

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43

Drug Wholesale Distributor Advisory Council Meeting
August 16, 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. Ayotte, Mr. Brecko, Mr. Ellis, Mr. Mahoney, Mr. Barnes, Ms. Zeiler.

The following council members were absent: Mr. Garcia, Mr. Brock

A quorum was present:

Tab 1: Approval of May 17, 2012 Meeting Minutes

Motion by: Mr. Mahoney and seconded by Mr. Barnes to approve the minutes. Motion Carried.

Tab 2: Chair's Report- Mr. Gary Cacciatore

1. Federal Pedigree –

Mr. Ayotte gave a brief report on this item regarding Prescription Drug User Fee Act. No action was needed.

Mr. Barnes asked when will the California serialization go into effect.

Mr. Cacciatore stated the dates are 2015 for Manufacturer, 2016 for Wholesaler and 2017 for Pharmacies.

TAB 3: Controlled Substance Reporting – Kristen Grosch

Ms. Grosch informed the council that the reporting has increased for the controlled substance reporting from 18% to 24%.

The department will soon begin testing the FTP process. We will be working with one of the distributors to test the process.

Mr. Dixon informed the council that the department will begin the enforcement of this in the near future.

44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
61
62
63
64
65
66
67
68
69
70
71
72
73
74
75
76
77
78
79
80
81
82
83
84
85
86
87

TAB 4: Executive Director Report- Reginald Dixon

1. 61N-1.011 Wholesale Distribution of Prescription Drugs. Exceptions

Mr. Dixon stated there was a question from the last meeting about this rule and the emergency medical reasons. After speaking with the Department of Health there was previous history on this rule promulgation that had been started at the Department of Health. There was an error when the rule went through the process and the word “or” was omitted from the published language. The Department can have this corrected by stating a technical error had occurred.

This rule does not apply if a distribution center is out of commission from an emergency such as a fire of the facility. The company needs to have a business continuity plan in place.

2. Borrow and Loan

Mr. Dixon stated there was a question at the last meeting about borrow and loan of prescription drugs from a hospital setting. After further research and discussion with different individuals the Department has come to the conclusion that the terminology of borrow and loan is outdated.

Mr. Dixon stated the Department will be working with the associations and industry on creating new terminology for this process. Mr. Barnes and Mr. McQuone will work with the Department on providing language for this process.

Mr. McQuone will provide the Department with a copy of the language once it is drafted.

Mr. Dixon stated that we will be educating our inspectors on this issue. The Department will be reviewing any cases that come in from the inspectors on a case by case basis for compliance.

3. 2013 Legislative Proposals

Mr. Dixon gave a brief over-view of the 2013 Legislative suggestions from the industry.

Mr. Dixon explained how the process works for the department.

Mr. Barnes stated there was previous discussion on repackager and the Department stated it would require a legislative change. I would like to add this to the legislative list.

Mr. Cacciatore stated to clarify the legislative fix that is required for that is it basically creating an out of state repackager permit.

88 Mr. Barnes stated that is one of them and the other is ownership when product is
89 transferred from the wholesaler to the repackager who actually owns it at that point of
90 time.

91
92 Mr. Jernigan stated there is an existing exemption from the definition of wholesale
93 distribution for an out and back transaction from a hospital or health care provider to a
94 repackager for that purpose. The problem is the existing statutory language contains the
95 word "return" and that implies it has to come to the hospital first. The question has been
96 can the hospital purchase drugs have them drop shipped to the repackager and then
97 shipped to the hospital.

98
99 That one word is creating a certain amount of inefficiency in handling and shipping
100 cost. You have to pay to ship the drugs to repackager from the hospital now. There are
101 existing exemptions that allow for the type of result that you're looking for with those
102 dollars. To have the drugs repackaged or if the health care system is large enough to
103 self repackage.

104
105 Mr. Cacciatore stated that if this is part of the Department's legislative package the
106 council could make a recommendation to support this.

107
108 Mr. Cacciatore stated that he had some comments from the audience that not all the
109 suggestions sent from the industry are on the list.

110
111 Mr. Dixon stated that the Department will go through and update the list and make it
112 available on the web-page.

113
114 Steve Miller of Air Liquide USA asked is there a formal decision making process of what
115 will be approved to move forward through legislation?

