Problems with State of Florida DOH Pedigree Form

During the development of USMeds.com, our staff were shocked with the number of problems with the current Florida Department of Health (DOH) paper pedigree form. While USMeds is designed to fully comply with Florida pedigree regulations, we feel it is necessary to discuss the problems in case Florida DOH decides to update the form. Other states are looking at Florida's pedigree form and creating something similar for their use. We hope they read this article before creating their own pedigree form.

Some of the problems are serious while others are just little problems that cause everyone time and resources. We are going to assume that the main goal of the Florida pedigree form is to prevent the distribution of counterfeit drugs. For reference, here is the Florida DOH pedigree form as it appears on the DOH website:

http://www.doh.state.fl.us/pharmacy/Pedigree/ap-DH2129Pedigree.pdf

Problem #1: Pedigree has non deterministic routing of medications
You cannot look at a Florida pedigree and determine the route of medications and dates of those transactions. That seems like a pretty important requirement for a drug pedigree but the Florida pedigree form fails to meet this requirement. This is because the form does not provide a location for indicating the type of transaction (Sale, Return) and whether the transactions are “custodial transactions” versus just “drop shipment” transactions. Some will point out that the right column of the form is exactly for this situation. If we attempt to use the pedigree form in this manner, the wholesaler that receives the drop shipment from the manufacturer would appear in the right column of the first transaction. The problem is that this wholesaler that took possession of the medications now does not appear in the left column of the pedigree form which is labeled “Ownership History”. In the drop shipment scenario, the majority of fields in the left column do not apply (name of recipient, signatures) but most wholesalers fill them out anyhow leading to confusion in who put their hands on the medications.

There’s another subtle issue for those who think the drop shipment scenario is handled by moving wholesalers that take physical custody to the right column. When entering information in the left column, the pedigree form requires the date purchased. The entries on the right require date received. Clearly, the State of Florida normally only cares about purchase dates except in the drop shipment scenario when the date received matters and the purchase date does not.

Problem #2: Pedigree fails to define the drug transactions
This is a fundamental problem with the Florida pedigree. Most pedigree formats specify the routing of medications as a series of transactions, indicated by a “from” entity (sender) , a “to” entity (receiver) and a collection of transaction data. The Florida pedigree instead defines a series of entities and basically goes on the premise that the transactions are defined by the order of the entities on the pedigree. (Sometimes straight down the left column, but other times across to the right.) The problem is that each of the entities of the Florida pedigree is actually involved in two transactions (receive and ship) so the data in the boxes can only be for one of the transactions. What this translates to is confusion on who should be filling the next box on the pedigree.

For those with a background in discrete mathematics and finite state machines: This is a classic Moore versus Mealy state machine design decision. A Moore state machine design is only practical when there is no transaction data and all the transitions are the same. Someone tell the Florida DOH that they should have used a Mealy state machine approach for their pedigree design.

Problem #3: No DEA number or state license information
Most pedigrees have between 2 and 4 entities which can be either manufacturers or wholesalers. These entities may be based in the USA and may have their drug storage at a location other than their headquarters. Over a period of 3 years, these entities can be purchased, go out of business
or merged with another entity. By not providing a place for license information in the pedigree, we are forced use the name and address of an entity to determine who it is. This is a complete nightmare for systems since company names vary by including or not including “Inc”, “Limited”, “Corp” and so forth. Address information varies with “Street” versus “St”, “Avenue” versus “Ave”, “North” versus “N” and so on.

Problem #4: There are 2 pedigree forms
The State of Florida uses a different pedigree form for repackaged medications. This is nearly double the work for systems developers. And if that wasn't bad enough, the State of Florida chose a landscape orientation for one and portrait orientation for the other. Brilliant!

Problem #5: Pedigree is not re-usable
When you get a Florida pedigree, it appears at first that you can add your company information into the next transaction box and then use it when you ship the medications (Outbound pedigree). Unfortunately, there are several locations on the Florida pedigree that are not re-usable. The first is the wholesaler name at the very top of the form. This is followed by the reference number and reference date near the top right of the pedigree. And of course, the signature, title and date at the bottom of the form only apply to the current transaction. Should you have to add another page to the pedigree, the “of 1 Pages” has to be changed to “of 2 pages”.

Ok, so the State of Florida pedigree is not intended to be re-usable. Therefore each entity in the chain of distribution must transpose the data from the inbound pedigree to their outbound pedigree. This means that the signatures that appear on inbound pedigrees are not passed along to the outbound pedigrees. The chances of errors are increased because of long invoice numbers and the repetitive task of transposing pedigree information in a wholesaler's warehouse. Since wholesalers are not required to provide their inbound pedigree, these mistakes are rarely detected.

