

1 STATE OF ALASKA
2 DEPARTMENT OF COMMERCE, COMMUNITY AND
3 ECONOMIC DEVELOPMENT
4 DIVISION OF CORPORATIONS,
5 BUSINESS & PROFESSIONAL LICENSING
6 BOARD OF PHARMACY

7 **DRAFT**

8 MINUTES OF MEETING
9 May 21-22, 2015

10
11 By authority of AS 08.01.070(2) and in compliance with the provisions of
12 Article 6 of AS 44.62, a scheduled meeting of the Board of Pharmacy was held
13 May 21-22, 2015, at the Atwood Building 550 W. 7th, Suite 1270, Anchorage
14 Alaska.

15
16 These **DRAFT** minutes were prepared by the staff of the Division of
17 Corporations, Business and Professional Licensing. They have not been
18 reviewed or approved.

19
20 The meeting was called to order by Chair, John Cotter at 9:04 a.m.

21
22 **Call to Order/Roll Call**

23
24 **Board Members Present constituting a quorum:**

25
26 John Cotter RPh, Fairbanks - Chair
27 Lori DeVito RPh, Soldotna - Vice Chair
28 Anne Gruening, Public Member, Juneau - Secretary
29 CJ Kim, RPh, Anchorage
30 Bill Altland RPh, Craig
31 Leif Holm, Pharm.D, North Pole
32 Taryl Giessel, Public Member, Eagle River

33
34 **Attending from the Division of Corporations, Business and Professional**
35 **Licensing were:**

36
37 Donna Bellino, Licensing Examiner – Juneau
38 Sara Chambers, Professional Licensing Operations Manager – Juneau
39 (via telephone)
40 Martha Hewlett, Administrative Officer – Juneau (via telephone)
41 Angela Birt, Chief Investigator - Anchorage
42 Brian Howes, Investigator – Anchorage
43 Ed Riefle, Sr. Investigator, Anchorage
44 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 **Agenda Item 5 – Budget REPORT/Division Update**

128

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

131

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

136

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

150

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

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

181
182 Ms. Chambers addressed the board regarding the passage of SB71 that will now
183 allow pharmacist to administer immunizations without a collaborative plan with a
184 physician. Ms. Chambers advised that she did not foresee any strong impacts on the
185 department, and if that is different to please let her know. The Board briefly
186 discussed possible ways to handle this change and will be reviewing the
187 collaborative plan regulation and determining what changes are necessary and best
188 plan for implementation when they discuss Agenda Item 7 Regulation Review in the
189 afternoon session. The Board will update Ms. Chambers as to what the outcome of
190 that discussion is.

191
192 Ms. Chambers thanked Mr. Holm and the Board for their assistance in addressing
193 the question received from a Naturopath Emily Kane. Sr. Investigator Riefle was
194 included in the Board's discussion and will advise Ms. Chambers of the outcome.
195

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

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

224
225 Ms. Chambers advised the Board the Division has stated openly that Licensing
226 Examiners, particularly Examiners that are managing boards are not compensated
227 nearly what they should be compensated for the complex work that they do. The
228 same work done in many other positions is done at a Range 18 or higher, but
229 Examiners are currently Range 13 employees. Ms. Chambers advised the Division is
230 doing everything they can to move the study forward and is just waiting to hear
231 back on the results of the study. Ms. Giessel asked if there was an opportunity to
232 comment and if there is an email or phone number to send those to. Ms. Chambers
233 advised that she is happy at any to time to accept a letter from the Board Chair for
234 example and send via email to either Ms. Bellino or Ms. Chambers and she would get
235 it to Classification. The Chiropractic board has already written a letter that she has
236 already submitted.

