncology and pre/post sedation care environments, I can use my vast experience to assure you that teaching patients prior to any sedative medication administration is significantly more effective than afterwards. In addition, many sedative or narcotic medications have either an amnesiac effect or make a patient less likely to remember events occurring during the time and following the medications administration.

For this reason, I personally routinely perform all discharge teaching before the procedure or medication delivery. I tell the patient, “This would not be the day to sign important documents or make life-changing decisions. It’s not the right day to go buy a car. You will wake up tomorrow and wonder where the car came from and why you picked that color.” My teaching paints an important picture in my patient’s mind but also explains the concept of why Dr. Santini consented Mr. Miller for his chemotherapy before he had his port placed. It explains why the teaching about the call bell, IV pump beeping and calling if he notices any changes to be more effective given before his port placement.

The plaintiff’s nurse expert, Mary Sweat, RN, MS indicates that Mr. Miller should have been instructed to minimize his movements when his port was accessed. This information does not reflect the proper instructions that should be given to a patient with a port. In fact, most patients have chosen port placement versus any other central vascular device because it is the device that allows for the most normal lifestyle and full body movements following healing of the incision. The only teaching that needs to be done regarding movement to any patient with a port is to make sure that the Huber needle wings stay flush on the chest, the dressing remains intact, and to not tug or pull forward on the tubing as it can inadvertently dislodge the Huber needle. Lateral movements typically don’t dislodge a properly placed Huber needle unless it is grossly too long (example: using a 1½” Huber needle in a port that typically required a ¾” Huber needle). All teaching regarding specifics of caring for the port should be done with a fully alert and oriented patient. Mr. Miller was not fully alert and oriented based on his own description during his deposition during the day following his port placement and initiation of his chemotherapy treatment.

The documentation in his medical chart shows the majority of the education being done before his procedure by L. Katz, RN. On page 819, on the admission history change report, Lisa Katz documented that Mr. Miller was oriented to “Bell controls, call bell/light, bathroom/shower, visitors, belongings, unit routine at 08:58am. Per deposition, it was both the practice of Ms. Thomas and Ms. Dixon to always advise the patient to call if they felt “different” and to reinforce past teaching with every patient contact for safety reasons. I have no reason to believe that their usual practice would have been different on this day than any other.

Both nurses were also aware that Lidocaine or another topically numbing agent was used during the port placement procedure. They were aware that though unlikely, if the
medication did leak from his port of any reason, that more likely than not, he was still numb from the surgery and would not have felt it based on the timing of the chemo initiation. For this reason, it would have been prudent for these nurses to prioritize their teaching to other things that would have been more likely to make a difference in his care at that particular time.

I believe that since Mr. Miller had just been sedated for a procedure and was going through the stress of starting chemotherapy, combined with his admission during his deposition that he was groggy for most of the day, that he would either not have been a candidate for in-depth discussion about his new port or able to remember whether any had occurred. Along those same lines, he may not have remembered if any emotional care was provided and to what degree it was given during the events of that day following the surgery.

Based on my experience, it is not unusual for anyone experiencing a frightening medical situation to be looking for someone to say something specific. If those words are not spoken, their emotions are unfulfilled and sometimes the person may even feel as if no psychological assistance was provided. For this reason, in recent times many hospital protocols have changed in the face of unexpected outcomes. In years past, the words “I’m sorry” had been considered an act of admission of wrongdoing. In recent times that view has also changed. If those were the words that Mr. Miller and his family were waiting for on that day, and either were not heard or appreciated, anything else said instead may not have made them feel emotionally cared for. Their unhappiness with what was said does not mean that nothing was said. In fact, there is evidence in the nursing notes of emotional care being delivered in the medical records by subsequent nurses on days following. The chaplain, Leslie Bolton, even came to talk with the patient at 4:48pm on the day of the extravasation. This indicates that the nurses may have been aware of their priorities but also knew the importance of assisting the patient emotionally, so they delegated their resources to have an appropriate person deliver emotional care when they were busy handling the urgent medical situation.

The plaintiff’s expert, Mary Sweat, RN, MS raised questions regarding the responsiveness of the nurses to the beeping IV pump. Again, related to the grogginess of Mr. Miller and extent of the IV pump programming that goes into starting a chemotherapy infusion, I question whether he was aware of the reasons the pump was beeping.