Problem #6: No drug expiration date
We just have to scratch our heads at why the expiration date of the medications would not appear on a drug pedigree. One thing that is certainly worse than counterfeit medications is expired counterfeit medications.

Problem #7: No drug quantity information after first transaction
There is only one place for a drug quantity at the top of the form. In situations where the inbound quantity and outbound quantity are different, it is unclear which number this is. In any case, the person at the end of the distribution chain has no idea if 1000 tablets were purchased from the manufacturer and they are receiving 5000 tablets from a wholesaler.

Problem #8: Manufacturer is specified differently than other entities
All of the entities on the pedigree are indicated the same way except for the manufacturer which is indicated on 2 lines that span the entire page. The authentication information is specified completely differently than the other entities, an automation nightmare.

Problem #9: The pedigree form has instructions in the same file
Since the Florida pedigree conveniently provides instructions in the same file as the form, everyone has to either convert this to a 1 page document or always waste time checking print only current page in their Windows printer dialog box. Just the fact that the Florida pedigree is provided to the public with the expectation that everyone will convert it to one page before using it is unbelievable.

Problem #10: Some lines have multiple data
There are lines on the form that are more than one item. One example is Date Purchased and Reference number. On this line, wholesalers will encode something like “4/20/2008 INV #12345”. This indicates the date (you pick the date format), some abbreviation to specify what the next
number is (purchase order, invoice number) and then the reference number itself. (Remember, this is the inbound information) While this line has 3 items encoded into it, it is one of the shortest lines in the box. A little further down, the authentication name and phone number span the entire box.

We expect that some people will make the point that some of the problems with the Florida pedigree form are related to space on the form. This is just one example of waste of valuable space on the form that could be put to better use.

Problem #11: Pedigree does not allow data entry
Many system programmers are forced to modify the official Florida pedigree form since the form does not allow the entry of data. (Besides having to dump the instruction page) It is very simple to provide a PDF that can be either automatically populated or typed into. It took us two hours to create this form that is used in the USMeds system. If the State of Florida had done this simple task, there would likely be far less versions of the Florida pedigree floating around Florida.

Here is our Florida pedigree form. You can type into the fields and then print it out:

https://secure.usmeds.com/meds/docs/FloridaPedigreeUSMeds.pdf

In addition, you can automatically populate fields by simply passing parameters:

https://secure.usmeds.com/meds/servlet/meds.Main?n=ShowPDFForm&form=FloridaPedigreeUSMeds.pdf&wholesalername=YourNameHere

If you click on this link, you will see that the Florida pedigree form is automatically populated with “YourNameHere” in the manufacture name at the top of the form.

Problem #12: Pedigree has place for recipient name and signature
We have yet to come across a Florida pedigree where the recipient name and signature is different than the authenticator name and signature. Most companies do not have the means for the folks in receiving department to sign the inbound pedigree. Why not have a place for the UPS guy to sign the pedigree too?

If there is a problem in receiving, the company is in the best position to investigate the problem and determine what processes to enforce to protect their property. You probably are under estimating how clever folks in receiving are. If they are going to steal medications, they would steal if from stock signed for by the other guy in receiving.

Problem #13: NDC is optional
We have to scratch our heads as to why the Florida pedigree has this item listed as optional. Luckily everyone has the sense to provide this on all pedigrees. Without this number, the Legend Drug Name line at the top of the pedigree would have to be parsed to determine the medication. It is commonly known that more than one NDC can exist for the same drug/strength/form combination, even for one manufacturer.

Problem #14: Pedigree allows multiple lot numbers
We saved this one for last since it's unconceivable that with the other issues with the Florida pedigree, wholesalers would use this pedigree form for multiple lot numbers and quantities of the same medication. Most systems limit their pedigree data structure to one lot number and expiration date. Providing more than one lot number per pedigree would result in additional complexity in selecting the medication after selecting the pedigree. Imagine if you are provided a Florida pedigree with multiple lot numbers on it. Your first question should be “which of these lot numbers are you sending to me?”.
**In Summary:**
We are horrified that other states may look at the State of Florida as a reference for their pedigree. We were able to find over a dozen issues with the Florida pedigree and we do not feel that it is providing any additional safety to the USA drug supply chain. In a follow up article, we will provide information on how the USMeds system addresses these issues. (Don't worry, our solution is not to stick an RFID on every medication bottle.) Hopefully someday, the federal government will create or adopt a well designed system to solve problems with the USA drug supply chain.