116
117 Mr. Dixon stated the Secretary will get with each Division Director and discuss the
118 recommendations for the legislative changes. The Secretary will go through and
119 prioritize the division's legislative proposals. He reviews what would be beneficial for
120 business and beneficial for regulatory activities

121
122 Mr. Dixon stated one of the issues with medical gas is most of the requirements we
123 have are in place based on the federal guidelines. We don't have an option of making
124 a statutory change that falls below the federal guideline.

125
126 Mr. Ayotte asked when will the Department have the legislative packet available.

127
128 Mr. Dixon stated by the end of September.

129
130
131

132 **4. Blood Establishment**

133
134 Mr. Dixon gave a briefing on the Restricted Prescription Drug Distributor permit for
135 Blood Establishments.

136
137 Mr. Dixon stated the Department will be working on rulemaking for 61N-1.023 to include
138 this new permit. The Department will open the rule and work with the Blood
139 Establishments on what specific drugs fit the category of the language then bring it back
140 to the council for review.

141
142 Mr. Dixon stated we may schedule a conference call just to discuss this issue.

143
144 **5. Centralized Repackaging**

145
146 Mr. Dixon stated Florida Statutes 499.01 subsection 5 was recently amended. It allows
147 restricted permit holders who have a health care entity permit to repackage and
148 distribute prescription drugs to other health care entities under common ownership.
149 There was a question on how is the Department going to administer this.

150
151 Part of the new statute is you notify the department 30 days before you start this new
152 practice.

153
154 The Department may need to perform an inspection of your facility. Then we update
155 your license with a modifier that has you performing repackaging.

156
157 When we do perform an inspection we will be treating you like a repackager. They will
158 look to make sure you have policy and procedures and security requirements.

159
160 **TAB 5: Other Business**

161
162 **Cancer Drug Donation Program**

163 Ms. Skrnich thanked Mr. McQuone of the Florida Society of Health System Pharmacist
164 for allowing the program to participate in their meeting.

165
166 Ms. Skrnich gave a review of the program and asked that the council keep the program
167 in mind when they are destroying drugs and donate them to one of the participating
168 hospitals.

169
170 **Proposed Meeting Dates for 2013**

171 Mr. Dixon stated these are proposed dates for the 2013 calendar year.

172
173 Mr. Cacciatore stated that the council had discussed having two face to face meetings.
174 Change it from February 14, 2012 to February 12, 2012. The council agreed.
175

176 Mr. Barnes stated at the last meeting we had talked about Senate Bill 517. Contract
177 pharmacies being able to contract with covered entities. Is this transaction going to
178 require a pedigree? Has there been any discussion on this.
179

180 Mr. Jernigan stated the wholesaler would provide a pedigree. The bill to ship to the
181 covered entity to the extent that you want to provide the drugs yourself as opposed to
182 having them dropped shipped. You can get a Restricted Government entity permit if you
183 have that permit the activities under that permit are and exception to the definition of
184 wholesale distribution. If it's not a wholesale distribution you don't have to pass a
185 pedigree.
186

187 The covered entity can get a Restricted Prescription drug distributor permit for
188 Government programs. It's a special type of permit for 340B covered entities. That
189 means you can take you're inventory that you receive purchased 340B drugs and
190 transfer them to contract pharmacies. You can also have the drugs in a different
191 licensing scenario dropped shipped from the source to the contracted entities.
192 The wholesaler is required to provide the pedigree to the recipient of the drugs. In the
193 second example that's not your hospital that's the contracted pharmacy. They will be
194 passing a pedigree to the recipient of the drugs.
195

196 Mr. Barnes stated that if we wanted to contact with pharmacies I need to get this permit.
197

198 Mr. Jernigan stated you don't have to if you are serving 340B patients out of your
199 hospital directly then you are not going to be operating solely on the drop shipment
200 supply to your contract pharmacy. You can get the permit that would allow you to send
201 the drugs to the contract pharmacy.
202

203 Mr. Cacciatore stated that would allow you to send drugs from your hospital to the
204 contracted pharmacy without pedigree because it's not a wholesale transaction.
205

206 Mr. Barnes stated the way it works is it's actually a replacement of inventory of
207 something that has been used on my patients.
208

209 Mr. Jernigan stated the legislature changed this in the spring to allow for the virtual
210 inventory system that you're describing. You use to keep it separate but you don't have
211 to do that anymore.
212

213 Mr. Cacciatore stated hearing none a motion to adjourn.
214

215 Motion by: Mr. Barnes seconded by Mr. Mahoney. Meeting was adjourned.
216
217
218
219