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

**BOARD OF PHARMACY
MINUTES OF MEETING
AUGUST 13-14, 2015**

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.

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

The meeting was called to order by Chair, John Cotter at 9:05 a.m.

Call to Order/Roll Call

Board Members Present constituting a quorum:

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

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

Donna Bellino, Licensing Examiner – Juneau
Brian Howes, Investigator – Anchorage

Visitors Present –

Richard Holt – Walmart
Ben Roland - Walgreens
Molly Gray, Executive Director for the AK Pharmacist Association

47 **Agenda Item 1- Review Agenda**

48

49 The board reviewed the agenda for Thursday August 13, 2015.

50

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

53

54 **RESOLVED to approve the agenda for Thursday August 13, 2015.**

55

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

57

58 The Board reviewed the minutes from the May 21-22, 2015 meeting.

59

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

62

63 **RESOLVED to approve the minutes from the May 21-22, 2015 meeting.**

64

65 **Agenda Item 3- Ethics**

66

67 Mr. Cotter called for any ethics disclosures to be made. No ethics violations to
68 report by board or staff.

69

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

71

72 Investigator Howes presented the Investigative Report for the period of May 6, 2015
73 through August 3, 2015. Including cases, complaints, and intake matters, since the
74 last report, the Division opened nineteen (19) files and closed seventeen (17)
75 Pharmacy Board matters. A total of twelve (12) matters remain on-going and under
76 active investigation or are pending litigation.

77

78 Investigator Howes presented to the Board for review an imposition of a civil fine
79 regarding an out-of-state pharmacy Case #2015-000380.

80

81 The Board reviewed the information presented from Investigator Howes and

82

83 **On a motion duly made by Taryl Giessel, seconded by Mr. Kim and approved**
84 **with 6 Yay votes and 1 abstention (Lori DeVito) is was**

85

86 **RESOLVED to accept the Imposition of Civil Fine of \$500.00 regarding**
87 **Case #2015-000380 for out-of-state pharmacy MedicoRx Specialty.**

88 Investigator Howes provided the Board with a report regarding the Alaska
89 Prescription Drug Monitoring Program (AKPDMP). The report included a
90 prescription count for Alaska from 2015-01 to 2015-08. The report also included
91 PDMP Requests from 07/15/2015 through 8/13/2015 totaling: 17,976.

92

93 **Agenda Item 5 - Recap from Controlled Substance Advisory Committee**

94

95 CJ Kim provided the Board with a recap of the two Controlled Substance Advisory
96 Committee meetings he attended in Anchorage. Mr. Kim attended his first meeting
97 with the advisory committee in June and attended a second meeting on August 4,
98 2015. Investigator Howes also attended the August meeting discussing the AKPDMP
99 and remained for Mr. Kim's recap to the Board.

100

101 Statutory authority for The Controlled Substance Advisory Committee was received
102 back in the 1980's, but did not convene until 2015. This is an advisory committee
103 that will make recommendations to the Governor regarding what changes should be
104 made with controlled substances in Alaska. The committee is comprised of the
105 Attorney General or the attorney general's designee, Commissioner of Health and
106 Social Services or commissioner's designee, Commissioner of Public Safety or
107 designee, Chair of the Board of Pharmacy or designee. Mr. Kim was Mr. Cotter's
108 designee. A peace officer appointed by the governor, a physician appointed by the
109 governor, a psychiatrist appointed by the governor and two individuals appointed
110 by the governor, as well as two State Attorney's.

111

112 Investigator Howes attended both meetings as requested to discuss the Alaska
113 Prescription Drug Monitoring Program (AKPDMP). As a result, the committee has
114 identified four main goals for the committee regarding the AKPDMP and the
115 following is taken from the meeting minutes received from the committee:

116

- 117 1) Statutory changes for the PDMP to generate unsolicited reports
- 118 2) Statutory changes for the PDMP to allow delegate accounts
- 119 3) Mandatory enrollment to prescribers- possibility linking to initial or renewal of
120 licensure
- 121 4) Mandatory review of the PDMP database (this could receive some
122 pushback/resistance)