More likely than not, Mr. Miller was not educated about the different types of situations that would cause an IV pump to beep; that some beeps are informational beeps (example: a beep alerting a switch from a primary infusion to a secondary infusion and vice versa) and some are action beeps requiring some action on a medical professional’s part. (example: a kinked or occluded line or completed infusion). In his grogginess and with his minimal experience having chemo infusions, he likely was not able to differentiate which beeps were ones that required nursing intervention and which did not. This is not something that would be explained to a groggy patient. All of the
beeps mentioned above are common to hear on any given day on any type of unit in the hospital.

**Overall Summary**
Reasonably prudent nurses like Ms. Thomas and Ms. Dixon will prioritize during a medical urgency or emergency like an extravasation. Upon administration of a vesicant, when an extravasation is noticed, the priority is to stop the burning process. The nurses assessed their patient at the time they anticipated the infusion would be finishing per hospital protocol/unit practice, noticed a potential extravasation and acted immediately. They stopped the toxin from entering his body by immediately stopping infusion and ultimately removing the Huber needle from his port. They assessed for blood return and noticed none. Mr. Miller’s doctor was notified. An antidote order was received and immediately sent for. M. Dixon’s shift had ended, yet she remained on duty and went to retrieve the antidote to assist her patient and fellow staff members. The dressing was removed from the patient’s chest when the Huber needle was removed. Emotional care was provided by the hospital chaplain.

A new peripheral intravenous (PIV) line was started in Mr. Miller’s arm and the antidote was given through this new PIV. The extravasation site was monitored and based on documentation by multiple nurses and doctors; it showed quick improvement with a decrease in swelling and redness even before the Totec was started at 5:00pm. There were no further complaints related to the extravasation on that day from the patient while he was in the care of M. Dixon and L. Thomas. The integrity of Mr. Miller’s port through a new Huber needle was also assessed. Documentation exists in the records stating that the patient and his family were given both an explanation and emotional care on days following the incident as well.

Extravasations are known to continue to cause issues in patients for months following vesicant injury. I have not been able to find information regarding studies in patients who continue to receive immunosuppressive therapy such as chemotherapy following extravasation after antidote administration with continued use of the occlusively dressed IV line in the area of the extravasation. There is limited information available to show patterns related to the expected healing in situations like Mr. Miller’s.

Based on my vast nursing knowledge, in a patient receiving an immunosuppressive therapy, I would anticipate issues might continue to arise. This patient had yet to receive the most comprehensive parts of his treatment. In addition, when he did receive treatment through the port that sat in the middle of the tissue exposed to the vesicant, there was an adhesive dressing over his port to maintain sterility. Most port dressings are of the same dimensions of the skin supposedly involved in the extravasation. Adults typically have dressings from 8"x8" to 12"x12." Dressings smaller than 5"x5" typically would not be occlusive and therefore would not be appropriate.

Based on my expert experience working with patients who have invasive intravenous lines both central and peripheral, as well as wounds in general, blistering, irritation, pain and itching are common side effects from adhesive dressings. Some patients need to
try a number of dressing or minimize skin contact with any adhesive as much as possible. Some patients have localized reactions to the Chlorhexidine, iodine, and/or alcohol products used to clean the skin prior to dressing placement. In addition, many nurses are poorly trained and do not understand the importance of letting disinfecting agents dry 100% before applying adhesive dressings over a central line, especially on already irritated/damaged skin. It is my opinion that this is part of the issue related to Mr. Miller’s prolonged healing, and not related to the prudent initial extravasation care properly provided by L. Thomas and M. Dixon.

This opinion was formulated because of the prevalence of this issue seen in my nursing practice in every hospital/outpatient center where I have worked. There is also no mention of different dressings being tried for this patient to minimize blistering and sensitivity during his subsequent care after the extravasation occurred. He appeared to have symptom flares in the size of the dressings normally used to cover adult-sized Mediports at the extravasation site during his chemo administration. I believe this may be why.

The plaintiff’s nurse expert, Mary Sweat, RN, MS brought up the question of whether administering chemotherapeutic agents should be considered “a task.” It is my expert opinion that this is semantics and nothing more. Surgeons may consider a task to be performing a central line placement, doing a physical examination or removing an appendix. A nurse can consider giving a bath, emptying a Foley catheter, placing an IV line or documenting in the medical records to be a task. A mother may consider picking up a child from school, getting groceries and making dinner to be a task. A pharmacist can consider preparing a chemo infusion, counting pills for a prescription or checking a doctor’s order to be a task. Each task is made of different smaller tasks. What connects all of the above is the fact that each can be “triaged,” “weighted” or “prioritized” in the performer’s mind as to how much effort and responsibility goes into each task, and what needs to be done in conjunction with it. One person can call it a “task” while another can call it a “list of things to do” and another can call it a “procedure.” Since L. Thomas considers that 11:00am-11:00pm shift to be given to the task nurse, it is not unusual that she would consider her duties to be tasks.

