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**STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY AND
ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS,
BUSINESS & PROFESSIONAL LICENSING**

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**BOARD OF PHARMACY
MINUTES OF MEETING
May 21-22, 2015**

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By authority of AS 08.01.070(2) and in compliance with the provisions of Article 6 of AS 44.62, a scheduled meeting of the Board of Pharmacy was held May 21-22, 2015, at the Atwood Building 550 W. 7th, Suite 1270, Anchorage Alaska.

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These minutes were prepared by the staff of the Division of Corporations,
Business and Professional Licensing.

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The meeting was called to order by Chair, John Cotter at 9:04 a.m.

25
26

Call to Order/Roll Call

27
28

Board Members Present constituting a quorum:

29
30
31
32

John Cotter RPh, Fairbanks - Chair
Lori DeVito RPh, Soldotna - Vice Chair
Anne Gruening, Public Member, Juneau - Secretary
CJ Kim, RPh, Anchorage
Bill Altland RPh, Craig
Leif Holm, Pharm.D, North Pole
Taryl Giessel, Public Member, Eagle River

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35

Attending from the Division of Corporations, Business and Professional Licensing were:

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44

Donna Bellino, Licensing Examiner – Juneau
Sara Chambers, Professional Licensing Operations Manager – Juneau
(via telephone)
Martha Hewlett, Administrative Officer – Juneau (via telephone)
Angela Birt, Chief Investigator - Anchorage
Brian Howes, Investigator – Anchorage
Ed Riefle, Sr. Investigator, Anchorage
Al Kennedy, Sr. Investigator, Anchorage

45

Visitors Present –

46

Richard Holt – Walmart

47 Molly Gray, Executive Director for the AK Pharmacist Assoc.
48 Sergio Vie, National Accounts Manager for Rare Disease Therapeutics,
49 Inc., Scottsdale, AZ.
50

51 **Agenda Item 1- Review Agenda**

52
53 The board reviewed the agenda for Thursday May 21, 2015.
54

55 **On a motion duly made by Ms. DeVito, seconded by Mr. Kim and approved**
56 **unanimously, it was**

57
58 **RESOLVED to approve the agenda for Thursday May 21, 2015.**
59

60 **Agenda Item 2- Review/Adopt Meeting Minutes**

61
62 The Board reviewed the minutes from the February 25 - 27, 2015 meeting.
63

64 **On a motion duly made by Ms. DeVito, seconded by Ms. Gruening and**
65 **approved unanimously, it was**

66
67 **RESOLVED to approve the minutes from the February 25 - 27, 2015**
68 **meeting.**
69

70 **Agenda Item 3- Ethics**

71
72 Mr. Cotter called for any ethics disclosures to be made. No ethics violations to
73 report by board or staff.
74

75 Mr. Cotter stated that the Board was ahead of schedule for the Investigative Report
76 and reviewed an email that Ms. Bellino brought with her that Sara Chambers
77 received from Naturopath Emily Kane.
78

79 Ms. Kane requested input from Ms. Chambers on whether Glutathione is considered
80 a drug. Ms. Kane does not believe it is, however, and would like to have it
81 compounded by a pharmacy in Juneau. Ms. Chambers forwarded the email to Ms.
82 Bellino for Board of Pharmacy review and input. Ms. Bellino forwarded the question
83 to board member Leif Holm who owns a compounding pharmacy in the North Pole.
84 Mr. Holm, who consulted the Professional Compounding Centers of America,
85 responded back in email that the implementation of the DQSA (Drug Quality
86 Security Act) that became law in November of 2013 has changed everything.
87 Glutathione in and of itself is not a legend drug, but being as it is compounded, the

88 FDA states that it cannot be compounded without a prescription. If caught by the
89 FDA, would be a major violation. Alaska does not recognize naturopaths with
90 prescriptive authority, so a prescription from one would not qualify under the
91 DQSA. Mr. Holm concluded that since Alaska does not have a specific law against the
92 practice of non-prescription compounds, one could continue the practice, but should
93 be advised if inspected by the FDA, would be a major violation.

94

95 The Board reviewed Ms. Kane's email and Mr. Holm's reply and discussed it. Mr.
96 Cotter then asked if the board had any disagreement on what was said, and the end
97 result was if a pharmacy fills it there has to be a prescription. If a naturopath wrote
98 it then a pharmacy should not fill it. If a prescriber writes the prescription then it
99 could be compounded and filled.

100

101 **Agenda Item 4 - Investigative Report - Investigator Howes**

102

103 Investigator Howes presented the Investigative Report for the period of February
104 12, 2015 through May 6, 2015. Including cases, complaints, and intake matters,
105 since the last report, the Division opened Twenty-Six (26) files and closed twenty-
106 seven (27) Pharmacy Board matters. A total of ten (10) matters remain on-going
107 and under active investigation or are pending litigation.

108

109 The Board thanked Investigator Howes for providing the Investigative Report
110 information prior to the meeting for inclusion in the Board meeting packets.

111

112 Investigator Howes advised he had a matter to discuss with the board and
113 requested to go into executive session.

114

115 **On a motion duly made by Lori DeVito, seconded by Ms. Gruening and**
116 **approved unanimously, it was**

117

118 **RESOLVED to go into executive session in accordance with**
119 **AS44.62.301(c) 3, for the purpose of discussing investigative matters.**

120

121 Board staff to remain

122

123 The Board entered into executive session at 9:20 a.m., and returned from executive
124 session at 10:09 a.m.

125

126

127

128

129 **Agenda Item 5 - Budget REPORT/Division Update**

130

131 Sara Chambers, Professional Licensing Operations Manager for the Division and
132 Martha Hewlett joined the meeting telephonically.

