

1                                   **Drug Wholesale Distributor Advisory Council Meeting**  
2                                                           **December 6, 2011**  
3                                                           **Draft Meeting Minutes**  
4

5 **9:30 a.m. Call to Order by Gary Cacciatore, Chair**

6 The meeting was called to order by the Chair, Mr. Cacciatore.  
7

8  
9 Roll Call taken by Dinah Skrnich.

10  
11 The following council members were present:

12  
13 Mr. Cacciatore, Mr. Ayotte, Mr., Brecko, Mr. Ellis, Mr. Garcia, Mr. Mahoney, Mr. Barnes  
14

15 The following council members were absent:

16  
17 Ms. Elliott and Dr. Walker  
18

19 A quorum was present  
20

21 **Tab 1. Introductions:**

22 Mr. Cacciatore asked the council to please introduce them selves and give a brief  
23 history of their background and who they represent.  
24

25 Mr. Cacciatore asked that Mr. Dixon introduce the Department staff:  
26

27 Mr. Dixon introduced himself as the Director of the Drugs, Devices and Cosmetics  
28 Program and then introduced Ms. Amy Bennett, Office Manager of the Drugs, Devices  
29 and Cosmetics Program and Kristen Grosch of the IT department and responsible for  
30 the Controlled Substance Reporting.  
31

32 Mr. Dixon then introduced Secretary Lawson who addressed the council.  
33

34 Secretary Lawson gave a brief statement and welcomed the council to the department  
35 and stated that he looked forward to working with the industry.

36 Secretary Lawson stated that Mr. Dixon and his team have his full support. The  
37 Department will do everything we can to send the message that we are partners in  
38 protecting the drug supply for the state of Florida but at the same time working with the  
39 industry.  
40

41 Mr. Dixon then introduced Mr. Mike Walker as his direct supervisor.  
42

43 Mr. Cacciatore thanked the secretary and Mr. Dixon then stated he would like to give  
44 some opening remarks.

45  
46 Mr. Cacciatore stated that he feels this is a new beginning with the council and working  
47 with the department here at DBPR. The council had made several suggestions to DOH  
48 before the transition but because everyone knew this was coming nothing ever became  
49 of those suggestions.

50  
51 Mr. Cacciatore stated that Mr. Dixon and Secretary Lawson are interested in working  
52 with this council and taking our recommendations and working through them to protect  
53 the public but at the same time reducing the burden on regulating the industry. Mr.  
54 Cacciatore stated there are things that the council can do and things that have already  
55 been brought up that need to be implemented to make it easier for legitimate business  
56 to work in Florida.

57  
58 Mr. Cacciatore stated those are his goals for the council encouraged the council  
59 members to feel free to bring up topics and add things to the agenda.

60  
61 Mr. Cacciatore asked if there were any other comments or concerns from the council.

62  
63 Hearing none, the meeting proceeded through the agenda.

## 64 65 **Tab 2. Drug Shortages**

66  
67 Mr. Cacciatore stated that he added this to the agenda because it is a hot topic both  
68 nationally and on individual state level. Particularly hospital pharmacies with injectable  
69 products cancer chemo therapy drugs. Mr. Dixon needs to be aware if it comes up  
70 during the legislative session or topics of discussion. The council has resources  
71 available that can address this topic. As far as the wholesaler's role in the supply chain  
72 and how it affects the drug shortage. There has been FDA and congressional hearings  
73 on this. Mr. Cacciatore noted that people from his company have testified on this and  
74 HDMA (Healthcare Distribution Management Association) has testified on this in front of  
75 Congress. President Obama has put out an executive order on the drug shortages. At  
76 least two states have had this come up either at legislature or their Board of Pharmacy  
77 for possible new rules.

78  
79 Mr. Cacciatore asked Mr. Barnes if he could address this topic being a hospital  
80 pharmacist.

81  
82 Mr. Barnes stated absolutely this is a serious issue and his hospital has been dealing  
83 with this for some time now. Mr. Barnes stated that his hospital has developed a  
84 committee and they monitor shortages weekly. They have crash carts that they can't get  
85 supplies for. There is chemotherapy and pain medicine shortages. The hospital was  
86 down morphine and fentanyl drugs used in anesthesia and only had a week supply. Mr.