Prior to administration of the Adriamycin, both nurses were aware that Dr. Santini had obtained informed consent for chemotherapy administration. The consent was checked along with the specifics of the medication they were about to administer to Mr. Miller.

The plaintiff’s nurse expert mentioned that L. Thomas and M. Dixon did not ascertain the amount of drug that exacerbated. However there is specific documentation that approximated 5ml of the drug being pooled under the Tegaderm. Knowing the concentration of the medication is 150mg in 75ml, it can be determined that 10mg of the drug may have been on his chest, however it is unknown if any of that was diluted with the carrier fluid (normal saline) that was running on the primary line. It is my expert opinion that the specific dosage was not needed to determine proper treatment and their documentation of the 5ml provides the information necessary to communicate the issue to any provider who was not at the bedside during the incident.
She also mentioned that the nurses did not document patient education for follow-up care. This would not have been done at the time of the initial extravasation treatment as care was focused on stopping the extent of tissue damage. It is my expert opinion that nurses and physicians who treated Mr. Miller on subsequent days would have had this duty much more so than L. Thomas, who’s shift ended that night at 11:00pm, and M. Dixon, whose shift ended just around the time that the extravasation was noted at 3:00pm.

I believe that L. Thomas, RN and M. Dixon, RN provided excellent care recognizing and caring for Mr. Miller before, during and after the extravasation.

Thank you for the opportunity to assist you with my opinion on this important case.

Sincerely,

Caryn Tina Jaffe, RN, CLNC
Exhibit E
Affidavit of Merit for an IV Therapy Case

STATE OF

IN THE CIRCUIT COURT FOR THE COUNTY OF

Plaintiff,

Case No.: -NH

, RN,
HEMATOLOGY AND ONCOLOGY, PC,

Defendants.

Attorneys for Plaintiff

AFFIDAVIT OF MERIT

, being sworn, says:

I certify that I have reviewed the notice of intention to file a claim pursuant to MCL 600.2912b and all medical records supplied to me by Plaintiffs' attorneys concerning the allegations contained in the notice. I also state the following:

1. I am a Registered Nurse licensed to practice in the state of Maryland and Washington DC, having graduated from Applied Associate Degree in Nursing from
   Washington College in 2000 and an
   Community College in 2000.

2. I have been a Certified Legal Nurse Consultant since 2007; I have extensive experience at The Hospital, Hospital and
   Medical Center with initiating and monitoring infusions and placing and monitoring IV lines.
3. Applicable Standard of Care

The standard of care required of DNS Hematology and Oncology and Hospital by and through its physicians, agents, nurses, attendings, interns and residents, involved in the care and treatment of including but not limited to RN was to:

a) Carefully and adequately program and administer 5-FU infusion pumps;

b) Ensure that a second check of the ordered 5-FU drug dosage calculation, proper medication, proper patient identification, and proper infusion pump programming was performed by a 2nd licensed care provider trained to administer, most commonly another RN.

c) Ensure that all checks and double checks performed by the 2nd trained and licensed care providers were documented in the patient’s medical record as both having been performed and noting that the dosages pump programming and patient receiving the medication was accurate.

d) Ensure that a proper infusion pump was used to protect the patient, one that allows for a locked keypad to prevent changes to rate of infusion.

e) Ensure that the infusion pump keypad was locked and the application of this lock was documented in the patient medical record.

6. Breach of the Standard of Care

Defendants breached the applicable standards of care and practice.

4. Actions That Should Have Been Taken or Omitted to Have Complied with the Applicable Standard of Care

Defendant nurse breached the standard of care because she did not input the correct rate of the ordered amount of 5-FU into the infusion pump, nor did she ensure that another nurse or trained licensed care provider perform a second check of drug dosage and pump program before administration; she failed to engage the keypad lock on the infusion pump; and she failed to document that all of the above patient safeguards were performed.

