Drug Wholesale Distributor Advisory Council Meeting
December 6, 2011
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. Ayotte, Mr., Brecko, Mr. Ellis, Mr. Garcia, Mr. Mahoney, Mr. Barnes

The following council members were absent:
Ms. Elliott and Dr. Walker

A quorum was present

Tab 1. Introductions:
Mr. Cacciatore asked the council to please introduce themselves and give a brief
history of their background and who they represent.

Mr. Cacciatore asked that Mr. Dixon introduce the Department staff:

Mr. Dixon introduced himself as the Director of the Drugs, Devices and Cosmetics
Program and then introduced Ms. Amy Bennett, Office Manager of the Drugs, Devices
and Cosmetics Program and Kristen Grosch of the IT department and responsible for
the Controlled Substance Reporting.

Mr. Dixon then introduced Secretary Lawson who addressed the council.

Secretary Lawson gave a brief statement and welcomed the council to the department
and stated that he looked forward to working with the industry.
Secretary Lawson stated that Mr. Dixon and his team have his full support. The
Department will do everything we can to send the message that we are partners in
protecting the drug supply for the state of Florida but at the same time working with the
industry.

Mr. Dixon then introduced Mr. Mike Walker as his direct supervisor.
Mr. Cacciatore thanked the secretary and Mr. Dixon then stated he would like to give some opening remarks.

Mr. Cacciatore stated that he feels this is a new beginning with the council and working with the department here at DBPR. The council had made several suggestions to DOH before the transition but because everyone knew this was coming nothing ever became of those suggestions.

Mr. Cacciatore stated that Mr. Dixon and Secretary Lawson are interested in working with this council and taking our recommendations and working through them to protect the public but at the same time reducing the burden on regulating the industry. Mr. Cacciatore stated there are things that the council can do and things that have already been brought up that need to be implemented to make it easier for legitimate business to work in Florida.

Mr. Cacciatore stated those are his goals for the council encouraged the council members to feel free to bring up topics and add things to the agenda.

Mr. Cacciatore asked if there were any other comments or concerns from the council.

Hearing none, the meeting proceeded through the agenda.

**Tab 2. Drug Shortages**

Mr. Cacciatore stated that he added this to the agenda because it is a hot topic both nationally and on individual state level. Particularly hospital pharmacies with injectable products cancer chemo therapy drugs. Mr. Dixon needs to be aware if it comes up during the legislative session or topics of discussion. The council has resources available that can address this topic. As far as the wholesaler's role in the supply chain and how it affects the drug shortage. There has been FDA and congressional hearings on this. Mr. Cacciatore noted that people from his company have testified on this and HDMA (Healthcare Distribution Management Association) has testified on this in front of Congress. President Obama has put out an executive order on the drug shortages. At least two states have had this come up either at legislature or their Board of Pharmacy for possible new rules.

Mr. Cacciatore asked Mr. Barnes if he could address this topic being a hospital pharmacist.

Mr. Barnes stated absolutely this is a serious issue and his hospital has been dealing with this for some time now. Mr. Barnes stated that his hospital has developed a committee and they monitor shortages weekly. They have crash carts that they can't get supplies for. There is chemotherapy and pain medicine shortages. The hospital was down morphine and fentanyl drugs used in anesthesia and only had a week supply. Mr.
Barnes noted that if you look at the types of drugs it's not the expensive ones it is often generic drugs. It's affecting patient care in a serious way throughout the state.

Mr. Cacciatore stated one of the concerns he has is the shortages could lead to grey market and diversion. Shortages of a particular product will cause grey market wholesalers to try to get that product and the price goes way up. Pharmacies have been getting notices from wholesalers to buy product back in order to get these products that are in short supply. This could be a violation.

Mr. Cacciatore stated he is concerned that everyone understands that wholesalers play an important role in this. Some of the suggestions made even at the FDA hearing are not helpful and they don't seem to understand how wholesaler's work. Wholesalers are not hoarding the product and giving it to their favorite customers. Mr. Cacciatore wants to be certain when the issue does come up that everyone in the supply chain from manufacturers, wholesalers, hospitals and distributors are all involved in the discussion to try and solve this together.