123 Ideas are easy, implementation is the hard part- questions below were asked and
124 will need to be answered:

125

- 126 • Who will need to be involved – Board of Pharmacy, Commerce, Medical Board,
127 Board of Nursing, Board of Dental Examiners – Any provider who can prescribe a
128 controlled substance
- 129 • What steps, logistical challenges will be faced?
- 130 • What is feasible/supportable?
- 131 • Who will be the stakeholders and will they ‘buy-in’?
- 132 • Review material from <http://www.pdmpexcellence.org/> for possible enhancements
133 to the PDMP
- 134 • The scope/authority of the committee is found at AS 11.71.100-120
- 135 • Streamline new drug entities away from statutes, move to more of a regulatory
136 process

137 The Board is in support of the 4 main goals regarding the PDPMP with full
138 understanding the 4th goal regarding mandatory review of the database has pros
139 and cons and with potential controversy and the Board is split on this goal and
140 would like additional information on how that would be implemented.

141
142 The Controlled Substance Advisory Committee will be trying to address the
143 increasing opioid problem in Alaska and is looking at the way controlled substances
144 are scheduled in the state. Mr. Kim anticipates the Board of Pharmacy to have an
145 active role within the committee. The meetings generally run 3 hours long and the
146 committee will meet every two months. Mr. Kim will continue to provide a recap
147 from the meeting and Ms. Bellino will forward it to all Board members upon receipt.

148
149 **Break:**

150 Off the record at 10:39. a.m.

151 On the record at 10:55 a.m.

152

153 Ms. DeVito left the meeting for the remainder of the morning session.

154

155 **Agenda Item 6 – Dan Nelson, Pharm D - Director of Pharmacy Chief Andrew**
156 **Isaac Health Center**

157

158 Dan Nelson addressed the Board telephonically seeking clarification from the Board
159 regarding dispensaries and how they handle refills, scope of practice and patient
160 safety concerns. Mr. Nelson shared his concern regarding a rural clinic that has a
161 dispensary and he has become aware anecdotally that this clinic is operating more
162 as a pharmacy without a pharmacist on site or involved in any way with the clinical
163 operations of the facility.

164

165 The question Mr. Nelson asked the Board is where a doctor's office that can dispense
166 stops and where a pharmacy begins as far as allowance for refills, taking
167 medications from stock bottles and putting them in smaller bottles, labeling them
168 and running them through a standard prescription retail software systems where
169 they can be billed out and checked for drug interactions and are doing things that
170 are only to be done by a pharmacist. Mr. Nelson also informed the Board that this
171 clinic is also using pharmacy signage and referring to a Medical Assistant as a
172 pharmacist. This facility is not a federal facility and is privately owned and is on the
173 road system. This facility is believed to be in the process of change of ownership
174 and attempting to transfer prescriptions during the change of ownership process
175 out to local pharmacies, that have balked at that since the clinic is not a pharmacy.
176

177 Board consensus regarding this conversation with Mr. Nelson, is that the Board will
178 reach out to the investigator to look into these allegations with this clinic further.
179 Mr. Cotter and Ms. Bellino will contact the investigator and discuss what the best
180 options are to proceed.

181

182 **Agenda Item 7 – Correspondence**

183

184 The Board reviewed Board correspondence and NABP Correspondence.

185

186 **Lunch:**

187

188 Off the record at 12:10 p.m.

189 Back on the record at 1:16 p.m.

190

191 **Agenda Item 8 – Application Review/Approval**

192

193 The Board reviewed applications that Ms. Bellino presented to the Board for
194 approval.

195

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

198

199 **RESOLVED to approve the following Applications reviewed for**
200 **Approval:**

201

202 **“YES” Answer Applications:**

203

203 **Out-of-State Pharmacies:**

204

205

Biocure
Homescrpts.com, LLC

206 Park Compounding

207

208 **Pharmacy Techs:**

209 Suzette Becker

210 Melinda Longlet

211 Jose Lopez

212 Crystal Samber

213 Kathryn Stalker- Kirk

214 Rheanna Hamrick

215

216 **Non "Yes" Answer Applications:**

217 **Pharmacies -**

218 **Safeway Pharmacy #1833**

219

220 **Pharmacists:**

221 Ashley Swart

222

223 **Shared Pharmacy Service Applications:**

224 South Peninsula Hospital

225

226 2:30 p.m. Ms. DeVito rejoined the meeting

227

228 **Agenda Item10 – Statute/Regulation Review**

229

230 Ms. Bellino addressed the Board for consideration of changing statute **Sec.**

231 **08.80.158 REGISTRATION OF PHARMACIES LOCATED OUTSIDE OF STATE (b)**

232 from annually to biennial because of the costs associated with the time and

233 resources required to send this report out to all out-of-state pharmacies.