5. Manner in Which the Breach of the Standard of Care Was the Proximate Cause of the Injury Alleged in the Notice

The Plaintiff’s long term damages were caused due to the failure of Defendants to provide the requisite degree of care. As a result, the Plaintiff suffered severe, permanent, and irreversible damage, with resulting sequelae.
Exhibit F
Anterior/Posterior Upper Extremity Vein Locations to Aid in Documentation of IV Line Placement
### Exhibt G

**Example of an Electronic Medical Record Invasive Device Flowsheet**

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<thead>
<tr>
<th>Row Name</th>
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</tr>
</thead>
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<tr>
<td>VITALS</td>
<td>1100</td>
</tr>
<tr>
<td>BP</td>
<td>82/59 mmHg</td>
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<tr>
<td>Temp</td>
<td>33.3 °C (100.3 °F)</td>
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<tr>
<td>Temp src</td>
<td>Rectal</td>
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<tr>
<td>Pulse</td>
<td>168</td>
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<tr>
<td>Resp</td>
<td>156</td>
</tr>
<tr>
<td>OXYGEN THERAPY</td>
<td>99%</td>
</tr>
<tr>
<td>SpO2</td>
<td>100%</td>
</tr>
<tr>
<td>O2 Flow Rate (L/min)</td>
<td>2 L/min</td>
</tr>
<tr>
<td>FIO2 (%)</td>
<td>100%</td>
</tr>
<tr>
<td>RESPIRATORY</td>
<td>--</td>
</tr>
<tr>
<td>Breathing Pattern</td>
<td>--</td>
</tr>
<tr>
<td>BREATH SOUNDS SPECIFIC</td>
<td>--</td>
</tr>
<tr>
<td>Breathing Sounds LUL</td>
<td>--</td>
</tr>
<tr>
<td>Breathing Sounds LRR</td>
<td>--</td>
</tr>
<tr>
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<tr>
<td>Resp</td>
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<tr>
<td>SpO2</td>
<td>100%</td>
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<tr>
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<tr>
<td>Temp</td>
<td>--</td>
</tr>
<tr>
<td>Temp src</td>
<td>Axillary</td>
</tr>
<tr>
<td>Pulse</td>
<td>--</td>
</tr>
<tr>
<td>Resp</td>
<td>--</td>
</tr>
<tr>
<td>OXYGEN THERAPY</td>
<td>100%</td>
</tr>
<tr>
<td>SpO2</td>
<td>100%</td>
</tr>
<tr>
<td>O2 Flow Rate (L/min)</td>
<td>2 L/min</td>
</tr>
<tr>
<td>FIO2 (%)</td>
<td>100%</td>
</tr>
<tr>
<td>Row Name</td>
<td>00/00/2000</td>
</tr>
<tr>
<td>IV INVASIVE LINE ASSESSMENT</td>
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<tr>
<td>PEDI PERIPHERAL IV (00/00/00 LEFT HAND)</td>
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<tr>
<td>IV Properties</td>
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<tr>
<td>Line Status</td>
<td>Infusing</td>
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<td>Line Care</td>
<td>Connections checked and tightened</td>
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<td>Dressing Status</td>
<td>Clean:DrY:Intact</td>
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<td>$ Assessment Type</td>
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<tr>
<td>Resp</td>
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<tr>
<td>SpO2</td>
<td>99%</td>
</tr>
<tr>
<td>RESPIRATORY</td>
<td>--</td>
</tr>
<tr>
<td>Respiratory Pattern</td>
<td>--</td>
</tr>
<tr>
<td>Respiratory (WDL)</td>
<td>--</td>
</tr>
</tbody>
</table>
Exhibit H
Additional Central Line Documentation

Section of the PICU’s EMR.

RNs document which line was used for specific medication administration.
Exhibit I
Identifying Healthcare Fraud Related to IV Therapy: SOAP Note

Name of the Patient:
Date of Attention: 00/00/0000

Diagnostic Attention: Acute Gastroenteritis.
Severe Dehydration.

Patient refers to having started her current condition last night after eating a meal in the evening that she felt did not fall well as it presented diarrheal evacuations NUCERO of three abundantly, fetid, these are accompanied with colicky pain of moderate intensity, decision making kaolin to decrease in quantity and number of evacuations, restarting from yesterday again with abundant liquid evacuations and this number is 8 times in 24 hours, today evacuations have been 7 to 8 hours of the same characteristics, adding itself being in the last times of bile features, malaise, myalgia and arthralgia.

