Pharmaceutical Failure Mode and Effects Analysis
Krystexxa™ (pegloticase)

Step 1:

Describe how the intended product will be procured and used, from acquisition through administration.

Who will prescribe the drug and for what type of patient?
Rheumatologists will prescribe Krystexxa™ for patients with refractory chronic gout.

Where will the drug be stored?
Unopened vials of Krystexxa™ will be stored in their cartons protected from light in the refrigerators of the pharmacy storeroom or IV room. Diluted solutions will be stored protected from light at room temperature up to 4 hours. They will be brought to room temperature before administration by allowing to sit at room temperature for 30 minutes. They will not be brought to room temperature by artificial means, i.e. microwave or warming baths.

Who will prepare and dispense it?
Pharmacy technicians will prepare the dose and pharmacists will check and dispense the dose.

How will it be administered?
The medication will be administered by intravenous infusion over, at least, a 2 hour duration.

Step 2:

Identify potential failure modes (how and where systems and processes may fail) while considering how the product will be used.

Could the drug be mistaken for another similarly packaged product?
Unknown

Does the label clearly express the strength or concentration?
Yes- 8mg/ml

Does the name sound or look like another drug on the formulary?
No

Are dosing parameters complex?
Yes- recommended dosing of Krystexxa™ is 8mg at 2 week intervals, treatment duration has not been established. The patients should be premedicated with antihistamines and corticosteroids. Gout flare prophylaxis with either NSAIDs or colchicine is also recommended, beginning at least 1 week prior to administration and continuing for at least 6 months.
Is the administration process error prone?

Krystexxa™ should be infused over at least 2 hours, no IV push or bolus. Once the dose is prepared by the pharmacy, administration should be complete within 4 hours due to stability limitations. The solution should be protected from light and extreme heat. Do not shake.

**Step 3:**

Once failure modes have been identified, determine the likelihood of making a mistake and the potential consequences of an error.

What would happen to the patient if the drug were given in the wrong dose, at the wrong time, to the wrong patient, by the wrong route, at the wrong rate? Krystexxav™ may exacerbate heart failure. It is contraindicated in patients with a G6PD deficiency. Krystexxa™ is not appropriate in patients with asymptomatic hyperuricemia. Krystexxa™ must be administered by a healthcare professional prepared to manage anaphylaxis and infusion reactions.

**Step 4:**

Identify any preexisting processes in place that could help detect the error before it reaches the patient, and evaluate their effectiveness based upon knowledge of human factors.

Nurses check two patient identifiers prior to administering medications. For the doses that will be administered in the Galveston Infusion Clinic, pharmacists will double check the compounded product prior to dispensing.

**· Step 5:**

If failure modes could cause errors with significant consequences, what actions could be taken to prevent the error, detect it before it reaches the patient, or minimize its consequences? (A few examples include: using an alternative product; preparing the drug in the pharmacy; standardizing drug concentrations, order communication and dosing methods; using auxiliary warning labels or computer alerts; and requiring entry of specific data into computer systems before processing orders).

Krystexxa™ is restricted to Rheumatology which limits the number of physicians able to prescribe the medication. For the doses that will be administered in the Galveston Infusion Clinic, the doses will be compounded by the pharmacy.

**Administration Information:**

What are the most common side effects that Nursing should be aware of to ensure proper monitoring?

Gout flares are most common side effect. Should be treated prophylaxis for flares. Most concerning side effects are infusion reactions and anaphylaxis which seems to occur more frequent in the non-responders to pegloticase. Nurses should monitor patients post infusion for approximately one hour.
Is there any associated laboratory monitoring that Nursing should be aware of to ensure proper patient care? If yes, please list.

Serum uric acid needs to be monitored. Serum uric acid levels should be monitored before each infusion. Label suggest discontinuation of therapy if 2 consecutive SUA above 6mg/dl occur. Two consecutive tests suggest patient is a non-responder.