Mr. Ayotte stated that there has been a hearing in Florida. The concern is Florida is a very unique state when it comes to rules and regulations of wholesale distributing. Mr. Ayotte asked how do we help legitimate pharmacies serve needy patients and get those drugs that don't really have a pedigree from Georgia or New Mexico? Mr. Ayotte noted that if you don't have that pedigree established in that state you have the drug in, you can't really ship it to Florida. Mr. Ayotte did note that there are emergency rules in place in case of a hurricane or something.

Mr. Ayotte stated we need someway to give the pharmacies and hospitals some guidance. Mr. Ayotte suggested a reminder of what the rules are so they are not getting a fax and then they are going to the internet and buying it. Mr. Ayotte said that pharmacies are just trying to find it someplace and that people are just thinking about their patient care and not what the rules are that could put them in a violation of law.

Mr. Cacciatore stated as a reminder to everyone of how the rules are set up in Florida. If a wholesaler buys a product directly from a manufacturer the pedigree that is provided is just a statement on the invoice that states that this products was purchased directly from a manufacturer.

The problem is when you have a shortage like this when a wholesaler has to purchase it from another wholesaler you have to show a full pedigree tracking it all the way back to the manufacturer. As Mr. Ayotte pointed out that, this would pose a problem when you can't get a full pedigree in time.

Mr. Brecko stated he has seen the same issue on the west coast. The concern is secondary wholesalers are actually sending list of drugs that they are looking for and soliciting retail pharmacies.
Mr. Ayotte stated that there is a website that you can go to for moving drugs like Craigslist. If you have 4 bottles of a drug with 15 pills you can list it and sell it for states that don’t have the regulatory structure that exists in Florida. You have lost all continuity of that product because you don’t know how that product has been stored, how it’s been shipped or where it’s been stored. Desperate times for these patients that need life saving chemotherapy products they are going to take what ever chance they can and the pharmacy profession just looks towards on how you help people.

Mr. Brock stated one more thing for Reggie and Secretary Lawson to know. Mr. Brock noted that he participated in a forum on the Florida chapter of the American Cancer Society. This was a topic on their agenda yesterday. Senator Sobel is very interested in this due to a colleague that has had an issue getting an oncology product. She is looking at doing some legislation. She is not sure of what she can do on a state perspective but is interested in doing something.

Mr. Mahoney stated he has seen numerous pedigree that are created not so much in Florida but elsewhere that are bogus and are moved by different companies within a day when they are out of a product and desperate hospital pharmacist are reaching at staws.

Mr. Barnes stated he will go on the record that his hospital has not done that.

Mr. Cacciatore asked Mr. Garcia if the Board of Pharmacy has discussed this at all.

Mr. Garcia stated no they have not but he will take some notes back to the Board for the December meeting in Gainesville.

The Board of Pharmacy is there to protect the public so we have to be very careful in understanding the circumstances on what we have. Mr. Garcia ask how can we at the same time protect the public from counterfeit product or a product that has not been shipped correctly back and given to a patient and cause more harm? Mr. Garcia stated we have to find a happy medium to make sure product is available but to ensure that those products are safe.

Mr. Whitten, Executive Director for the Board of Pharmacy stated he has received a lot of calls on the shortage of Vitamin K. Mr. Whitten stated he has gotten calls from institutional pharmacies that they can’t find it and it will be mid December before they would get any and he is concerned about hoarding.

Mr. Whitten asked Mr. Barnes if he has experienced any of this.

Mr. Barnes stated that they have gotten adult formulation and then you have to dilute that but then you have to go by 797 guidelines of how long will it be good for. Mr. Barnes stated that his wholesaler has received some and shipped his hospital an allocated amount. It’s one thing after another.
Mr. Ayotte said it's a rebound effect of inventory that you're out of it for awhile and then you overbuy it which then creates another shortage at the end of the buying period. It's just a natural reaction to make sure its not going to happen again.

