Drug Wholesale Distributor Advisory Council Meeting
May 17, 2012
Draft Meeting Minutes

9:30 a.m. Call to Order by Gary Cacciatore, Chair
The meeting was called to order by the Chair, Mr. Cacciatore.

Roll Call taken by Dinah Skrnich.

The following council members were present:
Mr. Cacciatore, Mr. Brecko, Mr. Brock, Mr. Ellis, Mr. Mahoney, Mr. Barnes

The following council members were absent: Mr. Ayotte, Ms. Zeiler and Mr. Garcia.

A quorum was present:

Tab 1: Approval of December 6, 2011 Meeting Minutes
Motion by: Mr. Brecko and seconded by Mr. Barnes to approve the minutes. Motion Carried.

Tab 2: Chair's Report
1. Definition of Wholesale Distribution and Exemptions:
Mr. Cacciatore stated that he added this to the agenda for review and discussion from the council.

Mr. Cacciatore stated I included a copy of the statute and rules. My purpose was to have a clear understanding of what exemptions there are from the definition of wholesale distribution and address the issue of emergencies. There is a provision in the rule that authorizes wholesale distribution of prescription drugs in case of emergency in 61N-1.011(1) (d) (e).

My issue is to understand section (e) of the rule.

(e) Transfers of prescription drugs in an emergency declared pursuant to Section 252.36, F.S., until the state of emergency is lifted, under the following conditions:

1. The manufacturer, wholesaler, or other person supplying the prescription drugs is authorized by Florida law to distribute prescription drugs in or into Florida; and

2. The prescription drugs are delivered to a temporary emergency medical station, officially designated by the state emergency operation center as a Disaster Medical Assistance Team or State Medical Response Team site;

3. The prescription drugs are delivered to a Pharmacy licensed under Chapter 465, F.S.;

Mr. Cacciatore stated is this just for a state of emergency situation. It's not clear to me if you have to meet all three of these conditions or that third one should the word "or" be inserted. I think the intent is the drug is delivered to temporary emergency medical station or to a pharmacy.

If it truly is an emergency what about distributions to practitioners or health care providers or chain warehouses to me that is an issue didn't know if anyone had given thought to that. I will open it up to the floor for comments.

Mr. Dixon stated when I looked at this rule I could see a situation where if during a state of emergency the Department of Health determined that only licensed pharmacies would be used as temporary emergency stations. Then both of those would make sense.

Mr. Dixon stated during the course of emergency I would think that the different hospitals and clinics would be emergency stations. Some place where patients would be taken care of for triage and care. We would have to do some research on this rule and speak with Department of Health and emergency medical services for response.

Mr. Jernigan stated this rule was crafted to meet the needs of Department of Health emergency response component and in coordination with the Department of Emergency Management. Mr. Jernigan suggested that if the council was going to make any changes to this rule that they reach out to Department of Health and emergency management to make sure this doesn't create any unintended consequences in the statewide emergency plans that expand across multiple agencies.

Mr. Cacciatore stated this addresses statewide emergencies but what about an emergency that affects a licensed wholesale distributor such as a fire in their warehouse. Do we need a provision to cover and emergency situation like that in order to meet the needs of the public?

Mr. Dixon stated that is something we need to research. The one thing to think about is when dealing with these types of definitions. I think it was a carve out for emergency medical reasons and not sure how favorable the joint administrative procedures committee would be when looking at a rule which is more of a business operation verses a public health situation. Some type of rule could be written but it would need to relate to on going public emergency.

If it's a drug shortage or viral epidemic we are responding to and a fire it seems like some rule could be written to allow you to continue to distribute that particular drug. I don't know if we have the authority to write a rule to allow continued operations verses limited continued operations to address a specific need of a patient or a particular type of medication. Would have to speak to Department of Health to see if that was the intent

of this rule. I would be happy to do the research and present it to the secretary for review.

Mr. Brecko stated that if one of the three largest wholesalers in Florida did have and emergency it would be extremely difficult for the other two wholesalers to cover that void. Something else to consider when working on this.

Mr. Cacciatore stated I appreciate the comments. I wanted to bring it up as a potential issue. As Mr. Jernigan pointed out maybe not change the part of the emergency medical situation part but perhaps look at other places to insert the rule.

Mr. Cacciatore stated Mr. Barnes has a related topic so I will turn it over to him. I would like to comment that anytime we can simplify a regulation for the industry and everyone else should be our goal.

Mr. Barnes stated he would like clarification 61N-1.011(a) that a hospital under emergency situation can transfer product to another hospital under and emergency situation or shortage.

Is this a sale transaction or borrow loan transaction? It seems to me it's allowed but is pedigree required for this sort of transaction or what records need to be kept.

(a) Transfers of a prescription drug between health care entities or from a health care entity to a retail pharmacy to alleviate a temporary shortage of a prescription drug arising from delays in or interruption of regular distribution schedules, and should not occur between the parties so as to amount to the health care entity regularly and systematically supplying that drug;

Mr. Cacciatore stated the issue here is the need comes up at a hospital situation you need a particular drug for a particular patient that you don't have in stock. It's common practice that you borrow or loan. You try to meet the needs of those patients and send a cab down the street to another hospital to pick it up and then once you get your stock you return to them.