87 Barnes noted that if you look at the types of drugs it's not the expensive ones it is often  
88 generic drugs. It's affecting patient care in a serious way throughout the state.  
89

90 Mr. Cacciatore stated one of the concerns he has is the shortages could lead to grey  
91 market and diversion. Shortages of a particular product will cause grey market  
92 wholesalers to try to get that product and the price goes way up. Pharmacies have been  
93 getting notices from wholesalers to buy product back in order to get these products that  
94 are in short supply. This could be a violation.  
95

96 Mr. Cacciatore stated he is concerned that everyone understands that wholesalers play  
97 an important role in this. Some of the suggestions made even at the FDA hearing are  
98 not helpful and they don't seem to understand how wholesaler's work. Wholesalers  
99 are not hoarding the product and giving it to their favorite customers. Mr. Cacciatore  
100 wants to be certain when the issue does come up that everyone in the supply chain  
101 from manufacturers, wholesalers, hospitals and distributors are all involved in the  
102 discussion to try and solve this together.  
103

104 Mr. Ayotte stated that there has been a hearing in Florida. The concern is Florida is a  
105 very unique state when it comes to rules and regulations of wholesale distributing.  
106 Mr. Ayotte asked how do we help legitimate pharmacies serve needy patients and get  
107 those drugs that don't really have a pedigree from Georgia or New Mexico? Mr. Ayotte  
108 noted that if you don't have that pedigree established in that state you have the drug in,  
109 you can't really ship it to Florida. Mr. Ayotte did note that there are emergency rules in  
110 place in case of a hurricane or something.  
111

112 Mr. Ayotte stated we need somehow to give the pharmacies and hospitals some  
113 guidance. Mr. Ayotte suggested a reminder of what the rules are so they are not getting  
114 a fax and then they are going to the internet and buying it. Mr. Ayotte said that  
115 pharmacies are just trying to find it someplace and that people are just thinking about  
116 their patient care and not what the rules are that could put them in a violation of law.  
117

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

122 The problem is when you have a shortage like this when a wholesaler has to purchase it  
123 from another wholesaler you have to show a full pedigree tracking it all the way back to  
124 the manufacturer. As Mr. Ayotte pointed out that, this would pose a problem when you  
125 can't get a full pedigree in time.  
126

127 Mr. Brecko stated he has seen the same issue on the west coast. The concern is  
128 secondary wholesalers are actually sending list of drugs that they are looking for and  
129 soliciting retail pharmacies.  
130

131 Mr. Ayotte stated that there is a website that you can go to for moving drugs like  
132 Craigslist. If you have 4 bottles of a drug with 15 pills you can list it and sell it for states  
133 that don't have the regulatory structure that exists in Florida. You have lost all continuity  
134 of that product because you don't know how that product has been stored, how it's been  
135 shipped or where it's been stored. Desperate times for these patients that need life  
136 saving chemotherapy products they are going to take what ever chance they can and  
137 the pharmacy profession just looks towards on how you help people.

138  
139 Mr. Brock stated one more thing for Reggie and Secretary Lawson to know. Mr. Brock  
140 noted that he participated in a forum on the Florida chapter of the American Cancer  
141 Society. This was a topic on their agenda yesterday. Senator Sobel is very interested in  
142 this due to a colleague that has had an issue getting an oncology product. She is  
143 looking at doing some legislation. She is not sure of what she can do on a state  
144 perspective but is interested in doing something.

145  
146 Mr. Mahoney stated he has seen numerous pedigree that are created not so much in  
147 Florida but elsewhere that are bogus and are moved by different companies within a  
148 day when they are out of a product and desperate hospital pharmacist are reaching at  
149 staws.

150  
151 Mr. Barnes stated he will go on the record that his hospital has not done that.

152  
153 Mr. Cacciatore asked Mr. Garcia if the Board of Pharmacy has discussed this at all.