Mr. Dix asked if the shortages are any worst in Florida then else where in the country? He has heard some of the non resident wholesalers won’t sell into Florida. They won’t do a full pedigree so you can have a sale from a wholesaler to another out of state wholesaler where they got a direct purchase statement then they can’t bring it into Florida unless they go back and get a full pedigree.

Mr. Dix stated he didn’t know if that would be causing the situation to be a little worse. Dealing with non resident wholesalers they often say they won’t sell into Florida because of the increased pedigree and scrutiny.

Mr. Cacciatore stated that is a good question and he didn’t know if there was any evidence of that. He mentioned that he could check with University of Utah which has a clearinghouse with a lot of this drug shortage information. Mr. Cacciatore stated he follow-up on that and see if they have any information specific to Florida verses the rest of the country.

Mr. Cacciatore asked if there were any more comments from the council or audience. Hearing none, the discussion moved on to tab 2.

Tab 2. Executive Director Report Reggie Dixon

Mr. Dixon stated that the transition is complete everything and everyone has been moved from the Department of Health to the Department of Business and Professional Regulation. Business is up and running and going very well. Mr. Dixon gave the council a brief over view of how the office structure was set up and who was responsible for compliance, applications and prosecution in the office. Mr. Dixon stated he thinks the industry will be pleased with how business is done at the Department and that Department employees pride themselves in customer service.

Mr. Dixon stated that the controlled substance reporting system is up and running and council members were provided a copy of the report on that. Kristen Grosh will go over that here shortly under her tab.

Mr. Dixon stated he gave everyone his direct contact information so he can be reached directly. Mr. Dixon believes that everyone who wants a meeting gets a meeting they get the time to explore what ever issues they have.

Mr. Dixon asked if anyone had any questions about the transition.
Mr. Ellis said he would just like to make a comment that he has been involved ever since pedigree started in Florida. Mr. Ellis stated that Mr. Dixon said two words that he thinks each of the council members the companies they represent think about all the time to be successful and that is customer service. Mr. Ellis that is the first time he has heard those words and that he is very encouraged that the industry and Department can finally work together towards some of the same goals.

Mr. Dixon stated he thinks the council will find that the Department is customer service oriented. He stated that we might not give you an answer, but that doesn’t mean we can’t give you a timeframe for follow-up.

Mr. Dixon stated that he and the Chairman spoke briefly on the rules yesterday and how suggestions from the council will work. Most legislation that ends up in a department bill will come out of the program office.

Mr. Dixon stated that the Department has a checklist to follow for legislation and if it’s the board offices responsibility or the council’s to handle. The Department will take the council’s recommendations as well as comments from industry and draft the language which is then taken to the Secretary for approval. The Department will then go to the legislative affairs office with the language and it is their responsibility to move it forward. Mr. Dixon stated it is a little late to start anything this year, but we could be early for next year.

**OFFAR Rule Review:**

Mr. Dixon stated during the transition the moving of the rules chapter from DOH to DBPR was overlooked. The department does have a rules attorney that deals with these types of things. The department will need to create a sub section under DBPR and transfer the DOH rules to the department. The language has been drafted and reviewed and sent to the Department of State.

Mr. Dixon gave a brief overview of the OFARR Office of Fiscal Accountability and Regulatory Reform. Once the council starts working on the rules they will have to be sent to this office for review and approval.

**Stakeholder Suggestion Blood Establishment:**

Mr. Dixon stated that during the transition there was an email sent out to the industry for comments and suggestions. The department has gone through these suggestions and organized them by topic and provided them to the council for review.

Mr. Cacciatore suggested that Mr. Dixon review each one with the council.

Mr. Dixon stated the first one on the list is Blood Establishments. Florida law does not track the federal code when it comes to blood establishments. The exemption that blood establishments have under federal law which allows them to provide transfusion
services is not the same as Florida law. One of the suggestions received was to modify Florida law in some way to bring it into compliance more with federal statute.