237
238 Lastly, Ms. Chambers spoke to the Board about another option that the Board has
239 and that would be for the Board to consider requesting an Executive Administrator
240 position. This topic has come up casually in the past, but it is one that various
241 Boards especially more complex boards like pharmacy have wondered how can they
242 add staff, how can they increase the pay range of our staff, how can they ask staff to
243 do more. Right now there may be certain things that the Board would like to ask Ms.
244 Bellino to do but can't because of union constraints. This is an opportunity to
245 pursue via statute an Executive Administrator position. The Public Accountancy
246 Board did this a few years ago and moved from a half time examiner position to a
247 full-time Executive Administrator. That could mean that the fees would likely

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

250
251 Mr. Cotter asked going back to reclassifying the Examiner position versus the
252 Executive Administrator which one of those two had the highest degree of success.
253 Ms. Chambers advised either one is a complex process. The classification section has
254 to look at all of the Occupational Licensing Examiner positions within the State. Our
255 Division has most of them, but there are some Examiner positions outside the
256 Division and they have to make a decision based on the varying levels of
257 responsibilities and complexity within the positions and Ms. Bellino's position is
258 considered on the high end on the demand level. It is hard to say what there
259 outcome will be and if it will affect all Examiners, some Examiners, no Examiners.
260 With a reclassification there is always a risk in opening it up that they could
261 reclassify the position down, highly unlikely in this case, but a possibility. Going
262 through legislation is like any piece of legislation and again in this budget climate
263 saying you would like an Executive Administrator may not get much traction,
264 however since you are advocating for the regulation of a whole new complex area as
265 the result of Federal implementation of compounding legislation and also seeing the
266 need for inspections it may be more likely to go through. From her vantage point
267 Ms. Chambers stated that the pharmacy program is more complex than at least one
268 or two other programs that already have an Administrator and is not a difficult
269 process to lift that language from any of the other six programs that have an
270 Executive Administrator. Tacking this request on the out-of-state wholesale drug
271 distributor bill is an option since that is already moving forward and not
272 unreasonable to be the impetus to be tipping point for this.
273 Ms. Chambers can't personally or professionally be an advocate for or against any
274 strategy pursued legislatively, but wanted the Board to know what options are
275 available to make an educated decision as a Board to pursue the legislation that is
276 appropriate.

277

278 **Break:**

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

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

281

282 **Agenda Item 6 – In-State/Out-of-State Inspections**

283

284 Funding and other challenges to participate in Multi-State inspection form in
285 development with NABP

286

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

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

298

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

309

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

323

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

329

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

333

334 **Lunch:**

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

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

337

338 **Agenda Item 7 – Sergio Vie, National Accounts Manager w/Rare Disease**
339 **Therapeutics in Scottsdale, AZ.**

340

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

352

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

358

359 Last summer the FDA issued guidance on compounding human drugs under section
360 503A of the FD&C Act. Of particular concern to this meeting, this guidance states
361 that the licensed pharmacist or licensed physician does not compound regularly
362 inordinate amounts of any drugs or that are essentially copies of commercially
363 available drugs. Basically the FDA does not want compounding done of a
364 commercially available product, if it's done regularly, in inordinate amounts, or
365 essentially a copy of an approved drug. The ideal situation would be for state and
366 FDA regulations to synch up to avoid any confusion, liability, and to protect the
367 public health.

368

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

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

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

390 The Board decided to first review correspondence before addressing regulations.
391

392 **Agenda Item 9 – Correspondence**
393

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

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

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

412

413 **Agenda Item 8 – Regulation Review**

414

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

420

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

433

434 **Break**

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

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

437

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

450

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

452

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

456

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

458

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

461

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

463

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

465

466 **Friday May 22, 2015**

467

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

469

470 **Call to Order/Roll Call**

471

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

473

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

481

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

485

486 Donna Bellino, Licensing Examiner – Juneau
487 Brian Howes, Investigator - Anchorage

488

489

490

491

492 **Agenda Item 1 Review Agenda –**

493

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

500

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

503

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

506

507 **Continuation of Agenda ITEM 10 Application Review/Approval –**

508

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

526

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

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

535

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

538

539 **RESOLVED to approve the following Applications reviewed for**
540 **approval:**