154  
155 Mr. Garcia stated no they have not but he will take some notes back to the Board for the  
156 December meeting in Gainesville.

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

163  
164 Mr. Whitten, Executive Director for the Board of Pharmacy stated he has received a lot  
165 of calls on the shortage of Vitamin K. Mr. Whitten stated he has gotten calls from  
166 institutional pharmacies that they can't find it and it will be mid December before they  
167 would get any and he is concerned about hoarding.

168  
169 Mr. Whitten asked Mr. Barnes if he has experienced any of this.

170  
171 Mr. Barnes stated that they have gotten adult formulation and then you have to dilute  
172 that but then you have to go by 797 guidelines of how long will it be good for. Mr.  
173 Barnes stated that his wholesaler has received some and shipped his hospital an  
174 allocated amount. It's one thing after another.

175  
176 Mr. Ayotte said it's a rebound effect of inventory that you're out of it for awhile and then  
177 you overbuy it which then creates another shortage at the end of the buying period. It's  
178 just a natural reaction to make sure its not going to happen again.

179  
180 Mr. Dix asked if the shortages are any worst in Florida then else where in the country?  
181 He has heard some of the non resident wholesalers won't sell into Florida. They won't  
182 do a full pedigree so you can have a sale from a wholesaler to another out of state  
183 wholesaler where they got a direct purchase statement then they can't bring it into  
184 Florida unless they go back and get a full pedigree.

185  
186 Mr. Dix stated he didn't know if that would be causing the situation to be a little worse.  
187 Dealing with non resident wholesalers they often say they won't sell into Florida  
188 because of the increased pedigree and scrutiny.

189  
190 Mr. Cacciatore stated that is a good question and he didn't know if there was any  
191 evidence of that. He mentioned that he could check with University of Utah which has a  
192 clearinghouse with a lot of this drug shortage information. Mr. Cacciatore stated he  
193 follow-up on that and see if they have any information specific to Florida verses the rest  
194 of the country.

195  
196 Mr. Cacciatore asked if there were any more comments from the council or audience.  
197 Hearing none, the discussion moved on to tab 2.

198  
199

## 200 **Tab 2. Executive Director Report Reggie Dixon**

201  
202 Mr. Dixon stated that the transition is complete everything and everyone has been  
203 moved from the Department of Health to the Department of Business and Professional  
204 Regulation. Business is up and running and going very well.

205 Mr. Dixon gave the council a brief over view of how the office structure was set up and  
206 who was responsible for compliance, applications and prosecution in the office. Mr.  
207 Dixon stated he thinks the industry will be pleased with how business is done at the  
208 Department and that Department employees pride themselves in customer service.

209  
210 Mr. Dixon stated that the controlled substance reporting system is up and running and  
211 council members were provided a copy of the report on that. Kristen Grosh will go over  
212 that here shortly under her tab.

213  
214 Mr. Dixon stated he gave everyone his direct contact information so he can be reached  
215 directly. Mr. Dixon believes that everyone who wants a meeting gets a meeting they get  
216 the time to explore what ever issues they have.

217 Mr. Dixon asked if anyone had any questions about the transition.  
218

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

225  
226 Mr. Dixon stated he thinks the council will find that the Department is customer service  
227 oriented. He stated that we might not give you an answer, but that doesn't mean we  
228 can't give you a timeframe for follow-up.

229  
230 Mr. Dixon stated that he and the Chairman spoke briefly on the rules yesterday and how  
231 suggestions from the council will work. Most legislation that ends up in a department bill  
232 will come out of the program office.

233  
234 Mr. Dixon stated that the Department has a checklist to follow for legislation and if it's  
235 the board offices responsibility or the council's to handle. The Department will take the  
236 council's recommendations as well as comments from industry and draft the language  
237 which is then taken to the Secretary for approval. The Department will then go to the  
238 legislative affairs office with the language and it is their responsibility to move it forward.  
239 Mr. Dixon stated it is a little late to start anything this year, but we could be early for next  
240 year.