Physical exploration of the patient has presented the following data:

Blood Pressure: 120/80 mm hg, Cardiac Frequency: 100 x min, Respiratory Frequency: 20 x min,
Temperature: 39 C, capillary glycaemia: 100 mgs

A patient with the apparent age and sex consistent which can be seen with pain facies is found, with skin palpity +, normochromic conjunctive, Eyestrain is decreased in mild form; pupils are isochoric and Norma- reflexive, The mouth seen with dry oral mucus, + furred language, hyperemic pharynx, clean auscultation of lung fields, heart sounds are rhythmic and of decreased intensity, with tachycardia but Tenderness level of colic frame with an intensity ++, epigastric level of intensity is +, peristalsis noise increases seen in their frequency and are accompanied with frequent and remote audible gurgling noises.

Treatment:
1. – 1000 ml Hartman Solution, pass pump infusion in 1 hour.
2. – 2000 ml C.C. Normal Saline Solution, pass pump in 4 hours.
3. – ONDASTERON 4 mgs intravenous.
4. – Ceftriaxone 500 mgs intravenous , slow and diluted.
5. – PARGEVERINE, 1 ampule diluted in 100 ml of normal saline solution, intravenous passing in 20
   Minutes.
6. – Ranitidine 50 mgs intravenous.
7. – FLAGYL 500 mgs intravenous, give on 30 minutes.
8. – Ketorolac diluted in solution, slow intravenous passing.
9. – Monitor the presence of nausea or vomiting.
10. – Semi Fowler position.
11. - close monitoring.
12. – 1 LOPERAMIDE tablet with every diarrheic evacuation.

The patient was evaluated in this unit every 15 minutes the first 2 hours, achieving improvement of
symptoms significantly, it was assessed after each subsequent half hour, Being in the first 4 hours
almost complete disappearance of pain, Good hydration, Improved gastric tolerance for what is decided
and handled at outpatient.

Treatment: FLAGYL 500 take one tablet every 8 hours for 7 days, FLONORM take every 8 hours,
IMODIUM take one tablet every 6 hours for 2 days, Control take one tablet every 12 hours for 3 days,
MILUPA HN25 take 3 tablespoons of powder diluted in a glass of water, three times a day.
## Exhibit J
### Identifying Healthcare Fraud Related to IV Therapy:
#### Vital Sign Flowsheet

**Vital Sign Flowsheet**

<table>
<thead>
<tr>
<th>Fecha</th>
<th>Hora</th>
<th>Temperatura</th>
<th>PA</th>
<th>Pulso</th>
<th>Respiraciones</th>
<th>dolor</th>
<th>Iniciales</th>
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<tbody>
<tr>
<td>00/00/00 08:00</td>
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<td>170/100</td>
<td>100</td>
<td>20</td>
<td>10</td>
<td>L.S.</td>
<td></td>
</tr>
<tr>
<td>00/00/00 08:15</td>
<td>39°</td>
<td>170/100</td>
<td>100</td>
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<td>10</td>
<td>L.S.</td>
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</tr>
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<td>100</td>
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<td>10</td>
<td>L.S.</td>
<td></td>
</tr>
<tr>
<td>00/00/00 09:15</td>
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<td>170/100</td>
<td>100</td>
<td>20</td>
<td>10</td>
<td>L.S.</td>
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<tr>
<td>00/00/00 09:30</td>
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<td>170/100</td>
<td>100</td>
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<td>10</td>
<td>L.S.</td>
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<tr>
<td>00/00/00 09:45</td>
<td>39°</td>
<td>170/100</td>
<td>100</td>
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<td>10</td>
<td>L.S.</td>
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</tr>
<tr>
<td>00/00/00 10:00</td>
<td>39°</td>
<td>170/100</td>
<td>100</td>
<td>20</td>
<td>10</td>
<td>L.S.</td>
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</tr>
<tr>
<td>00/00/00 10:15</td>
<td>39°</td>
<td>170/100</td>
<td>100</td>
<td>20</td>
<td>10</td>
<td>L.S.</td>
<td></td>
</tr>
<tr>
<td>00/00/00 10:30</td>
<td>39°</td>
<td>170/100</td>
<td>100</td>
<td>20</td>
<td>10</td>
<td>L.S.</td>
<td></td>
</tr>
<tr>
<td>00/00/00 10:45</td>
<td>39°</td>
<td>170/100</td>
<td>100</td>
<td>20</td>
<td>10</td>
<td>L.S.</td>
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*Contents*
Exhibit K
Identifying Healthcare Fraud Related to IV Therapy: Itemized Charges for Disposable Materials