There is a Senate bill 364 and House bill 475 which is a companion bill filed by Senator Gates. The bill attempts to accommodate or rectify that problem with blood establishments. The Department has not done analysis on this yet but Mr. Dixon does see this happening in the future. The issue will be bringing in other drugs when they perform these services. Mr. Dixon explained that the council would be responsible for writing the rules for this.

Mr. Barnes asked Mr. Dixon this bill would allow them to bring in other drugs into the hospital?

Mr. Dixon explained that part of the bill does describe any drugs that are complimentary or needed for transfusion services. What is complimentary, who decides this and how will that work? The way the bill is written now, it would allow these establishments to do that with input from the Department on the type of drugs.

Mr. Barnes stated the hospital pharmacy would not be in complete control of these drugs and that would put hospitals in violation.

Mr. Dixon stated the department could get more input and get with the legislative affairs director when analysis request comes through and let Mr. Barnes review the language.

Mr. Cacciatore stated from the wholesale perspective we would need to know if they will be purchasing prescription drugs. Mr. Cacciatore noted that it is harder for wholesalers to manage distribution of prescription drugs when states start setting up lists of certain drugs for certain types of establishments. Mr. Cacciatore cautioned that this should be considered when trying to put language together and setting up list for particular types of providers.

**Bond Requirement**

Mr. Dixon stated the next one on the list is the bond requirement. There is requirement for a one hundred thousand dollar bond or to have equal collateral for certain license types. The Department received one suggestion to amend the statute to give some relief to smaller wholesalers or businesses that have operated for a significant length of time. Perhaps a sliding scale if they operate for a length of time and if there are no issues for a few years then the bond requirement goes down.

Mr. Barnes asked if they put up the actual money or bond insurance?

Mr. Dixon stated that both approaches are used.

Mr. Ellis stated the bond is put aside to pay for a potential fine that could be imposed or if a facility was abandoned. He asked how often has that been used in the last 5 or 6
years since it was implemted? Mr. Barnes noted that's a large amount of money to just sit and not be used especially for a small company. Mr. Barnes suggested the council look at it again and perhaps waive it or scale it as Mr. Dixon stated. Mr. Barnes noted this may not be a big deal for a large company but for a small one it would be.

**Motion by** Mr. Ellis to recommend the department prepare language for a change in statute to address possible relief from the bond requirement for small businesses then develop a rule to address this. Seconded by Mr. Ayotte

Mr. Garcia stated this does need to be looked at and to find a happy median for everyone. Mr. Garcia suggested considering an individual applicant that has been in business for 50 years that wants to supplement their existing business. Such a business may not need to pay a hundred thousand dollar bond, but perhaps a lesser amount.

Mr. Ellis stated he wanted to remind everyone the purpose of the bond is for a fine if we find out that it has not been needed then we may want to look at it. This is a statute so we need to have a statute changed before we start on a rule.

**Motion Carried.**

Mr. Dixon stated the Department will take this back to the office and prepare a summary to take to the Secretary saying the council would like for us to find a way to waive or reduce or even write rules on the bond requirement and this is hindering or impacting smaller business. The Department can provide the council the update in February.

**Compounding Discussion**
Mr. Dixon stated the next issue is compounding which has been and issue for a long time even when he was at the Board of Pharmacy. This has been a very difficult one to address and one of the most difficult issues he has worked on. The goal is to balance the scale between getting the patients the medications that they need but to do that within the regulatory process that is set out which prohibits manufacturing and distributing without having the appropriate permit

Mr. Dixon stated the Department has heard from several folks that there is a perceived conflict between Chapter 499 and the Office Use Compounding rule that is in place right now for the Board of Pharmacy.
This was a suggestion that the Department revise the definition of wholesale distribution to carve out an exception for compounding for office use. This has been a very difficult issue for the Department any suggestions from the council would be appreciated.
Mr. Brock asked if office use means a physician gives the drug to the patient to be taken in the office or if the drug goes to the physician and then is administered to the patient in the office.