241  
242 **OFFAR Rule Review:**

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

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

251  
252 **Stakeholder Suggestion Blood Establishment:**

253  
254 Mr. Dixon stated that during the transition there was an email sent out to the industry for  
255 comments and suggestions. The department has gone through these suggestions and  
256 organized them by topic and provided them to the council for review.

257  
258 Mr. Cacciatore suggested that Mr. Dixon review each one with the council.

259  
260 Mr. Dixon stated the first one on the list is Blood Establishments. Florida law does not  
261 track the federal code when it comes to blood establishments. The exemption that blood  
262 establishments have under federal law which allows them to provide transfusion

263 services is not the same as Florida law. One of the suggestions received was to modify  
264 Florida law in some way to bring it into compliance more with federal statute.

265  
266 There is a Senate bill 364 and House bill 475 which is a companion bill filed by Senator  
267 Gates. The bill attempts to accommodate or rectify that problem with blood  
268 establishments. The Department has not done analysis on this yet but Mr. Dixon does  
269 see this happening in the future. The issue will be bringing in other drugs when they  
270 perform these services. Mr. Dixon explained that the council would be responsible for  
271 writing the rules for this.

272  
273 Mr. Barnes asked Mr. Dixon this bill would allow them to bring in other drugs into the  
274 hospital?

275  
276 Mr. Dixon explained that part of the bill does describe any drugs that are complimentary  
277 or needed for transfusion services. What is complimentary, who decides this and how  
278 will that work? The way the bill is written now, it would allow these establishments to do  
279 that with input from the Department on the type of drugs.

280  
281 Mr. Barnes stated the hospital pharmacy would not be in complete control of these  
282 drugs and that would put hospitals in violation.

283  
284 Mr. Dixon stated the department could get more input and get with the legislative affairs  
285 director when analysis request comes through and let Mr. Barnes review the language.

286  
287 Mr. Cacciatore stated from the wholesale perspective we would need to know if they will  
288 be purchasing prescription drugs. Mr. Cacciatore noted that it is harder for wholesalers  
289 to manage distribution of prescription drugs when states start setting up lists of certain  
290 drugs for certain types of establishments. Mr. Cacciatore cautioned that this should be  
291 considered when trying to put language together and setting up list for particular types  
292 of providers.

293  
294 **Bond Requirement**

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

301  
302 Mr. Barnes asked if they put up the actual money or bond insurance?  
303 Mr. Dixon stated that both approaches are used.

304  
305 Mr. Ellis stated the bond is put aside to pay for a potential fine that could be imposed or  
306 if a facility was abandoned. He asked how often has that been used in the last 5 or 6

307 years since it was implemented? Mr. Barnes noted that's a large amount of money to just  
308 sit and not be used especially for a small company. Mr. Barnes suggested the council  
309 look at it again and perhaps waive it or scale it as Mr. Dixon stated. Mr. Barnes noted  
310 this may not be a big deal for a large company but for a small one it would be.

311  
312 **Motion by Mr. Ellis** to recommend the department prepare language for a change in  
313 statute to address possible relief from the bond requirement for small businesses then  
314 develop a rule to address this. Seconded by Mr. Ayotte

315  
316 Mr. Garcia stated this does need to be looked at and to find a happy median for  
317 everyone. Mr. Garcia suggested considering an individual applicant that has been in  
318 business for 50 years that wants to supplement their existing business. Such a  
319 business may not need to pay a hundred thousand dollar bond, but perhaps a lesser  
320 amount.

321  
322 Mr. Ellis stated he wanted to remind everyone the purpose of the bond is for a fine if we  
323 find out that it has not been needed then we may want to look at it. This is a statute so  
324 we need to have a statute changed before we start on a rule.

325  
326 Motion Carried.

327  
328 Mr. Dixon stated the Department will take this back to the office and prepare a  
329 summary to take to the Secretary saying the council would like for us to find a way to  
330 waive or reduce or even write rules on the bond requirement and this is hindering or  
331 impacting smaller business. The Department can provide the council the update in  
332 February.