133

134 Ms. Hewlett presented the budget report for FY 15 3rd Quarter. The Board had no
135 issues with information presented to them. Ms. DeVito noted that the budget
136 reflected that the board is in a good position for a non-licensing renewal year and
137 for being three quarters through the year.

138

139 Ms. Chambers then spoke briefly to the board about the current state wide budget.
140 Ms. Chambers was hoping to provide a more comprehensive legislative report for
141 this meeting, but there are still elements of that realm that are unknown. The
142 Division is receiving regular updates from the Administration on information that
143 may be changing, and the latest information Ms. Chambers has been provided is the
144 Division does not expect to incur layoffs due to the fact that we are not funded by
145 the undesignated general fund and are receipt supported. The Division will likely
146 have to share in the reductions in spending authority that all agencies are
147 anticipated to share in. A reduction in authority could potentially hamper how the
148 Division does things and the service levels that we like to deliver to Alaskans, but it
149 is unknown at this time what that will look like and Ms. Chambers will message via
150 email to let the board members know what is anticipated and where the reductions
151 are going to be implemented within the Division.

152

153 Ms. DeVito addressed her concern that with possible reductions impacting the
154 Division, how does the Board proceed addressing the areas where there may be an
155 increase needed to meet necessary standards that are happening at the national
156 level. Ms. DeVito addressed this because the next agenda item is a discussion on
157 implementing a new multi-state inspection form and how Alaska can participate in
158 utilizing this inspection form. Ms. Chambers advised that she would first need to
159 receive some candid information from the Board after the Board completes its
160 discussion and anticipates what is needed. We can only budget with the information
161 we have, and if there is an increase in the need for inspections or a change in that
162 regard then we certainly need to see what that would look like, taking the outcomes
163 that the board hopes to have and transferring into what resources are needed.
164 Ms. Chambers also advised as soon as this information is determined it can be added
165 in to the mix for FY '16 which starts on July 1, 2015. This is a good time for this
166 discussion and the Board identifies its desired outcome to determine what
167 additional resources may be needed including additional financial resources that
168 may need to be allocated. Ms. DeVito advised that she anticipates any changes
169 would happen in steps and not all at once.

170 Ms. Chambers addressed the Board regarding a legislative item that has been
171 simmering with Representative Wilson's office and is the out-of-state Wholesale
172 Drug Distributor bill. Ms. Chambers received a copy of the draft bill even though it
173 was not introduced into a committee. Ms. Chambers wanted to let the Board know
174 that she has seen the bill and appreciates the Boards review and input that was
175 provided to Representative Wilson's office and asked the Board if it has any
176 additional information that would help the Division to plan for resources. Any
177 foreseen increase in clerical work, increase in Examiner and/or Enforcement work
178 would be extremely important because a bill that includes a fiscal note and an
179 increase to those requirements, we need to be asking for the additional staff and
180 authority to accomplish it. If there is someone on the Board who is designated as
181 the legislative liaison please let Ms. Chambers know so that the fiscal note is asking
182 for what the Board truly needs.

183
184 Ms. Chambers addressed the board regarding the passage of SB71 that will now
185 allow pharmacist to administer immunizations without a collaborative plan with a
186 physician. Ms. Chambers advised that she did not foresee any strong impacts on the
187 department, and if that is different to please let her know. The Board briefly
188 discussed possible ways to handle this change and will be reviewing the
189 collaborative plan regulation and determining what changes are necessary and best
190 plan for implementation when they discuss Agenda Item 7 Regulation Review in the
191 afternoon session. The Board will update Ms. Chambers as to what the outcome of
192 that discussion is.

193
194 Ms. Chambers thanked Mr. Holm and the Board for their assistance in addressing
195 the question received from a Naturopath Emily Kane. Sr. Investigator Riefle was
196 included in the Board's discussion and will advise Ms. Chambers of the outcome.
197

198 Ms. Chambers Thanked Ms. Bellino for the great work she has been doing with the
199 Board. Ms. Bellino had not yet had the chance to let the Board of Pharmacy know
200 that she had given her resignation. Ms. Chambers wanted the Board members to
201 know that how much faith and belief that the Division has in their staff members
202 and what a fantastic job Ms. Bellino has done juggling all of the demands of her
203 position. The Division needs to provide more resources and if the out-of-state
204 wholesale drug distributor bill passes and inspections increase, there may be
205 additional impetus to try to overcome the constraints of the current budget climate
206 too be able to meet the needs of the law and to deliver the services that the boards
207 and licensees require. This would allow to get additional help in place for many of
208 the programs that are overloaded and the Pharmacy program is one of them.

209

210 Ms. Giessel asked Ms. Chambers who decides the pay range for the administrative
211 staff. Ms. Chambers advised that all employee job classes are governed by the
212 Department of Administration through the classification section. All employees who
213 work for the State work under a particular job class, and approximately a year and
214 half ago the Division initiated a request to consider reclassification of the Licensing
215 Examiner position. All of the analysis, desk audits, and studies have been completed
216 and it is now in the Department of Administrations hands to look at whether
217 increasing the pay range of the licensing examiners, particularly those examiners
218 that manage boards like Ms. Bellino, is appropriate. The DOA has the final say on
219 that process and they are very aware of many of the boards concerns about
220 adequate compensation for the work that is being asked of the examiner to do as
221 well as the desire to decrease turnover. A few weeks ago, Ms. Chambers asked for a
222 status update of the study, but with the current state budget climate attempting to
223 decrease, it is an unknown if an increase in job classification would move forward,
224 but the Division is doing everything they can to make sure the that the classification
225 section goes into the study with their eyes wide open.