Mr. Dixon said the issue and concern is the compounded medication is not being ordered for a specific patient.

Mr. Barnes stated that kind of gets into manufacturing. Inspectors could come in and say that is manufacturing and the pharmacies would not be in compliance.

Mr. Garcia stated the position that has been taken by the board of pharmacy. This is considered the art of a pharmacist to be able to compound non-commercially available products to be able to send to the physician’s office for use but it’s been for pediatrics use mostly.

Mr. Cacciatoire stated that the council does not need to get into a debate about compounding. That issue should be left to the Board of Pharmacy. There may be a conflict in the laws if the Board of Pharmacy says that a pharmacy may compound for a physician’s office for the physician’s use in the office or administration and that is within the practice of pharmacy even if it’s not generally patient specific.

Mr. Cacciatoire stated the movement of that compounded drug to the pharmacy would generally be considered a wholesale transaction unless there is an exemption from that. In Texas when the law was changed to allow pharmacists to compound for office use one of the main issues they had to get over was there had to be an exemption from the definition of wholesale distribution to allow that and it was part of the legislative package. It sounds like that part is missing here.

Mr. Cacciatoire stated the exemption from the wholesale distribution definition would be for a compounded drug that is sent to a physician’s office if it’s specifically allowed by statute or by Board of Pharmacy rule as part of the practice of pharmacy. Mr. Cacciatoire stated he considered this to be part of the practice of pharmacy even though it’s not dispensing to a patient. Mr. Cacciatoire stated he would not consider that a wholesale distribution.

Mr. Ayotte asked when a pharmacist compounds and excessive amount is that distribution. Is there a certain amount they can do for a product?

Mr. Dix stated they can compound in anticipation of a prescription. No quantity amount is set in the rule they are allowed to compound in anticipation of receiving prescriptions. If they generally receive 25 a week they can make up a batch for 25 and have it sit there and dispense it throughout that week. There is no magic number if inspectors come in and see enough for a thousand and their volume is 25 a week they can take enforcement action.
Mr. Cacciatore said what you Mr. Ayotte might be thinking of is DEA’s 5% rule that allows a pharmacy not to have to have a wholesale registration as long as their wholesaling is not greater than 5% of their dispensing. Mr. Cacciatore stated he didn’t know if there is a 5% rule for general wholesaling or if pharmacies that do any distribution have to get a registration with a special type of permit.

Mr. Dix said is that distribution? That is the question?

Mr. Ayotte said his suggestion would be that we put in the section of code that it’s exempted from the definition of wholesale distribution.

Mr. Dix stated one thing about the compounding rule is it puts some ownership on the pharmacist actually doing the compounding to do some due diligence to make sure they are not compounding an amount outside the normal course of what that physician office receives and uses. It puts the ownership on the pharmacist and the pharmacy.

Mr. Dixon stated some of the concerns he has received is it makes the pharmacist reluctant to compound for office use because they fear of the DDC program will charge them with manufacturing or distributing commercially available drugs and this would subject them to a large fine or risk shutting down their pharmacy.

Mr. Brecko asked what is distinction between the two licenses retail and retail wholesale licenses? Is it where they can sell a minimum amount of product wholesale where they keep the inventory separate?

Mr. Dixon said he didn’t know if we are talking about licensing as much as what pharmacists are allowed to do when their practice of pharmacy moves from compounding limited amounts of drugs for specific patients to be administered versus compounding large amounts of drugs and providing those at a discounted rate for a physicians office for use at the doctors discretion. It’s a fine line and could be difficult as regulators to try and enforce that. Mr. Dixon notes that if it’s difficult for the regulators it’s difficult for the pharmacist.

Mr. Brock stated from a historical perspective the compounding rule only allowed pharmacists to compound medicines based on a specific order for a specific patient but a change happened to allow lead way to make a certain amount in advance knowing they were going to sell a certain amount.