### 333 Compounding Discussion

334  
335 Mr. Dixon stated the next issue is compounding which has been an issue for a long  
336 time even when he was at the Board of Pharmacy. This has been a very difficult one to  
337 address and one of the most difficult issues he has worked on. The goal is to balance  
338 the scale between getting the patients the medications that they need but to do that  
339 within the regulatory process that is set out which prohibits manufacturing and  
340 distributing without having the appropriate permit

341  
342 Mr. Dixon stated the Department has heard from several folks that there is a perceived  
343 conflict between Chapter 499 and the Office Use Compounding rule that is in place right  
344 now for the Board of Pharmacy.

345 This was a suggestion that the Department revise the definition of wholesale distribution  
346 to carve out an exception for compounding for office use. This has been a very difficult  
347 issue for the Department any suggestions from the council would be appreciated.



349 Mr. Brock asked if office use means a physician gives the drug to the patient to be taken  
350 in the office or if the drug goes to the physician and then is administered to the patient in  
351 the office.

352  
353 Mr. Dixon said the issue and concern is the compounded medication is not being  
354 ordered for a specific patient.

355  
356 Mr. Barnes stated that kind of gets into manufacturing. Inspectors could come in and  
357 say that is manufacturing and the pharmacies would not be in compliance.

358  
359 Mr. Garcia stated the position that has been taken by the board of pharmacy. This is  
360 considered the art of a pharmacist to be able to compound non-commercially available  
361 products to be able to send to the physician's office for use but it's been for pediatrics  
362 use mostly.

363  
364 Mr. Cacciatore stated that the council does not need to get into a debate about  
365 compounding. That issue should be left to the Board of Pharmacy.

366 There may be a conflict in the laws if the Board of Pharmacy says that a pharmacy may  
367 compound for a physician's office for the physician's use in the office or administration  
368 and that is the within the practice of pharmacy even if it's not generally patient specific.

369  
370 Mr. Cacciatore stated the movement of that compounded drug to the pharmacy would  
371 generally be considered a wholesale transaction unless there is an exemption from that.  
372 In Texas when the law was changed to allow pharmacists to compound for office use  
373 one of the main issues they had to get over was there had to be an exemption from the  
374 definition of wholesale distribution to allow that and it was part of the legislative  
375 package. It sounds like that part is missing here.

376  
377 Mr. Cacciatore stated the exemption from the wholesale distribution definition would be  
378 for a compounded drug that is sent to a physician's office if it's specifically allowed by  
379 statute or by Board of Pharmacy rule as part of the practice of pharmacy. Mr.  
380 Cacciatore stated he considered this to be part of the practice of pharmacy even though  
381 it's not dispensing to a patient. Mr. Cacciatore stated he would not consider that a  
382 wholesale distribution.

383  
384 Mr. Ayotte asked when a pharmacist compounds and excessive amount is that  
385 distribution. Is there a certain amount they can do for a product?

386  
387 Mr. Dix stated they can compound in anticipation of a prescription. No quantity amount  
388 is set in the rule they are allowed to compound in anticipation of receiving prescriptions.  
389 If they generally receive 25 a week they can make up a batch for 25 and have it sit there  
390 and dispense it throughout that week. There is no magic number if inspectors come in  
391 and see enough for a thousand and their volume is 25 a week they can take  
392 enforcement action.

393  
394 Mr. Cacciatore said what you Mr. Ayotte might be thinking of is DEA's 5% rule that  
395 allows a pharmacy not to have to have a wholesale registration as long as their  
396 wholesaling is not greater than 5% of their dispensing. Mr. Cacciatore stated he didn't  
397 know if there is a 5% rule for general wholesaling or if pharmacies that do any  
398 distribution have to get a registration with a special type of permit.

399  
400 Mr. Dix said is that distribution? That is the question?

401  
402 Mr. Ayotte said his suggestion would be that we put in the section of code that it's  
403 exempted from the definition of wholesale distribution.

404  
405 Mr. Dix stated one thing about the compounding rule is it puts some ownership on the  
406 pharmacist actually doing the compounding to do some due diligence to make sure they  
407 are not compounding an amount outside the normal course of what that physician office  
408 receives and uses. It puts the ownership on the pharmacist and the pharmacy.