226
227 Ms. Chambers advised the Board the Division has stated openly that Licensing
228 Examiners, particularly Examiners that are managing boards are not compensated
229 nearly what they should be compensated for the complex work that they do. The
230 same work done in many other positions is done at a Range 18 or higher, but
231 Examiners are currently Range 13 employees. Ms. Chambers advised the Division is
232 doing everything they can to move the study forward and is just waiting to hear
233 back on the results of the study. Ms. Giessel asked if there was an opportunity to
234 comment and if there is an email or phone number to send those to. Ms. Chambers
235 advised that she is happy at any to time to accept a letter from the Board Chair for
236 example and send via email to either Ms. Bellino or Ms. Chambers and she would get
237 it to Classification. The Chiropractic board has already written a letter that she has
238 already submitted.

239
240 Lastly, Ms. Chambers spoke to the Board about another option that the Board has
241 and that would be for the Board to consider requesting an Executive Administrator
242 position. This topic has come up casually in the past, but it is one that various
243 Boards especially more complex boards like pharmacy have wondered how can they
244 add staff, how can they increase the pay range of our staff, how can they ask staff to
245 do more. Right now there may be certain things that the Board would like to ask Ms.
246 Bellino to do but can't because of union constraints. This is an opportunity to
247 pursue via statute an Executive Administrator position. The Public Accountancy
248 Board did this a few years ago and moved from a half time examiner position to a
249 full-time Executive Administrator. That could mean that the fees would likely

250 increase dramatically due to it being a more robust position, but this may be
251 something the Board would like to consider.

252
253 Mr. Cotter asked going back to reclassifying the Examiner position versus the
254 Executive Administrator which one of those two had the highest degree of success.
255 Ms. Chambers advised either one is a complex process. The classification section has
256 to look at all of the Occupational Licensing Examiner positions within the State. Our
257 Division has most of them, but there are some Examiner positions outside the
258 Division and they have to make a decision based on the varying levels of
259 responsibilities and complexity within the positions and Ms. Bellino's position is
260 considered on the high end on the demand level. It is hard to say what there
261 outcome will be and if it will affect all Examiners, some Examiners, no Examiners.
262 With a reclassification there is always a risk in opening it up that they could
263 reclassify the position down, highly unlikely in this case, but a possibility. Going
264 through legislation is like any piece of legislation and again in this budget climate
265 saying you would like an Executive Administrator may not get much traction,
266 however since you are advocating for the regulation of a whole new complex area as
267 the result of Federal implementation of compounding legislation and also seeing the
268 need for inspections it may be more likely to go through. From her vantage point
269 Ms. Chambers stated that the pharmacy program is more complex than at least one
270 or two other programs that already have an Administrator and is not a difficult
271 process to lift that language from any of the other six programs that have an
272 Executive Administrator. Tacking this request on the out-of-state wholesale drug
273 distributor bill is an option since that is already moving forward and not
274 unreasonable to be the impetus to be tipping point for this.
275 Ms. Chambers can't personally or professionally be an advocate for or against any
276 strategy pursued legislatively, but wanted the Board to know what options are
277 available to make an educated decision as a Board to pursue the legislation that is
278 appropriate.

279

280 **Break:**

281 Off the record at 10:46. a.m.

282 On the record at 11:00 a.m.

283

284 **Agenda Item 6 - In-State/Out-of-State Inspections**

285

286 Funding and other challenges to participate in Multi-State inspection form in
287 development with NABP

288

289 Chief Investigator Birt and Sr. Investigator Ed Riefle joined the meeting to discuss
290 this subject that was led by Ms. DeVito. Chief Birt and Sr. Investigator Riefle were

291 invited to the meeting to assist the board in how to move forward given the current
292 state budget situation. Ms. DeVito attended a meeting in January that NABP
293 sponsored to develop a unified inspection report so all the states can have some
294 continuity. The primary focus of the inspection report was sterile compounding due
295 to the new federal law that was put into effect in November of 2013 as a result of the
296 New England Compounding incident, but there also is a tie to wholesale drug
297 distributors and all of the other aspects of pharmacy as well, and thus a blueprint
298 was created. The end goal is to have states work hand in hand with this unified
299 inspection report.

300

301 Ms. DeVito's concern is where Alaska is as a state, and believes our state is in the
302 bottom 2% of the country on this and Ms. DeVito's fear is Alaska not being able to
303 become compliant with the federal requirements for inspections and in particular
304 for out-of-state pharmacies coming into Alaska. Ms. DeVito did advise that even
305 with money being a problem there are some things that can be done through
306 regulation change and identifying what inspection reports submitted from out-of-
307 state pharmacies that would be acceptable. There are a lot of out-of-state
308 pharmacies and in particular compounding/sterile compounding pharmacies that
309 now only use VPP inspections through NABP. Per Ms. DeVito, the bottom line is we
310 have to do something and determine what is an expeditious way to get there.

311

312 Chief Birt advised that in the interim the Board could post an advisory opinion on
313 the Boards website telling the field where they plan to go. This opinion would state
314 what the Board intends to achieve through regulation and will set the conditions for
315 people to understand where the Board is headed and they can be in compliance and
316 not off in another direction and potentially have to make major changes. The
317 Medical and Dental Boards use advisory opinions to let their respective fields know
318 that are they are working on something that is not codified in law yet, but this is the
319 direction they are going so they can begin to head in that direction. This will help
320 while working on changes through the regulations process. Investigations cannot
321 enforce what is not written as law. Chief Birt stated this is a good first step and
322 suggested some of the Board members get together to work on a draft opinion first,
323 and then review/approve with entire Board before posting to the website. Also
324 determine the best way to bring people's attention to it and that it is important.

325

326 The Board will work on a statement of intent of what the Board would like to
327 achieve in changing inspection standards and send it to the Attorney General's office
328 and have them provide the language on how to work into statute or regulation. If
329 the Board advises what is needed to be done and why, they should be able to offer
330 the best way to proceed.