If the pharmacy has a doctor’s practice that normally prescribes 25 prescriptions of one compounded drug. Because they can anticipate those prescriptions are coming, there is a rational basis to allow the compounding pharmacist some lead time to be able to compound not for a specific prescription, but for one they knew was coming or anticipated.
Mr. Garcia stated that a proposed change will allow that or exempt or try and help define and separate.

Mr. Cacciatore stated he did not think the council had enough information to make a recommendation to propose a change at this time. Mr. Cacciatore suggested this topic be tabled until the next meeting and said he would look into this.

Mr. Dixon asked is there anything the Department can do to help assist?.

Mr. Cacciatore asked for the BOP rules on compounding. Mr. Barnes asked for a copy also of the BOP rules.

Mr. Dixon said the department could reach out to the people that made this suggestion and provide the council with examples to put it in context for the council.

Mr. Brock stated perhaps the Board of Pharmacy wants to bring forth a specific recommendation back to the council if that would be appropriate.

Mr. Ayotte stated he believed it's a board of pharmacy issue.

Mr. Garcia stated that he thinks as an advisory council that we are looking after the wholesale piece of it. This is a very heated topic for the board for legislation and there are very strong feelings out there on this issue. From the advisory council we could say there are some definition issues out there and do we feel comfortable from the wholesale perspective to be able to say is this and whether an exemption is needed or not. The question for the council should not be whether a pharmacist can compound or not. This puts it as a different question.

Mr. Cacciatore asked if there were any other comments hearing none Mr. Dixon continued.

**Renewal Form**

Mr. Dixon said the next suggestion the Department had covers licensing and trying to come up with ideas to allow the Department to make a short form renewal.

This would prevent industry from having to submit personal information statements and background checks with each renewal. How can the Department make it easier on the industry? The Department is in the process of putting as many of these applications on line as possible.

Mr. Cacciatore stated that his company has at least 27 licenses in Florida so Cardinal Health was glad to see this. Mr. Cacciatore explained that he did not want to eliminate some of these requirements because as an industry we need to protect the supply chain, but believes the requirements have gone too far with renewals when industry
needs to supply a copy of the lease for a facility that has been in the same place for 20 years or a personal statement for corporate officers when nothing has changed since the last renewal.

Mr. Cacciatore stated he was pleased to see the Department come up with a short form for renewals.

Mr. Cacciatore suggested supporting anything that would make the application process easier.

Mr. Brock stated if there are any significant changes then information should be resubmitted, but if there are no changes industry should not have to submit all those documents again.

Motion by Mr. Brock, and seconded by Mr. Brecko that the council supports and will work with the Department on developing a short form license renewal and determining the best way to accomplish this through rule and/or legislative changes. Motion Carried.

Mr. Mahoney asked is there any record of how many wholesalers have been licensed and the length of time they have held that license.

Mr. Dixon stated he could get a record of how long each of them has been licensed.

Authentication of Pedigree

Mr. Dixon stated the next suggestion dealt with electronic authentication of pedigrees. Given the validation of the process between the purchaser and seller sometimes relying on that person to get back, this could delay the delivery of those drugs to patients. The Department tried to give the council a summary of what the suggestion was but also recognizes that there are some issues with the authentication process and they would like for the council and the Department to consider alternatives.

Mr. Dixon stated if the council could provide some suggestions, he could reach out to the industry and let them know the council is considering the suggestions. The Department could ask the industry to give alternatives that would work but not get rid of the authentication piece all together.

Mr. Cacciatore stated that the authentication rules are complicated and he personally doesn't understand them. Mr. Cacciatore suggested that the council needs to understand the rule and review it at the next meeting and have it explained in detail.

After discussion on the authentication process Mr. Ellis stated he has a good understanding of this and he would be happy to give overview of authentication process to the council in February.

Mr. Cacciatore recognized Dan Bellingham from HDMA.
Mr. Bellingham stated that his organization gave a presentation to the council about a year ago on this issue. They would be happy to do that again if the council would like.

Mr. Brock stated he wishes the council could have a workshop to further address this for improvement. Mr. Brock cautioned that the council needs to be very careful not to move backwards because of all the hard work that has been done in Florida.