409  
410 Mr. Dixon stated some of the concerns he has received is it makes the pharmacist  
411 reluctant to compound for office use because they fear of the DDC program will  
412 charge them with manufacturing or distributing commercially available drugs and this  
413 would subject them to a large fine or risk shutting down their pharmacy.

414  
415 Mr. Brecko asked what is distinction between the two licenses retail and retail wholesale  
416 licenses? Is it where they can sell a minimum amount of product wholesale where they  
417 keep the inventory separate?

418  
419 Mr. Dixon said he didn't know if we are talking about licensing as much as what  
420 pharmacists are allowed to do when their practice of pharmacy moves from  
421 compounding limited amounts of drugs for specific patients to be administered verses  
422 compounding large amounts of drugs and providing those at a discounted rate for a  
423 physicians office for use at the doctors discretion. It's a fine line and could be difficult as  
424 regulators to try and enforce that. Mr. Dixon notes that if it's difficult for the regulators it's  
425 difficult for the pharmacist.

426  
427 Mr. Brock stated from a historical perspective the compounding rule only allowed  
428 pharmacists to compound medicines based on a specific order for a specific patient but  
429 a change happened to allow lead way to make a certain amount in advance knowing  
430 they were going to sell a certain amount.

431 If the pharmacy has a doctor's practice that normally prescribes 25 prescriptions of one  
432 compounded drug. Because they can anticipate those prescriptions are coming, there  
433 is a rational basis to allow the compounding pharmacist some lead time to be able to  
434 compound not for a specific prescription, but for one they knew was coming or  
435 anticipated.

436

437 Mr. Garcia stated that a proposed change will allow that or exempt or try and help  
438 define and separate.

439  
440 Mr. Cacciatore stated he did not think the council had enough information to make a  
441 recommendation to propose a change at this time. Mr. Cacciatore suggested this topic  
442 be tabled until the next meeting and said he would look into this.

443  
444 Mr. Dixon asked is there anything the Department can do to help assist?.

445  
446 Mr. Cacciatore asked for the BOP rules on compounding. Mr. Barnes asked for a copy  
447 also of the BOP rules.

448  
449 Mr. Dixon said the department could reach out to the people that made this suggestion  
450 and provide the council with examples to put it in context for the council.

451  
452 Mr. Brock stated perhaps the Board of Pharmacy wants to bring forth a specific  
453 recommendation back to the council if that would be appropriate.

454  
455 Mr. Ayotte stated he believed it's a board of pharmacy issue.

456  
457 Mr. Garcia stated that he thinks as an advisory council that we are looking after the  
458 wholesale piece of it. This is a very heated topic for the board for legislation and there  
459 are very strong feelings out there on this issue. From the advisory council we could say  
460 there are some definition issues out there and do we feel comfortable from the  
461 wholesale perspective to be able to say is this and whether an exemption is needed or  
462 not. The question for the council should not be whether a pharmacist can compound or  
463 not. This puts it as a different question.

464  
465 Mr. Cacciatore asked if there were any other comments hearing none Mr. Dixon  
466 continued.

467  
468 **Renewal Form**

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

471  
472 This would prevent industry from having to submit personal information statements and  
473 background checks with each renewal. How can the Department make it easier on the  
474 industry? The Department is in the process of putting as many of these applications on  
475 line as possible.

476  
477 Mr. Cacciatore stated that his company has at least 27 licenses in Florida so Cardinal  
478 Health was glad to see this. Mr. Cacciatore explained that he did not want to eliminate  
479 some of these requirements because as an industry we need to protect the supply  
480 chain, but believes the requirements have gone too far with renewals when industry

481 needs to supply a copy of the lease for a facility that has been in the same place for 20  
482 years or a personal statement for corporate officers when nothing has changed since  
483 the last renewal.

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

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

488  
489 Mr. Brock stated if there are any significant changes then information should be  
490 resubmitted, but if there are no changes industry should not have to submit all those  
491 documents again.