331

332 Once that clarification is received the Board will then work on a draft advisory
333 opinion detailing what the Board of Pharmacy and the State are moving towards for
334 both in-state and out-of-state pharmacy inspections.

335

336 **Lunch:**

337 Off the record at 11:59 a.m.

338 Back on the record at 1:10 p.m.

339

340 **Agenda Item 7 – Sergio Vie, National Accounts Manager w/Rare Disease**
341 **Therapeutics in Scotsdale, AZ.**

342

343 The purpose Mr. Vie addressed the Board was to seek clarification from the Board
344 of Pharmacy regarding some questions that have come up recently about Alaska's
345 compounding laws. Rare Disease Therapeutics is a small family owned
346 pharmaceutical company that is dedicated to rare diseases and orphaned drugs. In
347 his capacity as National Accounts Manager, Mr. Vie often can act as a partner and/or
348 advisor to some of his customers, and per Mr. Vie currently there are pharmacists in
349 Alaska that are being asked to violate some FDA regulations which can jeopardize
350 public health and put that pharmacist at risk. The objective of this discussion with
351 the Board is to understand the current compounding regulations in Alaska so he can
352 appropriately advise his customers how to comply with Alaska and federal
353 compounding regulations.

354

355 Last year Rare Disease Therapeutics received FDA approval for a drug that treats
356 Acute Lymphoblastic Leukemia which is the most common childhood leukemia in
357 the United States. The FDA thought that this drug Purizan was such an unmet
358 medical need that it was fast tracked through the FDA approval process two and
359 half months ahead of schedule.

360

361 Last summer the FDA issued guidance on compounding human drugs under section
362 503A of the FD&C Act. Of particular concern to this meeting, this guidance states
363 that the licensed pharmacist or licensed physician does not compound regularly
364 inordinate amounts of any drugs or that are essentially copies of commercially
365 available drugs. Basically the FDA does not want compounding done of a
366 commercially available product, if it's done regularly, in inordinate amounts, or
367 essentially a copy of an approved drug. The ideal situation would be for state and
368 FDA regulations to synch up to avoid any confusion, liability, and to protect the
369 public health.

370

371 The pharmacist's that Mr. Vie is currently working with are being told by the
372 insurance companies to try and compound first and if that fails then they will work
373 on approval/authorization of Purizan.

374

375 So Mr. Vie's question to the Board is; what is the Board's stance on compounding an
376 FDA commercially available drug when being told by insurance companies to try it
377 first, which is in direct violation of section 503A of the FD&C Act.

378

379 Mr. Holm who is a compounding pharmacist advised Mr. Vie that he has not
380 experienced insurance companies advising to try the compounded version first, but
381 has not been asked to compound this type drug. Mr. Holm also stated that he as a
382 compounder does not compound anything that is commercially available and
383 strictly follows FDA compounding guidelines. Ms. DeVito enforced the same
384 sentiment. The Board understood the very small group this type of drug will help,
385 but when asked would you compound it or use the commercially available drug
386 legally a pharmacist would have to use the commercially available drug. It isn't
387 about making the product it is the cost difference of product and educating the
388 insurance companies to cover the expense of this new drug. The rules are the rules
389 and a pharmacist in Alaska cannot compound this drug. Bottom line, follow FDA
390 guidance and regulations.

391

392 The Board decided to first review correspondence before addressing regulations.

393

394 **Agenda Item 9 - Correspondence**

395

396 The Board reviewed correspondence and NABP Correspondence. Included an email
397 from Lana Bell, Chief Pharmacist/ Pioneer Homes Pharmacy seeking clarification on
398 what constitutes a legal signature on an order sent electronically from the
399 prescriber to the pharmacy's fax. The two regulations cited **12 AAC 52.460(10)** the
400 regulation states – "if a facsimile prescription drug order, the prescribing
401 practitioner's signature, or authorized agent's signature". **12 AAC 52.490** the
402 regulation states "A pharmacist may dispense a prescription transmitted
403 electronically under this section if the prescribing practitioner includes the
404 following information on the prescription before it is transmitted: (2) electronic
405 signature or manual signature of the prescribing practitioner". Their pharmacy has
406 run into a situation where a nurse electronically signed a prescription drug order
407 for the provider (using her credentials, not the providers), then electronically
408 submitted the order to the pharmacy fax.

409

410 Board consensus on interpretation is that the authorized agent's name has to be in
411 conjunction with the physician/prescribers name. The Board will also post

412 clarification as a fact or advisory on the website and Mr. Holm would like to change
413 the regulation to better clarify its intent.

414

415 **Agenda Item 8 – Regulation Review**

416

417 SB71 “An Act relating to the practice of pharmacy; and relating to the administration
418 of vaccines and related emergency medications.” Now that this is law the Board
419 must develop new standards for the independent administration by a pharmacist of
420 vaccines and related emergency medications under **AS 08.80.168** including the
421 completion of an immunization training program approved by the board.

422

423 The Board discussed various ways to accomplish this and if there should also be
424 continuing education requirements for immunizations. Ms. DeVito will look at the
425 four states she is licensed in to see how these other states regulations deal with
426 immunizations that do not require a collaborative plan. Ms. DeVito and Mr. Kim will
427 also look at some other states regulations as well and report back to the Board their
428 findings. This will help to build a template from the aspect for certification
429 requirements, BLS and CE requirements and want to make it part of pharmacy
430 practice and we want to have an easy method to record through the new
431 applications and the renewal process for the CE. Ms. Bellino will also check to see if
432 there is anyway the new database can delineate if a pharmacist is certified to
433 immunize when processing a license whether it’s a new application or at renewal.
434 The Board will review information gathered at the August board meeting.