234

235 Ms. Bellino and her Supervisor Sher Zinn discussed the cost, time and effort

236 required versus the benefit of having this information when the same information is

237 required every two years for renewal.

238

239 **Current statute:**

240 **Sec. 08.80.158 REGISTRATION OF PHARMACIES LOCATED OUTSIDE OF STATE**

241 (b) A pharmacy registering with the board under (a) **of this section shall furnish**
242 **to the board annually**

243 (1) The location, names, and titles of all principal corporate officers and all pharmacists

244 who are dispensing prescription drugs to residents of the state;

245 (2) A copy of a current valid license, permit, or registration to conduct operations in the

246 jurisdiction in which it is located, and a copy of the most recent report resulting

247 from an inspection of the pharmacy by the regulatory or licensing agency of the
248 jurisdiction in which the pharmacy is located

249 The Board discussed what the disadvantage would be by eliminating the annual
250 report requirements and if there should be anything put in its place. The Board
251 discussed and decided there would not be anything lost by eliminating the annual
252 update, but, would like to put in its place the requirement that the pharmacist-in-
253 charge for any out-of-state pharmacy be required to become licensed in Alaska.

254

255 **Break**

256 Off the record at 3:11 p.m.

257 On the record at 3:24 p.m.

258

259 Out-of-State-Wholesale Distributor bill –

260 The Board reviewed with Ms. Bellino the need to find sponsorship for this bill so it
261 can be introduced in the upcoming legislative session. The Board also discussed the
262 importance that this bill includes seeking the statutory authority for the hiring of an
263 Executive Administrator position for the Board of Pharmacy. Ms. Giessel will reach
264 out to some potential sponsors and provide them with information as to the intent
265 and purpose of the bill and include critical points for the bill draft.

266

267 The Board worked on an advisory statement to be posted on the Board of Pharmacy
268 website on how pharmacies should proceed with immunizing now that as of August
269 9th, 2015 SB71 became law. The advisory statement will provide guidance to
270 pharmacist and pharmacies for the interim while the Board works on updating
271 regulations regarding pharmacist collaborative practice authority.

272

273 Sterile Compounding –

274 Mr. Cotter led the discussion with the Board on the best way to proceed on how to
275 create more detailed sterile compounding regulations. Mr. Cotter researched other
276 states regulations regarding sterile compounding and how to include USP 797 which
277 is the standard for sterile compounding. UPS 797 standards are enforceable if a
278 pharmacy does not meet them. This regulation review is not an easy undertaking,
279 but is necessary since the passage of the Drug Quality Supply Act (DQSA) in
280 November 2013. The biggest challenge Mr. Cotter is facing is how specific the
281 regulations should be and how to pair down all the information and incorporate it
282 into specific regulations. Mr. Cotter with the assistance of Lori DeVito will work on
283 this and have an update for the November BOP meeting. Ms. Bellino will contact
284 Josh Bolin at NABP to see how other states are handling revamping or developing
285 sterile compounding regulations.

286

287 **12 AAC 40.981, Federal licensure exemptions for persons who practice in an**
288 **Alaska tribal health program,** is a proposed new section that establishes
289 standards for board recognition of a federal licensing exemption for practitioners
290 working in tribal health programs.

291
292 The Board is in support of this regulation and is watching the proposed regulation
293 from the medical board as it will be going out of public comment soon. The Board of
294 Pharmacy and Board of Dental Examiners are watching this closely and if this
295 regulation takes effect both boards will follow suit and submit for board recognition
296 to the pharmacy and dental boards.

297
298 Ms. Bellino advised the Board the following previously submitted regulations
299 changes will be going out for public comment before the November Board meeting:

- 300
301 1) **12 AAC 52.080,** Internship requirements for a pharmacist license, is proposed to be
302 changed to alter the requirements for internship.
303 2) **12 AAC 52.100, Temporary pharmacist license,** is proposed to be changed to
304 alter the requirements for a temporary pharmacist license
305 3) **12 AAC 52.991, Disciplinary decision or conviction reporting requirement,** is
306 proposed to be changed to alter the provisions relating to the requirement that a
307 licensee report in writing to the board any disciplinary decision or conviction.