492  
493 **Motion by Mr. Brock, and seconded by Mr. Brecko that the council supports and will**  
494 **work with the Department on developing a short form license renewal and determining**  
495 **the best way to accomplish this through rule and/or legislative changes. Motion Carried.**  
496

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

499  
500 Mr. Dixon stated he could get a record of how long each of them has been licensed.

501  
502 **Authentication of Pedigree**

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

509  
510 Mr. Dixon stated if the council could provide some suggestions, he could reach out to  
511 the industry and let them know the council is considering the suggestions. The  
512 Department could ask the industry to give alternatives that would work but not get rid of  
513 the authentication piece all together.

514  
515 Mr. Cacciatore stated that the authentication rules are complicated and he personally  
516 doesn't understand them. Mr. Cacciatore suggested that the council needs to  
517 understand the rule and review it at the next meeting and have it explained in detail. .

518  
519 After discussion on the authentication process Mr. Ellis stated he has a good  
520 understanding of this and he would be happy to give overview of authentication process  
521 to the council in February.

522  
523 Mr. Cacciatore recognized Dan Bellingham from HDMA.  
524

525 Mr. Bellingham stated that his organization gave a presentation to the council about a  
526 year ago on this issue. They would be happy to do that again if the council would like.  
527

528 Mr. Brock stated he wishes the council could have a workshop to further address this for  
529 improvement. Mr. Brock cautioned that the council needs to be very careful not to move  
530 backwards because of all the hard work that has been done in Florida.  
531

532 Mr. Cacciatore stated this should be a standard agenda item and be discussed for  
533 possible legislative changes for next year.  
534

535 Mr. Dixon suggested that from this meeting the Department is going to pull information  
536 together for the council and suggested it would be good for the Department to send it to  
537 the chair for review and let the chair and Department decide what topics to put on the  
538 agenda. If it is determines that one topic would take up a considerable amount of time,  
539 it is possible that only one or two topics will be placed on the agenda for that meeting.  
540

541 The council agreed to this suggestion.  
542

#### 543 **Common Control**

544 Mr. Dixon stated the next suggestion is dealing with retail pharmacies under common  
545 control. Is there a way to give some relief to those retail pharmacies under common  
546 control to allow them to transfer drugs from one store to another. This currently requires  
547 a retail pharmacy wholesale distributor's permit. This is coming to the council for  
548 consideration and guidance.  
549

550 Mr. Brecko asked if these are small chains or large chains.  
551

552 Mr. Garcia stated there are so many definitions out there for chains. He suggested  
553 looking at common ownership rather than trying to define a chain..  
554

555 After discussion between the council, there was a  
556

557 **Motion by Mr. Ayotte** suggesting the Department look at the common control  
558 suggestions that were provided to the Department and that have been discussed today,  
559 seconded by Mr. Garcia.  
560

561 Mr. Ayotte stated he would amend his motion to allow the Department to come up with  
562 the terminology that best suits this. Motion carried  
563

564 Mr. Mahoney asked what is the difference between control and ownership? Mr.  
565 Mahoney stated he has seen a proliferation of loose affiliations as part of a group. He  
566 was not sure if they are just friends or there is cross ownership especially with stock  
567 transfers going on as transactions.  
568

569 Mr. Dixon stated he believes common control includes ownership. Mr. Dixon didn't  
570 know if ownership was the issue. He stated  
571 common control is broader than ownership. He didn't believe you have to have  
572 ownership to have common control.

573  
574 Mr. Mahoney suggested you could have five different pharmacies and different  
575 ownership at each one, but they seem to embrace the same policies and procedures. Is  
576 that common control?

577 This takes on characteristics like a buying group.

578  
579 Mr. Cacciatore stated this is just a recommendation from the council, the Department  
580 may not support the recommendation but the council is giving them some direction.

581  
582 Mr. Dixon stated the last suggestion is more housekeeping to transfer Chapter 499 to  
583 the Department of Business and Professional Regulations. This may be part of a  
584 revised bill that goes through and he just wanted to make the council aware of it.

585  
586 Mr. Ayotte reminded the council if PDUFA passes with some pedigree provisions, it  
587 certainly would be good to align it with Florida law.