435

436 **Break**

437 Off the record at 2:38 p.m.

438 On the record at 2: 50 p.m.

439

440 The Board reviewed compounding regulations from other states to determine the
441 best way to proceed in writing more detailed compounding regulations. Mr. Cotter
442 looked at Arizona’s and Texas’s compounding regulations for guidance. This change
443 is necessary as a result of the passage of the DQSA in November 2013. More
444 detailed compounding regulations would also assist in participation and use of a
445 Multi-state inspection form. Mr. Holm shared his concern that adding more
446 regulations could be potentially cost prohibitive for the small compounding
447 pharmacies. Mr. Cotter chose the two states that he did because one of the states
448 was way too cumbersome and the other state was more concise in mapping out
449 necessary compounding requirements without being onerous to the professionals.
450 Mr. Cotter will work with Ms. DeVito to whittle down what is presented in these
451 other states regulations and present the outcome at the August Board meeting.

452

453 **Agenda Item10 – Application Review/Approval**

454

455 The Board reviewed applications that Ms. Bellino presented to the Board for
456 approval, but upon completion it was decided due to the late hour to read the
457 disposition of the applications into the record at the start of Friday's meeting.

458

459 Ms. Giessel had to leave the meeting early and left at 4:00 p.m.

460

461 **On a motion duly made by Ms. DeVito, seconded by Mr. Kim and approved**
462 **unanimously, it was**

463

464 **RESOLVED to recess the meeting to 9:00 a.m. on Friday 5/22/15.**

465

466 Off the record at 5:02 p.m.

467

468 **Friday May 22, 2015**

469

470 The meeting was called to order by John Cotter, Board Chair, at 9:10 a.m.

471

472 **Call to Order/Roll Call**

473

474 Those present, constituting a quorum of the board, were:

475

476 John Cotter RPh, Fairbanks - Chairman
477 Lori DeVito RPh, Soldotna - Vice Chairman
478 Anne Gruening Public Member, Juneau – Secretary
479 CJ Kim RPh, Anchorage
480 Leif Holm Pharm D, North Pole
481 Bill Altland RPh, Craig
482 Taryl Giessel Public Member, Eagle River

483

484 In attendance from the Division of Corporations, Business & Professional
485 Licensing, Department of Commerce, Community and Economic
486 Development were:

487

488 Donna Bellino, Licensing Examiner – Juneau
489 Brian Howes, Investigator - Anchorage

490

491

492

493

494 **Agenda Item 1 Review Agenda -**

495

496 The board reviewed the agenda and began the meeting with the continuation of
497 application review and invited Investigator Howes to join the discussion for options
498 on the best way to proceed with a "yes" answer application that was tabled from the
499 April mail ballot. Some of the board members had questions on this application. Mr.
500 Cotter also advised that Sara Chambers is scheduled to call in at 10:00 to speak with
501 the Board further about pursuing an Executive Administrator position.

502

503 **On a motion duly made by Mr. Cotter, seconded by Mr. Kim and approved**
504 **unanimously, it was**

505

506 **RESOLVED to approve the amended agenda with changes for Friday**
507 **May 22, 2015.**

508

509 **Continuation of Agenda ITEM 10 Application Review/Approval -**

510

511 Investigator Howes prior to the start of the meeting reviewed the "yes" answer
512 pharmacy technician application for Rheanna Hamrick. This application was tabled
513 from the April Mail Ballots. The Board sought Investigator Howes input due to the
514 two DUI's reported with the application. Investigator Howes advised the Board to
515 have Ms. Bellino request a copy of Ms. Hamrick's assessment that was completed as
516 part of her treatment recommended by an Alcohol Safety Action Program (ASAP)
517 through MAT-SU/Anchorage. Investigator Howes believes this would help to
518 determine where she is/was at after this last DUI and if treatment was required.
519 This would also reveal if she is now free and clear and satisfied all requirements.
520 Mr. Cotter commented that a copy of this assessment would be from a year ago and
521 would that make any difference, Mr. Howes felt that it would still be good to know at
522 the time of the event what is in the ASAP assessment. Mr. Cotter also asked if she
523 should get a third DUI would the Board be notified of it. Investigator Howes stated
524 the applicant is required to notify the Board of within 30 days of a conviction. Three
525 DUI's within 10 years is a felony if convicted. Ms. Bellino will request a copy of the
526 assessment from the applicant and will relook at the application at the August
527 meeting.

528

529 Mr. Holm suggested what would be the best way to let licensees know that the
530 failure to the report an incident within 30 days will generate board action. The
531 Board discussed options, put something on the website in the form of an advisory
532 statement, mailing, utilize the association to help with communication, include a
533 statement with the next renewal. Mr. Cotter asked if the pharmacy board could send
534 email notification to all pharmacy licenses and is there a way to go to the BOP

535 website to receive communication from the Board. Investigator Howes advised to
536 look at the Nursing board's website to review what they have in place.

537

538 **On a motion duly made by Ms. DeVito and seconded by Ms. Gruening and**
539 **approved unanimously, it was**

540

541 **RESOLVED to approve the following Applications reviewed for**
542 **approval:**

543

544 **Pharmacists Pending:**

545 Laci Blackburn pending passing MPJE score and VOL from GA

546 Elizabeth Borgmeyer pending NABP Application, passing MPJE score

547 Heidi Brainerd pending passing MPJE score

548 Won Choi pending receipt of passing MPJE/NAPLEX scores and

549 VOL from NY

550 Trevor Embry pending passing MPJE/NAPLEX passing scores and Transcript

551 Christopher Sperry pending VOL from MT and WA

552 Jeffrey Stein pending passing MPJE score and transcript

553 Kellen Wiltbank pending passing MPJE/NAPLEX scores, VOL from OR, WA,

554 Affidavit of Intern Hours

555

556 **In-State Pharmacies:**

557 Foodland Pharmacy

558 Walgreens Pharmacy #16059

559

560 **In-state Wholesale Distributor:**

561 Interior Hardware – Medical Gases

562

563 **Shared Pharmacy Service Applications:**

564 Bartlett Hospital with Medication Review

565 All 23 Safeway Pharmacies with ARX Pharmacy

566

567 **“YES” Answer Applications:**

568 Anita King – Pharmacy Technician

569 Kathleen Brakebush - Pharmacist

570

571 **Collaborative Plan Applications for:**

572

573 Anchorage Neighborhood Health Center Pharmacy

574 • Immunization

575 • Anticoagulation

576 **On a motion duly made by Ms. DeVito, seconded by Ms. Gruening and**
577 **approved unanimously, it was**