541

542 **Pharmacists Pending:**

543 Laci Blackburn pending passing MPJE score and VOL from GA

544 Elizabeth Borgmeyer pending NABP Application, passing MPJE score

545 Heidi Brainerd pending passing MPJE score

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

547 VOL from NY

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

549 Christopher Sperry pending VOL from MT and WA

550 Jeffrey Stein pending passing MPJE score and transcript

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

552 Affidavit of Intern Hours

553

554 **In-State Pharmacies:**

555 Foodland Pharmacy

556 Walgreens Pharmacy #16059

557

558 **In-state Wholesale Distributor:**

559 Interior Hardware – Medical Gases

560

561 **Shared Pharmacy Service Applications:**

562 Bartlett Hospital with Medication Review

563 All 23 Safeway Pharmacies with ARX Pharmacy

564

565 **“YES” Answer Applications:**

566 Anita King – Pharmacy Technician

567 Kathleen Brakebush - Pharmacist

568

569 **Collaborative Plan Applications for:**

570

571 Anchorage Neighborhood Health Center Pharmacy

572 • Immunization

573 • Anticoagulation

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

576
577 **RESOLVED to table the following previously tabled applications**
578 **for further review pending receipt of requested information:**

579
580 Rheanna Hamrick – Pharmacy Technician, Board request for ASAP/Mat-Su
581 Evaluation
582 RX Unlimited Pharmacy – Out-of-State Pharmacy, Board request for updated
583 information pending California Board of Pharmacy action.
584

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

590
591 **On a motion duly made by Mr. Cotter, seconded by Ms. DeVito and approved**
592 **unanimously, it was**

593
594 **RESOLVED to go into executive session in accordance with**
595 **AS.44.62.301(c)(2), for the purpose of discussing Mr. Engberson’s**
596 **reinstatement application.**

597
598 Board staff to remain during executive session.

599
600 Off the record at 9:46 a.m.

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

602
603 **On a motion duly made by Ms. DeVito, seconded by Mr. Kim, and approved by a**
604 **roll call vote, it was**

605
606 **RESOLVED to deny the reinstatement application of a previously**
607 **surrendered pharmacist license for applicant Ron Engberson. The board**
608 **made its determination based on review of the following:**

- 609
610
- 611 • **Reinstatement Application, Ronald H. Engberson**
 - 612 • **Judgement and Order, in Case No. 3AN-12-13617CR, which shows the**
613 **applicant, pleaded guilty to Forgery in the Second Degree, a class C**
felony on March 11, 2013.

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

619 **12 AAC 52.075 GOOD MORAL CHARACTER.** As used in AS 08.80, “good moral
620 character” includes not having been convicted of a felony or another crime that
621 affects the applicant’s ability to practice pharmacy competently and safely.
622

623 **12 AAC 52.920 DISCIPLINARY GUIDELINES.** (a) In addition to acts specified in AS
624 08.80 or elsewhere in this chapter, each of the following constitutes engaging in
625 unprofessional conduct and is a basis for or the imposition of disciplinary sanctions
626 under AS 08.01 075:

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

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

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

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

639 Anne Gruening left the room at 9:58 a.m.
640

641 Mr. Cotter then called for Public Comment at 10:00 a.m. and there was none given.
642

643 10:05 a.m. Ms. Gruening came back into room.
644

645 **Agenda Item 2 – Sara Chambers, Professional Licensing Operations Manager**
646

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

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

691
692 Ms. Chambers also advised the Board that there are two different considerations;
693 one is the complexity of the job, and the other is volume of workload. Not adding
694 new staff, but just reclassifying the Examiner position to an EA would not gain
695 anything in workload, but would put that position on the hook for more policy

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

704
705 If an EA position were added we would first have to see how it goes and work
706 together on any legislative or program changes that would be adding
707 responsibilities that would help to educate us as to whether an additional full-time
708 examiner, part-time examiner needed, or someone who flexes during a certain time
709 of the year, cross training other staff. The Division would work closely with the
710 Board and be as flexible as possible. Ms. Chambers then stated that she and Sher
711 Zinn, Records and Licensing Supervisor whom Ms. Bellino reports to are in
712 agreement that right now, there is a need for extra hands on deck as far as Examiner
713 and office assistant help.