308 The following regulation projects have been submitted and are in process:

- 309
310 1) Pharmacy Technician Certification
311 2) Emergency preparedness

312 The Board, with such a big “to do” list, and only having two meetings left before Mr.
313 Kim and Ms. DeVito are off the Board due to term limits, discussed how best to
314 proceed to get the most accomplished. The Board discussed the option of a working
315 session with all or part of the Board in between meetings to clean up and complete
316 the larger regulation projects that the Board has started to work on, but due to the
317 scope of them is difficult to accomplish in regular confines of a Board meeting.

318
319 The Board also would like to minimize application review at board meetings to only
320 review tabled applications from a mail ballot. This would help to free up time to
321 devote to completing the larger and more difficult current and future regulation
322 projects.

323
324 **On a motion duly made by Ms. Giessel, seconded by Ms. DeVito and approved**
325 **unanimously, it was**

326 **RESOLVED to recess the meeting to 9:00 a.m. on Friday August 14, 2015.**

327

328 Off the record at 4:45 p.m.

329

330 **Friday August 14, 2015**

331

332 The meeting was called to order by John Cotter, Board Chair, at 9:05 a.m.

333

334 **Call to Order/Roll Call**

335

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

337

338 John Cotter RPh, Fairbanks - Chairman

339 Lori DeVito RPh, Soldotna - Vice Chairman

340 Anne Gruening Public Member, Juneau – Secretary

341 CJ Kim RPh, Anchorage

342 Leif Holm Pharm D, North Pole

343 Taryl Giessel Public Member, Eagle River

344

345 Bill Altland was not in attendance for the Friday portion of the
346 meeting.

347

348 In attendance from the Division of Corporations, Business & Professional
349 Licensing, Department of Commerce, Community and Economic
350 Development were:

351

352 Donna Bellino, Licensing Examiner – Juneau

353

354 Visitors Present –

355 Richard Holt – Walmart

356 Ben Roland - Walgreen

357 Morgan McLeod – Roadrunner Pharmacy

358

359

360

361

362

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365

366

367 **Agenda Item 1 Review Agenda –**

368

369 The board reviewed the agenda and decided to add time to work on the
370 immunization advisory statement.

371

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

374

375 **RESOLVED to approve the amended agenda with changes for Friday**
376 **August 14, 2015**

377

378 Mr. Cotter Called for Public Comment at 9:15 a.m.

379

380 Morgan McLeod Sales Representative with Roadrunner Pharmacy addressed the
381 Board. Roadrunner Pharmacy is a veterinary specific compounding pharmacy
382 based out of Phoenix, Arizona. Mr. McLeod is addressing states boards around the
383 country regarding compounding, hospital use compounding in the wake of the New
384 England Compounding issues a couple years ago. A lot of state boards are reviewing
385 their compounding regulations to see what they should be doing going forward to
386 protect the public. Roadrunner Pharmacy would like to make sure that state boards
387 of pharmacy are aware of the differences between veterinarian practices and human
388 practices and how veterinarians use compounded drugs in their hospitals.
389 Veterinarians are expected to be an emergency facility for their patients and if they
390 are not allowed to have specific compounded drugs on hand it can cause the death
391 of patients. A lot of the medications veterinarians use are human based and
392 manufactured for humans and do not necessarily fit for the needs that they are
393 trying to make them apply. Roadrunner Pharmacy has researched to see if they
394 would qualify as a 503b outsourcing facility, but cannot since they are strictly
395 animal based and the FDA does not allow for that.