578

579 **RESOLVED to table the following previously tabled applications**
580 **for further review pending receipt of requested information:**

581

582 Rheanna Hamrick – Pharmacy Technician, Board request for ASAP/Mat-Su
583 Evaluation

584 RX Unlimited Pharmacy – Out-of-State Pharmacy, Board request for updated
585 information pending California Board of Pharmacy action.

586

587 The next item of discussion was related to applicant, Ron Engberson. Mr. Engberson
588 submitted an application for Reinstatement of A Pharmacist License Lapsed More
589 Than Two Years. Mr. Engberson’s license expired 6/30/2012 and the Board of
590 Pharmacy adopted his license surrender on June 7, 2013. It was decided further
591 discussion would be done in executive session.

592

593 **On a motion duly made by Mr. Cotter, seconded by Ms. DeVito and approved**
594 **unanimously, it was**

595

596 **RESOLVED to go into executive session in accordance with**
597 **AS.44.62.301(c)(2), for the purpose of discussing Mr. Engberson’s**
598 **reinstatement application.**

599

600 Board staff to remain during executive session.

601

602 Off the record at 9:46 a.m.

603 On the record at 9:54 a.m.

604

605 **On a motion duly made by Ms. DeVito, seconded by Mr. Kim, and approved by a**
606 **roll call vote, it was**

607

608 **RESOLVED to deny the reinstatement application of a previously**
609 **surrendered pharmacist license for applicant Ron Engberson. The board**
610 **made its determination based on review of the following:**

611

- 612 • **Reinstatement Application, Ronald H. Engberson**
613 • **Judgement and Order, in Case No. 3AN-12-13617CR, which shows the**
614 **applicant, pleaded guilty to Forgery in the Second Degree, a class C**
615 **felony on March 11, 2013.**

- 616 • **'Surrender of License', Case No. 2012-00301, adopted on June 7, 2013,**
617 **for "possessing, writing, and filling forged prescriptions using the**
618 **prescription pad of a Physician Assistant (PA) located in Idaho and**
619 **dispensing controlled substances for my own use."**
620

621 **12 AAC 52.075 GOOD MORAL CHARACTER.** As used in AS 08.80, "good moral
622 character" includes not having been convicted of a felony or another crime that
623 affects the applicant's ability to practice pharmacy competently and safely.
624

625 **12 AAC 52.920 DISCIPLINARY GUIDELINES.** (a) In addition to acts specified in AS
626 08.80 or elsewhere in this chapter, each of the following constitutes engaging in
627 unprofessional conduct and is a basis for or the imposition of disciplinary sanctions
628 under AS 08.01 075:

629 (15) failing to use reasonable knowledge, skills or judgment in the practice of
630 pharmacy

631 (b) The board will in its discretion, revoke a license if the licensee

632 (3) violates AS 08.261(a) The board may deny a license to an applicant or, after a
633 hearing impose a disciplinary sanction authorized under AS 08.01.075 on a person
634 licensed under this chapter when the board find the applicant or licensee, as
635 applicable, (4) has been convicted of a felony or has been convicted of another crime
636 that affects the applicant's or licensee's ability to practice competently and safely
637

638 **Roll call:** Kim, Yea – Holm, Yea – Altland, Yea – Giessel, Yea – Gruening, Yea –
639 DeVito, Yea – Cotter, Yea – 7 Yeas, 0 Nays – Motion passed.

640

641 Anne Gruening left the room at 9:58 a.m.

642

643 Mr. Cotter then called for Public Comment at 10:00 a.m. and there was none given.

644

645 10:05 a.m. Ms. Gruening came back into room.

646

647 **Agenda Item 2 – Sara Chambers, Professional Licensing Operations Manager**

648

649 Ms. Chambers joined the meeting telephonically to discuss and answer the Boards
650 additional questions about the creation of an Executive Administrator position and
651 budget implications. Mr. Cotter wanted to get Ms. Chambers input on the changes
652 that he sees are happening with pharmacy. Mr. Cotter stated that the Pharmacy
653 program is getting busier and busier with more regulation projects, increase in
654 applicants, and other projects needing to be taken on. Mr. Cotter believes the
655 management component is starting to become overwhelming for the position as
656 currently structured.