Mr. Barnes stated that assessment is correct.

The council asked that Mr. Dixon contact the Department of Health to discuss the purpose of 61N-1.011 the emergency management rule and follow up with the council at the next meeting.

Follow up phone conference call to discuss borrow and loan process with Mr. McQuone, Mr. Barnes, Mr. Whitten and Mr. Dixon.

Mr. McQuone stated when the council was talking about medical reasons and look at (f) talks about transfers of drugs when a shortage of the is product is documented by the manufacturer;
For future revision of this rule if you could have it state by the manufacturer or wholesaler. And entity might be notified by a wholesaler but I wouldn't know how far back that notification went to the manufacturer or not. I would be trusting that I have a business relationship with my wholesaler if the wholesaler said the drug is in short supply we can't provide it that would be adequate and I would not have to authenticate it or verify it that it went all the way back to the manufacturer. That I could get documentation sometime from either the manufacturer or wholesaler.

Mr. Cacciatore thanked Mr. McQuone for his comment and suggested he bring that up on the conference call for discussion.

Tab 2: Federal Pedigree
Mr. Cacciatore stated this is a standing item on the agenda to monitor the federal legislation.

Ms. Salimone of Holland and Knight gave a brief statement in regards to the federal legislation.

Mr. Cacciatore stated this sounds like it would be and amendment to the language. This is something we will need to monitor and make any changes as they come forward.

Tab 3: Executive Director's Report – Reginald Dixon

1. Returns Rule

Mr. Dixon stated I met with the Secretary and Department attorney and have some language for you to review. This rule has been noticed for development the new draft language is in your agenda material. It expands the timeframe for the return up to 14 days and corrects some of the terminology. Please review section (f) for the language. The reasoning for only having 14 days is the rules attorney had some concerns about the authority of the department to expand that rule.

Mr. Dixon stated this is just the first initial draft for this rule. In consultation with the rules attorney the suggestion has been made to have a rules hearing on all the rules we notice for development. Then comments can be made from the public at the beginning of the process. The department can review those comments and suggestions as they move forward with rule making.

Mr. Cacciatore suggested as the council and department move forward with rule changes that they consider deleting sections that don't have any applicability any more.

2. Legislation Summary

Mr. Dixon stated I have provided you the legislative summary in your meeting material.

Mr. Dixon gave the council a brief update on where the department is with implementation.

SB 364 Blood Establishment- It creates a new permit Restricted RX Drug Distributor permit. The department has created and application and should start issuing in July. The department will need to get rules in place to site to the application. The blood establishments have requested a meeting with the department to discuss the rules for this permit. Once we start writing rules we may call on the council to review and discuss this issue.

SB 517 – Clean up language with definition of distribution and definition of drug and establishment. It removed the 340B requirement for separate inventory. Most of implementation of this is training with inspectors which have taken place.

Mr. Cacciatore asked Mr. Dixon the definition of drug was clarified. Drug components in medical devices are clearly drugs within the scope of the department's regulation. Can you expand on that?

Mr. Dixon stated there have been instances in the past where people have produced a device that actually had a medication component of that device. That the medication component of the device was not within the purview of the department to regulate and we wanted to clarify that it is.

Mr. Barnes stated at the last meeting I asked about if the perpetual inventory requirement in allowing contracted pharmacies where a 340B entity contracts with a retail pharmacy and product is ordered by the covered entity but actually housed at the retail pharmacy. Does that require a pedigree is there any further clarification on this?

Mr. Dixon stated he did not have it on his follow up list but I will research this and it can be discuss on the conference call.

Mr. Cacciatore stated on the new exemption for licensure the health care entity does not need a repackager license to repackage drugs in Florida for their own use. The third bullet point has as long as they repackage in accordance under the federal manufacturing standards does that mean they have to be registered.

Mr. Dixon stated they don't have to be registered but they have to understand what the requirements are. We have some health systems that do have repackager permits. We

wanted to make sure the hospitals that repackage followed the same standards that the repackagers follow currently.

Mr. Cacciatore stated but federal requirements under FDA act they exempt hospitals that are packaging for their own use. That's not considered manufacturing by the FDA its considered part of the practice of pharmacy.

Mr. Jernigan stated the discussions that took place before this was put in place. It was to address health care entities that wanted to repackage down to unit dose type delivery model outside the context of a pharmacy. There is nothing in this law to prohibit a hospital pharmacy from prepackaging its drug for its use for its patients. This was put in place for facilities that don't have pharmacy licenses and therefore not practicing pharmacy at that location.

Mr. Barnes stated if there are 3 hospitals under common control and you have one hospital doing all the packaging for the other two hospitals do they have to meet the state and federal current good manufacturing standards.