588  
589 Mr. Cacciatore stated that we have taken a position on that already on a previous  
590 conference call.

591  
592 Mr. Cacciatore stated the next agenda item is Ms. Grosh.

593  
594 **TAB 4 Controlled Substance Reporting**

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

597  
598 Mr. Brecko stated he attended the workshop for the E-FORCSE conference. They had  
599 at least four doctors concerned about doctor shopping from patients. They were looking  
600 for a mechanism to be notified themselves when this occurs.

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

608  
609 Mr. Cacciatore stated he wanted to clarify that you have the PDMP program which is  
610 separately tracked with Becki Poston and the Department of Health.

611

612 Mr. Cacciatore stated the CSR is for wholesalers. The wholesalers have asked DEA for  
613 years to share the information on what is being reported and they have denied that  
614 request. Now that the Department will be collecting that information, they may get the  
615 same request.

616  
617 Mr. Ayotte asked what is it that wholesalers want to know, the amount they buy in  
618 quantities or just that they are buying it from different people.

619  
620 Mr. Brecko stated that he spoke to Ms. Poston about this and it would be a good idea to  
621 know both.

622  
623 Ms. Grosh stated that the Department is looking at running reports and looking at  
624 making the electronic process a little easier for the mom and pop places that don't do a  
625 large volume. There have been suggestions from Department of Health to allow FTP  
626 process from some of the larger distributors. These are some of the processes the  
627 Department is looking at for later.

628  
629 Mr. Brecko stated if they can do it for doctors I think we need to look at it.

630  
631 **Motion by Mr. Brecko asking Mr. Dixon to get a legal opinion from the general**  
632 **counsel's office on what information from the Controlled Substance Reporting system**  
633 **can be shared with the industry on what is being reported. Seconded by Mr. Barnes.**  
634 **Motion passed**

635  
636 Mr. Brecko stated if community pharmacies are purchasing from multiple distributors,  
637 the industry would like to know this.

638  
639 Mr. Dixon presented a certificate to Ms. Grosh for her assistance with the controlled  
640 substance reporting website.

641  
642  
643 **TAB 5: 2012 Meeting Date**

644  
645 Ms. Skrnich informed the council there was one change to the schedule that the  
646 December meeting was previously set for a Friday and was changed to Thursday.

647  
648 Mr. Cacciatore stated he wanted to remind everyone that we operate under the  
649 Sunshine laws. Council members cannot discuss topics amongst themselves. People  
650 can come to council members for discussion.

651  
652 Mr. Dixon stated if someone came to a council member with suggestions and if a  
653 council member wanted the information to go out to the council, those suggestions  
654 should be forwarded to him or to Dinah Skrnich and the information will be sent out.  
655 Please send any such information to Dinah Skrnich with a copy to Mr. Dixon.

656  
657  
658  
659  
660  
661  
662  
663  
664  
665  
666  
667  
668  
669  
670  
671  
672  
673  
674  
675  
676  
677  
678  
679  
680  
681  
682  
683  
684  
685  
686  
687  
688  
689  
690  
691  
692  
693  
694  
695  
696  
697  
698

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.



699 Mr. Cacciatore stated he was sure it was 90 days and this allows wholesalers to  
700 redistribute that product without a full pedigree showing the initial sale and return  
701

702 Mr. Ayotte stated he thought it would be helpful for the council to know what the council  
703 has voted on the past year and revisit those again and refresh ourselves.  
704

705 Mr. Cacciatore stated he I thought that was a very good idea and asked the Department  
706 to go back and capture those motions from the past year.  
707

708 **Audience Discussion**

709 Mr. Billingham asked the council about the criminal background discussion. More  
710 specifically geared to manufacturers or wholesalers that they cannot distribute to  
711 anyone that has failed a background check from the bill 7095. This has been an issue  
712 for wholesalers coming out of that bill.  
713

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

720 Mr. Cacciatore said this language can be included on the return language.  
721

722 Mr. Cacciatore asked if there was any further business or audience questions.  
723

724 Hearing none, the meeting was adjourned.  
725  
726  
727  
728  
729  
730  
731