657 Ms. Chambers described how the position works with the six programs that
658 currently have an Executive Administrator and reviewed pros, cons, options with
659 the Board. The programs that have EA's are: Nursing, Medical, Real Estate
660 Appraisers, Public Accountancy, AELS (Architects, Engineers and Land Surveyors),
661 and the Board of Marine Pilots. The Board of Marine Pilots position is different than
662 the others because it is also an investigator position. EA positions are partially
663 exempt positions and are not a unionized position. These positions are appointed
664 by the Governor and supervised by Sara. There is a recruitment process that can
665 include the Board. A recommendation of whom the Board would like to hire for the
666 position is forwarded to the Governor's office where the approval to hire is given.
667 This is not a political appointment, just a necessary extra step. The EA position
668 serves at the pleasure of the administration and take a great deal of instruction from
669 the board while still following under Ms. Chambers for direct supervision. The way
670 the EA position is different in the day to day practice from the Examiner position is
671 that the EA is given broad authority to work on any issue that is within the Board's
672 mission. The Board would delegate authority and direct the EA to speak on behalf of
673 the Board, i.e., public education as needed, speak at conferences, work on policy
674 issues. It would be expected that the EA would be an authority on these issues
675 whether that authority was gained from prior experience or could be current job
676 experience. The EA could also attend Federal conferences such as the Board is
677 experiencing within the last few years with the passage of DQSA law and for any
678 issues that could arise in the future. There is more independent work and a higher
679 expectation of policy level involvement. The pay difference between the Examiner
680 position and an Executive Administrator position is pretty dramatic. Currently the
681 Examiner position is a Range 13 and there are various nuances within the State pay
682 system. The longer you are with the State the higher your step is so there are some
683 very well compensated Range 13 Examiners that have been with the State for 10-15
684 years or longer. Executive Administrator positions are a Range 18 - 23 and to give
685 some prospective Ms. Chambers position is a Range 22. This would mean there
686 would be a significant impact to the budget not only due to the increase in salary but
687 the benefits package as well. Ms. DeVito asked Ms. Chambers what kind of an
688 increase it would be between a Range 13 and a Range 18 including benefits. Ms.
689 DeVito is trying to get the lowest amount a change like this would cost. Ms.
690 Chambers advised a reasonable range from Range 13A to a Range 18A would be a
691 difference of approximately \$20,000 including benefits and this would be the lowest
692 range of EA entry position.

693
694 Ms. Chambers also advised the Board that there are two different considerations;
695 one is the complexity of the job, and the other is volume of workload. Not adding
696 new staff, but just reclassifying the Examiner position to an EA would not gain
697 anything in workload, but would put that position on the hook for more policy

698 activity responsibility. If a new position were to be requested to add an EA then the
699 Board would have to work out with the Division what additional time that Examiner
700 would spend to support that position. The Division makes those decisions
701 independently and it's not that the Board's input is not important, but the Division
702 has the final say because Examiner's need to be flexible to cover the positions that
703 are the most critical in the Division. Pharmacy has been pretty insulated from a lot
704 of changes in responsibilities because of the various dynamics and needs to work on
705 certain programs more heavily certain times of the year.

706
707 If an EA position were added we would first have to see how it goes and work
708 together on any legislative or program changes that would be adding
709 responsibilities that would help to educate us as to whether an additional full-time
710 examiner, part-time examiner needed, or someone who flexes during a certain time
711 of the year, cross training other staff. The Division would work closely with the
712 Board and be as flexible as possible. Ms. Chambers then stated that she and Sher
713 Zinn, Records and Licensing Supervisor whom Ms. Bellino reports to are in
714 agreement that right now, there is a need for extra hands on deck as far as Examiner
715 and office assistant help.

716
717 Mr. Cotter asked Ms. Chambers that what he is hearing is that currently there is a
718 full-time position with Ms. Bellino doing the examiner work and she has a half-time
719 position to help get the work done in addition to clerical staff. Ms. Chambers
720 advised that office assistant help supports a variety of licensing programs and the
721 examiner requests office assistant help as they need it, but there is not enough help
722 to go around. The Division from time-time especially in renewals and busy times of
723 the year add an additional part-time examiner to supplement Ms. Bellino's workload
724 and assist to take on some of that workload to keep licenses moving forward. It
725 really comes down to the time of the year and the availability of additional staff to
726 support her workload for the pharmacy program. Mr. Cotter also asked Ms.
727 Chambers in her opinion that in the course of the next year if the Board added an EA
728 and kept a full-time Examiner how much of an increase in FTE cost that would be.
729 Ms. Chambers advised that the estimated cost would be about \$100, 000 because a
730 Range 18A is between \$90-95,000. Mr. Cotter asked with that said what are the
731 budget constraints being that the Board pays for that and is that problematic with
732 the State budget or is it just the fact that it's going to be paid for by the Board and is
733 not an issue. Ms. Chambers advised that the position would have to be added
734 through legislation because there are no additional positions being added anywhere
735 in the State through the administrative process right now. It would have to be
736 legislation that the Board would pursue to request to add to your current chapter,
737 and if that were done the Division would respond with a fiscal note that would show
738 the cost and then be able to speak to the Board's work load, and the need for this

739 position, and could respond in committee to this request. This would be the only
740 way to make this happen in A) the current budget climate and B) likely would be
741 successful because a fiscal note would add new budget authority and we wouldn't
742 have to try to have to scrape that up from somewhere else which we just don't have.

743
744 Ms. DeVito asked if the Board would have to develop a job description for the EA
745 position or if the state has an existing one. Ms. Chambers advised that there are a
746 variety of EA job descriptions and they are all tailored to that specific role. If the
747 Board were to pursue that and it were to be successful then we would work
748 together to identify what the Board would like to see and believes is critical. Copies
749 of the existing EA positions would be provided to the Board and then the Division
750 would take the Boards input and turn it into a position that the Board envisions.

751
752 Ms. DeVito also asked that in the creation of the EA position could the Board have
753 the EA position take on some of the examiner duties to reduce the costs. Ms.
754 Chambers said that currently happens right now with other Boards and provided
755 the examples of the Real Estate Commission that has an EA and a Project Assistant.
756 The Project Assistant is a Range 16 due to some specialized duties and the two of
757 them run the Real Estate commission program. Both positions are engaged in
758 licensing as part of their duties as well as other elements of their jobs. The CPA
759 Executive Administrator runs her program alone and doesn't have an Examiner
760 because the need isn't there for one. The EA can do all of the work just like the
761 Marine Pilot Coordinator position. AELS has an EA position and one examiner
762 position. This is the program Ms. Chambers advised is most like the pharmacy
763 program because they are both busy all the time and we could work an Examiner
764 position to be very flexible and do that all the time in the Division and certainly
765 don't want someone sitting around while other Boards are drowning. Ms. DeVito
766 asked Ms. Chambers about the Nursing Board structure. Ms. Chambers stated that
767 the nursing program represents over one-third of the licensing activity and are by
768 far the biggest licensing program with over 20,000 licensees. The Nursing Board EA
769 has a records and licensing supervisor just for the Board of Nursing, four licensing
770 Examiners, one dedicated office assistant, a Nursing Consultant who is also a
771 registered nurse. There is a lot of policy activity and is a very dynamic program that
772 overlaps with other organizations and agencies within the State. The Nursing Board
773 also has two dedicated investigators and has asked for a third.