Mr. Cacciatore stated this should be a standard agenda item and be discussed for possible legislative changes for next year.

Mr. Dixon suggested that from this meeting the Department is going to pull information together for the council and suggested it would be good for the Department to send it to the chair for review and let the chair and Department decide what topics to put on the agenda. If it is determines that one topic would take up a considerable amount of time, it is possible that only one or two topics will be placed on the agenda for that meeting.

The council agreed to this suggestion.

Common Control

Mr. Dixon stated the next suggestion is dealing with retail pharmacies under common control. Is there a way to give some relief to those retail pharmacies under common control to allow them to transfer drugs from one store to another. This currently requires a retail pharmacy wholesale distributor’s permit. This is coming to the council for consideration and guidance.

Mr. Brecko asked if these are small chains or large chains.

Mr. Garcia stated there are so many definitions out there for chains. He suggested looking at common ownership rather than trying to define a chain.

After discussion between the council, there was a

Motion by Mr. Ayotte suggesting the Department look at the common control suggestions that were provided to the Department and that have been discussed today, seconded by Mr. Garcia.

Mr. Ayotte stated he would amend his motion to allow the Department to come up with the terminology that best suits this. Motion carried

Mr. Mahoney asked what is the difference between control and ownership? Mr. Mahoney stated he has seen a proliferation of loose affiliations as part of a group. He was not sure if they are just friends or there is cross ownership especially with stock transfers going on as transactions.
Mr. Dixon stated he believes common control includes ownership. Mr. Dixon didn’t know if ownership was the issue. He stated common control is broader than ownership. He didn’t believe you have to have ownership to have common control.

Mr. Mahoney suggested you could have five different pharmacies and different ownership at each one, but they seem to embrace the same policies and procedures. Is that common control? This takes on characteristics like a buying group.

Mr. Cacciatore stated this is just a recommendation from the council, the Department may not support the recommendation but the council is giving them some direction.

Mr. Dixon stated the last suggestion is more housekeeping to transfer Chapter 499 to the Department of Business and Professional Regulations. This may be part of a revised bill that goes through and he just wanted to make the council aware of it.

Mr. Ayotte reminded the council if PDUFA passes with some pedigree provisions, it certainly would be good to align it with Florida law.

Mr. Cacciatore stated that we have taken a position on that already on a previous conference call.

Mr. Cacciatore stated the next agenda item is Ms. Grosh.

**TAB 4 Controlled Substance Reporting**

Ms. Grosh gave a brief report to the council on the controlled substance reporting. There was no action needed on this.

Mr. Brecko stated he attended the workshop for the E-FORCSE conference. They had at least four doctors concerned about doctor shopping from patients. They were looking for a mechanism to be notified themselves when this occurs.

Mr. Brecko asked if there a mechanism that the state can report to wholesalers information on how many other wholesalers are selling controlled substances to a particular customer without including information on how much each wholesaler sold to a specific individual. If the Department could tell wholesalers this pharmacy is buying controlled substances from 5 or 7 different suppliers, it would give wholesalers the information to determine if this a pill mill or not. Mr. Brecko asked if this can be researched at some point down the road.

Mr. Cacciatore stated he wanted to clarify that you have the PDMP program which is separately tracked with Becki Poston and the Department of Health.
Mr. Cacciatore stated the CSR is for wholesalers. The wholesalers have asked DEA for years to share the information on what is being reported and they have denied that request. Now that the Department will be collecting that information, they may get the same request.

Mr. Ayotte asked what is it that wholesalers want to know, the amount they buy in quantities or just that they are buying it from different people.

Mr. Brecko stated that he spoke to Ms. Poston about this and it would be a good idea to know both.

Ms. Grosh stated that the Department is looking at running reports and looking at making the electronic process a little easier for the mom and pop places that don’t do a large volume. There have been suggestions from Department of Health to allow FTP process from some of the larger distributors. These are some of the processes the Department is looking at for later.

Mr. Brecko stated if they can do it for doctors I think we need to look at it.