714
715 Mr. Cotter asked Ms. Chambers that what he is hearing is that currently there is a
716 full-time position with Ms. Bellino doing the examiner work and she has a half-time
717 position to help get the work done in addition to clerical staff. Ms. Chambers
718 advised that office assistant help supports a variety of licensing programs and the
719 examiner requests office assistant help as they need it, but there is not enough help
720 to go around. The Division from time-time especially in renewals and busy times of
721 the year add an additional part-time examiner to supplement Ms. Bellino's workload
722 and assist to take on some of that workload to keep licenses moving forward. It
723 really comes down to the time of the year and the availability of additional staff to
724 support her workload for the pharmacy program. Mr. Cotter also asked Ms.
725 Chambers in her opinion that in the course of the next year if the Board added an EA
726 and kept a full-time Examiner how much of an increase in FTE cost that would be.
727 Ms. Chambers advised that the estimated cost would be about \$100, 000 because a
728 Range 18A is between \$90-95,000. Mr. Cotter asked with that said what are the
729 budget constraints being that the Board pays for that and is that problematic with
730 the State budget or is it just the fact that it's going to be paid for by the Board and is
731 not an issue. Ms. Chambers advised that the position would have to be added
732 through legislation because there are no additional positions being added anywhere
733 in the State through the administrative process right now. It would have to be
734 legislation that the Board would pursue to request to add to your current chapter,
735 and if that were done the Division would respond with a fiscal note that would show
736 the cost and then be able to speak to the Board's work load, and the need for this

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

741

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

749

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

772

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

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

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

798
799 Mr. Cotter asked Ms. Chambers what happens if the out-of-state wholesale bill does
800 not go through because this bill has not been successful in the last couple of sessions
801 and we would be putting the hopes of this happening on the bill. Ms. Chambers
802 stated that if we are able to receive sizeable federal funding again this is all a
803 question mark right now, the funding is proposed to have a five year life span and
804 it's possible if we get that award that would be enough leverage to go through the
805 administrative process to get the position and not have to go through the legislative
806 process. Ms. Chambers then gave an example that if we have \$250,000 in federal
807 funds each year for the next five years and the PDMP database costs \$85,000 per
808 year then the Division could recommend to the office of Management and Budget
809 that the balance of that money be used for the creation of a new PCN that is all
810 federally funded and it does not have anything to do with Alaska's budget.

811
812 This is an award we need to be fulfilling now and it's very possible that if that were
813 to happen through the administrative process that this fall the Board would have
814 and Executive Administrator position who would not only in place but could also be
815 there to advocate for the out-of-state wholesale distributor bill.

816
817 Mr. Cotter asked Ms. Chambers the best way to proceed from this discussion, would
818 it be to write a role summary and get that added to the out-of-state wholesale bill

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

833
834 Ms. Chambers is happy to serve as a resource for the Board and for the Board to
835 please call or email with any questions. The Board thanked the Ms. Chambers for
836 her time, guidance and assistance on this.

837
838 The Board had some follow up discussion and asked Ms. Bellino if she would
839 consider rescinding her resignation. Ms. Bellino said she would speak with her
840 supervisor, Sher Zinn about that upon her return.

841
842 **AGENDA ITEM 3 FY '15 Annual Report-**

843
844 The Board reviewed and discussed what is required for the FY '15 Annual Report.
845 Chairman Cotter will review.

846
847 **AGENDA ITEM 7 - New/Old Business -**

848
849 The board signed wall certificates and provided travel receipts from the meeting.

850
851 Mr. Cotter asked Ms. Bellino if she could get access to a lap top for board meetings so
852 the Board can create a spreadsheet to track regulation projects and legislative items.
853 Ms. Bellino advised that yes there are lap tops available and she will request one and
854 will have one reserved for the August meeting.

855
856 The Board Chair, Mr. Cotter reviewed the action items from this meeting and
857 upcoming agenda items for the August meeting.

858

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.

865
866
867

Respectfully Submitted:

868
869
870

Donna Bellino
Licensing Examiner

871
872
873

Approved:

874
875
876

John Cotter, RPh., Chair

877
878
879

Date: _____

880
881
882

883
884
885

886
887
888

889
890
891

892
893
894

895
896
897

898
899

900
901