<table>
<thead>
<tr>
<th>Material Desechable</th>
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<tr>
<td>1000 ml sol Hartman</td>
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</tr>
<tr>
<td>2000 ml sol Salina normal</td>
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</tr>
<tr>
<td>4 mgs de Ondanestron IV</td>
<td></td>
</tr>
<tr>
<td>500 mgs de Ceftriaxona IV</td>
<td></td>
</tr>
<tr>
<td>1 ampulla de Pergoverina en 100 ml de sol Salina normal</td>
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</tr>
<tr>
<td>50 mgs de Ranitidina IV</td>
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<tr>
<td>500 mgs de Flagyl 500 IV</td>
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<tr>
<td>Ketorolaco diluido en solución</td>
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<tr>
<td>Loperamida tabletas</td>
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<td>Price</td>
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<td>Tubo venenoso</td>
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<td>2 Tubo est or flavo</td>
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<td>2 Bolsa 5cc, 1000 cc</td>
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<td>10 Electrodes ad para monitor a/50</td>
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<td><strong>SUBTOTAL</strong></td>
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Exhibit L
Identifying Healthcare Fraud Related to the IV Therapy Medication Administration Record

Medication Administration Record

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<tr>
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</tr>
</tbody>
</table>

Diagnóstico: 
Compl. TEPUS

Instrucciones específicas: 
Nombre del médico: 

Fecha de nacimiento: 02/10/01
Persona que administró: 
Iniciales: 

Alérgico: 

Nombre: 

48

Contents
<table>
<thead>
<tr>
<th>Medication</th>
<th>Time</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flagyl 500mg</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>Ketorolaco 50mg</td>
<td>15</td>
<td>75</td>
</tr>
<tr>
<td>Loperamid 4mg</td>
<td>15</td>
<td>3</td>
</tr>
</tbody>
</table>

**Diagnosis:** Gastroenteritis

**Instructions:**

**Contraindications:**

**Name of Physician:**

**Date of Administration:** 02/10

**Person who administered:**

**Initiates:**
Exhibit M
Identifying Healthcare Fraud Related to IV Therapy: Example of an Incomplete IV Therapy Flow Sheet

Record medicina IV

<table>
<thead>
<tr>
<th>Fecha</th>
<th>Hora</th>
<th>Tamano cateter</th>
<th>interinos</th>
<th>lugar</th>
<th>fecha descontinuacion</th>
<th>razn descontinuacion</th>
<th>iniciales</th>
<th>comentarios</th>
</tr>
</thead>
<tbody>
<tr>
<td>9/27</td>
<td>8:00</td>
<td>22</td>
<td>1</td>
<td>1</td>
<td>9/27</td>
<td>N</td>
<td></td>
<td>CATETER INTACTO</td>
</tr>
</tbody>
</table>

Lugar del suero

Razon y codigos de descontinuacion
- S = sangrado
- C = coagulo
- B = bueno
- I = infiltrado

G = gotera
N = ya no se necesita
Exhibit N  
Ambulatory Surgery Center IV Flow Sheet

Name: ___________________________  Procedure: ___________________________
Chart #: _________________________  Sedation: Y / N
Date: ______________

IV SECTION

Peripheral IV Started: Y/N  
Order given by: ___________________________
Gauge: ____  Type: BRAUN WINGED SAFETY  
Location: ___________________________
Number of attempts: ____  PIV placed by: ___________________________
Location of additional attempts ______________________________________________________________

Strong blood return noted in PIV catheter.  Y / N
Catheter advanced fully into the peripheral vein.  Y / N
PIV flushes without resistance.  Y / N
IV fluids run via gravity drip without resistance, swelling, bruising, redness, or patient complaints of pain at or near the 
PICV site.  Y / N
Upon removal of the PIC, the catheter is fully intact. No bruising or signs/symptoms of phlebitis is noted at or near the 
old PIV site.  Y / N
Additional IV medications administered during treatment today. (Include patient response to medication)

____________________________________________________________________________________

____________________________________________________________________________________

____________________________________________________________________________________

IV Fluids Given ___________________________  Amount of IV fluid infused _____ cc

POST PROCEDURE NOURISHMENT SECTION (check all that apply)

____ Peanut butter crackers  ____ cheese crackers  ____ Other (Specify)  ____ Pt. declined PO solid food
____ Water  ____ Sprite  ____ Sprite Zero  ____ Ginger Ale  ____ Diet Ginger Ale  ____ Pt. declined PO liquids

TEMPERATURE SECTION

Preprocedure temperatures
Extremity / location ___________________________  Right ____ ____  Left ____ ____

Postprocedure temperatures
Extremity / location ___________________________  Right ____ ____  Left ____ ____

Registered Nurse’s Signature ___________________________  Date ______________

Contents