774
775 Mr. Cotter asked Ms. Chambers given the current fiscal climate what the likely hood
776 would be to make this happen and if so what the time frame would be. Ms.
777 Chambers responded that she estimated that the only way for this to happen would
778 be through legislation next session and if the Board has a sponsor, if Representative
779 Wilson is going to sponsor the existing bill licensing out-of-state wholesale

780 distributors the easiest thing to do would be to add the request of the EA position to
781 that bill.

782 One other element to this and another tool in the tool box is the potential to fund
783 the EA position through the PDMP project. This is a whole other element that falls
784 under the Board of Pharmacy. Funding the PDMP has gone back and forth and the
785 Board is aware that the State is becoming more and more interested in developing a
786 comprehensive opioid control program and the Division has been engaged in that
787 conversation. The Division has been named in two federal grants to receive funding
788 to fund the current PDMP database with the possibility of adding more funding for
789 staff to be involved in that program. Ms. Chambers and Chief Investigator Birt both
790 envision that role to have more of a programmatic element than enforcement
791 element. The grants are written in such a way to include education and to have a lot
792 of interaction with other agencies. This is all theoretical at this point because the
793 grants are being considered and there has not been any award notice yet, and it is
794 unknown if the State would receive one or both of these grants. If one or both
795 grants are awarded it would be begin in September. Ms. Chambers believes if that
796 happens we could get economically responsibly creative in having that funding and
797 the PDMP program element going under an EA position or something similar and
798 that could help to defray the cost to pharmacy licensees . This could also help to
799 reduce the fiscal note in the out-of-state wholesale bill.

800
801 Mr. Cotter asked Ms. Chambers what happens if the out-of-state wholesale bill does
802 not go through because this bill has not been successful in the last couple of sessions
803 and we would be putting the hopes of this happening on the bill. Ms. Chambers
804 stated that if we are able to receive sizeable federal funding again this is all a
805 question mark right now, the funding is proposed to have a five year life span and
806 it's possible if we get that award that would be enough leverage to go through the
807 administrative process to get the position and not have to go through the legislative
808 process. Ms. Chambers then gave an example that if we have \$250,000 in federal
809 funds each year for the next five years and the PDMP database costs \$85,000 per
810 year then the Division could recommend to the office of Management and Budget
811 that the balance of that money be used for the creation of a new PCN that is all
812 federally funded and it does not have anything to do with Alaska's budget.

813
814 This is an award we need to be fulfilling now and it's very possible that if that were
815 to happen through the administrative process that this fall the Board would have
816 and Executive Administrator position who would not only in place but could also be
817 there to advocate for the out-of-state wholesale distributor bill.

818
819 Mr. Cotter asked Ms. Chambers the best way to proceed from this discussion, would
820 it be to write a role summary and get that added to the out-of-state wholesale bill

821 and over to Representative Wilson's office or would it be best to see what happens
822 with the grant funding and proceed that way. Mr. Cotter also asked Ms. Chambers
823 who could walk the Board through getting all this done, the two areas that Ms.
824 Chambers would recommend first, the time frame for the PDMP grant funding
825 would be known if it has been awarded well before the start of the January
826 legislative session. If the federal money is received and there is enough to fund that
827 higher level position Ms. Chambers would probably be the point person and
828 working that through the system to create the position. If that does not happen and
829 there is not enough money to create the position then the Board would need to
830 work directly with Representative Wilson's office to add the language for the
831 Executive Administrator position added to the bill. Ms. Chambers suggested the
832 Board look at the Public Accountancy statute. It is one sentence that there shall be
833 an Executive Administrator to perform functions as requested by the Board and the
834 Division.

835
836 Ms. Chambers is happy to serve as a resource for the Board and for the Board to
837 please call or email with any questions. The Board thanked the Ms. Chambers for
838 her time, guidance and assistance on this.

839
840 The Board had some follow up discussion and asked Ms. Bellino if she would
841 consider rescinding her resignation. Ms. Bellino said she would speak with her
842 supervisor, Sher Zinn about that upon her return.

843
844 **AGENDA ITEM 3 FY '15 Annual Report-**

845
846 The Board reviewed and discussed what is required for the FY '15 Annual Report.
847 Chairman Cotter will review.

848
849 **AGENDA ITEM 7 - New/Old Business -**

850
851 The board signed wall certificates and provided travel receipts from the meeting.

852
853 Mr. Cotter asked Ms. Bellino if she could get access to a lap top for board meetings so
854 the Board can create a spreadsheet to track regulation projects and legislative items.
855 Ms. Bellino advised that yes there are lap tops available and she will request one and
856 will have one reserved for the August meeting.

857
858 The Board Chair, Mr. Cotter reviewed the action items from this meeting and
859 upcoming agenda items for the August meeting.

860

859 **On a motion duly made by Ms. Giessel, seconded by Mr. Kim and approved**
860 **unanimously, it was**

861
862 **RESOLVED to adjourn the meeting.**

863
864 The board adjourned at 12:05 p.m.

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Respectfully Submitted:



Donna Bellino
Licensing Examiner

Approved:



John Cotter, RPh., Chair

Date: 5-13-15