396

397 Not all of the compounding medications that Roadrunner Pharmacy produces are
398 patient specific, as they do send out “clinic use” medications for acute conditions for
399 veterinary hospital use. Currently Roadrunner is under the same restrictions as
400 compounding pharmacies that compound for human use and as such, cannot
401 compound in bulk unless you are a 503b outsourcing facility. The Board asked what
402 other state boards are doing in regard to this issue and Mr. McLeod advised that
403 currently it varies from allowing a 4-7 days of dispensing ability and acute condition
404 prep for those cases that come in and that it’s going to be important to have the
405 medications right away as a continuation of therapy . The Board advised Mr.
406 McLeod that this discussion came at the right time as they are reviewing and
407 addressing compounding regulations. Mr. Holm asked if Mr. McLeod if there are any

408 states that currently have compounding regulations for veterinarians only and Mr.
409 McLeod advised that he did not have an answer for that, but states like California
410 and Nevada are moving towards differentiating between human and animal
411 compounding with dispensing and hospital use, but nothing regarding sterile
412 requirements. Ms. DeVito noted that her understanding was there was not going to
413 be any differentiation, and veterinary products would be treated like human and
414 there was concern with batch processing and shipping without a prescription. Mr.
415 McLeod stated that Roadrunner is not trying to be a manufacturer or wholesaler
416 they are a compounder producing small batches that would just like for veterinaries
417 to have access to medications that are needed.

418

419 Rich Holt from Walmart addressed the Board that he was glad the Board was going
420 to work on the advisory statement that will be put on the Board's website, because
421 there is a lot of confusion as to what pharmacies should do to be compliant with the
422 new law and if a collaborative practice agreement is needed since Walmart's are set
423 to expire in October. The Board advised Mr. Holt that Medicaid does not recognize
424 pharmacists has a provider and may need a collaborative practice agreement for
425 payment purposes and the Board will make its advisement and it will be Walmart's
426 decision on how they would like to proceed.

427

428 Ben Roland, Area Supervisor for Walgreens servicing Alaska and Seattle,
429 Washington introduced himself to the Board.

430

431 Mr. Cotter received an email at the end of Thursday from Mrs. Klouda at Bernie's
432 Pharmacy in Anchorage with a question for the Board of Pharmacy. Mr. Cotter
433 decided to return her call so she could speak with the Board. Mrs. Klouda advised
434 that the pharmacy is doing some renovations to the pharmacy and would like to
435 install a gate between the area of the pharmacy and the office area. Her concern is
436 whether the gate will be sufficient. Mrs. Klouda reviewed the regulations and could
437 not find any specifics other than it has to be secure and she would like to send a
438 picture to make sure the gate meets the definition of secure. The Board advised that
439 Mrs. Klouda send pictures to Ms. Bellino who will forward them to the Board for
440 review. Once the Board reviews the pictures they may have Investigator Howes
441 review the pictures and set up a time to come to the pharmacy to confirm that the
442 addition of the gate keeps the pharmacy secure.

443

444 Break

445 Off the record at 9:54 a.m.

446

447 A fire alarm sounded at the Atwood Building and the all occupants were asked to
448 evacuate the premises.

449 On the record at 10:46 a.m. from the fire drill.

450

451 Agenda Item 2 – Budget Review/Division Update from Sara Chambers,
452 Professional Licensing Operations Manager

453

454 The alarm sounded right before 10:00 a.m. the call with Sara Chambers, was not
455 able to take place. The Board did try to reach Sara by phone, but was not able to.

456

457 AGENDA ITEM 3 – New/Old Business –

458

459 The Board reviewed the FY '15 Annual Report that the Board worked on at the May
460 meeting and updated Alaska Board of Pharmacy Goals and Objectives for FY 2016.

461

462 The Board drafted the advisory statement for the Board of Pharmacy website
463 regarding collaborative practice agreements.

464

465 The Board reviewed and updated the Project Tracking spreadsheet Mr. Cotter put
466 together to assist in keeping track of the various stages for all of the regulation
467 projects the Board is working on. Ms. Bellino will update the spreadsheet based on
468 the discussion and forward it to Mr. Cotter for review.

469

470 The Board signed Wall Certificates

471

472 On a motion duly made by Ms. Giessel, seconded by Mr. Kim and approved
473 unanimously, it was

474

475 **RESOLVED to adjourn the meeting.**

476

477 The board adjourned at 11:58 p.m.

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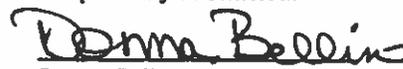
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489

490

Respectfully Submitted:



Donna Bellino
Licensing Examiner

Approved:



John Cotter, RPh., Chair

Date: 12-15-15