**Motion by** Mr. Brecko asking Mr. Dixon to get a legal opinion from the general counsel’s office on what information from the Controlled Substance Reporting system can be shared with the industry on what is being reported. Seconded by Mr. Barnes. Motion passed.

Mr. Brecko stated if community pharmacies are purchasing from multiple distributors, the industry would like to know this.

Mr. Dixon presented a certificate to Ms. Grosh for her assistance with the controlled substance reporting website.

**TAB 5: 2012 Meeting Date**

Ms. Skrnich informed the council there was one change to the schedule that the December meeting was previously set for a Friday and was changed to Thursday.

Mr. Cacciatore stated he wanted to remind everyone that we operate under the Sunshine laws. Council members cannot discuss topics amongst themselves. People can come to council members for discussion.

Mr. Dixon stated if someone came to a council member with suggestions and if a council member wanted the information to go out to the council, those suggestions should be forwarded to him or to Dinah Skrnich and the information will be sent out. Please send any such information to Dinah Skrnich with a copy to Mr. Dixon.
Mr. Brecko stated I feel this was productive meeting and suggested having another meeting face to face.

Mr. Cacciatore stated what May and December.

Mr. Dixon stated that the legislative session is early this year, but it is normally March to May and to keep that in mind. The Department will be working on all the implementation plans then.

Mr. Cacciatore stated that we will have the August meeting as mandatory face to face and February optional to come or call in by phone.

Mr. Cacciatore opened the floor to other business.

Mr. Barnes asked Mr. Dixon if it would be possible to arrange for GHS, a company doing serialization, to make a presentation on serialization to the council. The bill has been proposed by California for federal laws and serialization.

Mr. Cacciatore stated he would like to know more about the company and asked Mr. Barnes to send more information to Mr. Dixon.

Mr. Ayotte asked about the suggestion made already regarding the 90 day return.

Mr. Cacciatore stated the council voted already on a recommendation to change the rule for returns. Mr. Cacciatore clarified the rule doesn't say you can't return a product after 7 days. You can, but after 7 days in order to redistribute that product you have to create a pedigree; a full pedigree.

If a pharmacy got the product with a direct purchase pedigree statement, there is no way to create a full pedigree after it is returned. If a wholesaler gets a product back after 7 days, even though it's in date and good product and the pharmacy attests that they bought the product from the wholesaler and that it was stored correctly, the product can't be redistributed, it goes into the morgue and is destroyed. This is a total waste of healthcare resources.

Mr. Cacciatore stated fortunately it's not a statute it's a regulation so it can be changed. The council voted to give the industry some more leeway there and change the language to allow for returns up to he believed 90 days.

Motion by Mr. Cacciatore to reiterate the previous motions and get the rule making process started and through OFARR for this change. Second Mr. Garcia. Motion carried.
Mr. Cacciatore stated he was sure it was 90 days and this allows wholesalers to 
redistribute that product without a full pedigree showing the initial sale and return

Mr. Ayotte stated he thought it would be helpful for the council to know what the council 
has voted on the past year and revisit those again and refresh ourselves.

Mr. Cacciatore stated he thought that was a very good idea and asked the Department 
to go back and capture those motions from the past year.

**Audience Discussion**

Mr. Billingham asked the council about the criminal background discussion. More 
specifically geared to manufacturers or wholesalers that they cannot distribute to 
anyone that has failed a background check from the bill 7095. This has been an issue 
for wholesalers coming out of that bill.

Mr. Whitten stated, the Department of Health cannot report that to you due to federal 
law. That maybe part of the Department’s glitch bill and Mr. Whitten said he can give 
some feedback on this after the next meeting. Mr. Dix stated on the returns issue there 
was discussion that was approved by the council and language was proposed on 
returns by chains to return drugs back to the chain pharmacy warehouse. But he has 
not seen anything from this proposal.

Mr. Cacciatore said this language can be included on the return language.

Mr. Cacciatore asked if there was any further business or audience questions.

Hearing none, the meeting was adjoumed.