Mr. Jernigan stated it depended on the hospital operating within the scope of its pharmacy license. This license picks up where the practice of pharmacy leaves off as regards to health care entities prepackaging or repackaging that activity by a health care entity. If you are within the scope of your pharmacy license and you are prepacking you will not need this. If you are outside of that scope at a distribution center for a large hospital system does not have a pharmacy license then you would need to abide by good state and federal practices.

Mr. McQuone stated your model is one of the three hospitals that elected to repackage for distribution to the other two hospitals all under common control. You maybe held to standards that are part of your accreditation or best practices or good standards. But not necessarily the federal good manufacturing practices.

Mr. Dixon stated as long as you are the pharmacy for the hospital and not the distribution center for the hospital.

Mr. Dixon stated the point of this was to assist folks who have large distribution centers which they want to use to supply their hospitals and clinics. Not the type of practice you have with the pharmacy license and service two hospitals.

HB 5511 It finalizes the DDC transfer and creates a division under the Department with some language clean up.

HB 1089 is in regards to personal information of inspectors.

Mr. Dixon stated there is another bill in regards to schools to be able to purchase epi pens from wholesale distributors. I will send it to you in a separate email this week but not sure if it passed or not. Will follow up and let you know.

3. PIS Renewals

Mr. Dixon stated the program office has met with the attorneys and working on creating a short form renewal for PIS.

Upon initial application do complete PIS if nothing changes in the next two years then on the 3rd year do another full form. We are still working on it and some rule language as well.

Mr. Bayo stated 3 years is a start but as long as amended by rule if there is no change to the PIS then why not go to five years.

Mr. Ellis stated if there is no change why does there need to be a time frame.

Mr. Dixon stated the concern is the office is trying to balance this with what we know was the stated intent of the legislature and just be conservative.

Mr. Ellis stated on the full PIS form if we have submitted fingerprints once that you won't have to do that again.

Mr. Dixon stated that the department didn't want you to do more then what you're doing already.

Mr. Mahoney stated he would like to thank the department on making this easier for the industry.

Mr. Ellis stated he would second that since he just completed his renewal.

4. Hospitals and Repackager

Mr. Dixon stated the next item is hospitals and repackaging. We have done a summary on this and the secretary is still considering this. I have this on my calendar to follow up with him. Hope by the next meeting will give you something within the next 30 days.

Mr. Barnes asked if there needs to be another conference call.

Mr. Dixon stated we can do a phone conference the 1st week of June send out a short agenda and discuss this with Mr. Jernigan and Mr. Barnes.

5. Kudos

Mr. Dixon gave a brief description to the council on employee recognition program Kudos.

TAB 4: Controlled Substance Reporting – Kristen Grosh

Ms. Grosch gave updates in regards to the CSR. The data entry screen has been implemented for the smaller company's manual process and the zero reporting. Started the analysis of the FTP reporting and as soon as it is available we will let you know. The report you requested on the pharmacies that are receiving the same drug from multiple distributors is in the works.

Ms. Grosch stated that hopefully these new implementations will make it easier for some companies and the zero reporters.

Mr. Barnes asked so the next reporting the graph will look like there are more in compliance.

Mr. Dixon stated the program office is looking at auditing and compliance in regards to the CSR since it has been a year that this has been in place. We are working on that without spending valuable resources.

Mr. Jernigan stated the graphic looks worst then it actually is. The people who are required to report to the CSR are a specific subset of permits that are also engaging in the distribution of controlled substances in or into Florida. The graphic represents 100 % of the entire universe of those types of permits who are known to have DEA registrations of wholesaler or manufacturer variety. But that does not mean all those need to be required to register because they may not be distributing those products in or into Florida.

The actual compliance rate is substantially higher then what appears in the graph. I don't have to tell anyone on the call that a handful of companies account for the vast majority of the over all volume in terms of this graph is the number of permitees. The actual compliance rate in terms of volume has to be at least 80 plus percent.

Mr. Ellis stated he would like to reaffirm what Mr. Jernigan stated because there are a lot of prescription drug wholesalers who do not provide those services to there customers. If there is someone to delete them out it would change the graph.

Mr. Cacciatore stated just to clarify just because you hold a Florida wholesale license and a DEA registration and not shipping into the state that they don't have to report zero or report at all.

Mr. Jernigan answered correct.

TAB 5: Other Business

Mr. Cacciatore stated I have a question for Mr. Whitten about the pharmacy re-permitting process for customers. Will they all get new license numbers and expiration dates?

Mr. Whitten stated they will not get new licenses there will be a modifier added to their current license and you can view this on the web portal. The expiration date will remain the same.

Mr. Mahoney asked if there will be a pharmacy download database that can be used.

Mr. Whitten stated you should be able to do this on the web portal and if you have any issues let me know.

Mr. Mahoney asked how many are opting not to pursue this.

Mr. Whitten stated there will probably be a handful that doesn't complete this process.

Mr. Cacciatore asked if there were any other questions from the council or public.

Mr. Cacciatore stated hearing none this meeting is adjourned.