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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
NOVEMBER 12 - 13, 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 November 12-13, at the Atwood Building 550 W. 7th, Suite ACC 106, 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 9:08 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

Lori DeVito RPh, Soldotna, participated in the meeting telephonically
Not present at meeting: Anne Gruening, Public Member, Juneau

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

Donna Bellino, Licensing Examiner – Juneau
Brian Howes, Investigator – Anchorage
Al Kennedy, Senior Investigator – Anchorage
Sara Chambers, Operations Manager – Juneau – Telephonically

Visitors Present –

Richard Holt – Walmart
Ryan McDonald - Walgreens

47 Molly Gray, Executive Director for the AK Pharmacist Association

48
49 **Agenda Item 1- Review/ Amend Agenda**

50
51 The board reviewed the agenda for Thursday November 12, 2015.

52
53 Taryl requested time on the Friday agenda to discuss and work on a draft for the
54 wholesale drug distributor bill.

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

58
59 **RESOLVED to approve the agenda as is for Thursday November 12,**
60 **2015.**

61
62 **Agenda Item 2- Review/Adopt Meeting Minutes**

63
64 The Board reviewed the minutes from the August 13-14, 2015 meeting.

65
66 **On a motion duly made by Mr. Kim, seconded by Ms. Giessel and approved**
67 **unanimously, it was**

68
69 **RESOLVED to approve the minutes from the August 13-14, 2015**
70 **meeting.**

71
72 **Agenda Item 3- Ethics**

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

76
77 **Agenda Item 1 – Board Business/Correspondence –**

78
79 The Board reviewed/discussed correspondence and one Report of Theft of Loss
80 received since the August Board meeting.

81
82 The Board reviewed/discussed a request received from a pharmacy applicant
83 through NABP requesting Board permission to take the NAPLEX exam a sixth time.
84 In accordance with NABP's testing policy, the Board of Pharmacy must provide
85 approval to NABP for requests that exceed the five time testing limit before a
86 candidate is permitted to register for the examination. The Board took a roll call

87 vote to decide whether or not to allow the applicant a sixth time to take the NAPLEX
88 exam.

89
90 **On a motion duly made by Mr. Kim, seconded by Mr. Altland and approved by**
91 **a roll call vote, it was**

92
93 **RESOLVED to approve applicant request to take the NAPLEX exam for a**
94 **sixth (6th) time.**

95
96 **Roll call: DeVito, Yes, Altland, Yes, Cotter, Yes, Holm, Yes**
97 **Giessel, No, Kim, No**
98 **4 Yes, 2 No's – Motion passed.**
99

100 The Board reviewed a Memorandum received from the FDA Assistant
101 Commissioner for Compliance Policy, regarding a Five Year, Single-Signature "Long-
102 Term Drug Compounding Information Sharing Agreement" or "Long-Term Drug
103 Compounding ISA". The document was sent to State Government Officials Involved
104 in the Protection of Public Health and offers the State of Alaska the opportunity to
105 enter into a confidentiality agreement to facilitate the exchange of non-public
106 information concerning compounded drug products (human and veterinary drugs)
107 and related public health, and safety information (referred to as non-public
108 compounding information) for a five-year period. This document is not signed by
109 the Board of Pharmacy.

110
111 **On a motion duly made by Mr. Kim, seconded by Ms. Giessel and approved**
112 **unanimously, it was**

113
114 **RESOLVED to accept the Memorandum received from the Assistant**
115 **Commissioner for Compliance Policy regarding the Five-Year, Single**
116 **Signature "Long-Term Drug Compounding Information Sharing**
117 **Agreement" or "Long Term Drug Compounding ISA".**
118

119 **Break:**
120 **Off the record at 10:50 a.m.**
121 **Back on the record at 11:04 a.m.**
122

123 **Agenda Item 2 – Budget Review/Division Update**
124

125 The Board called Sara Chambers, Operations Manager for the Budget Review. The
126 Board welcomed Ms. Chambers to the meeting and she reviewed the year-end

127 report for FY15 Schedule of Revenue and Expenditures. First Quarter for FY16 will
128 be forwarded to the Board when available within the next few weeks.

129
130 Ms. Chambers advised the Board that a new contract has been signed with a new
131 company to manage the Alaska Prescription Drug Monitoring Program (AKPDMP).
132 The new company selected was the result of a competitive bid as the current
133 contract with HID was expiring. The new company is Appriss and their software is
134 called PMP AwareRxE. The cost of the new contract is \$5,000 a year less than the
135 current contract that expired. The new software also has the capability to deliver
136 weekly reporting, so we are getting more service for less money.

137
138 Ms. Giessel asked who is going to pay for this, is it HHS, general state funds, Board
139 paid for, grant, and what are we looking at and what is the future funding
140 mechanism if this is temporary funding? Ms. Chambers advised that a grant through
141 Health & Social Services for this fiscal year is higher than previous fiscal years that
142 HHS has funded the program. A grant for \$125,000 was awarded and will provide
143 \$75,000 for the software and additional funding to cover staff costs and other
144 related expenses to the AK PDMP. This is new grant that Ms. Chambers worked on
145 with Health & Social Services and is an additional grant, The second grant that HHS
146 applied for was not received, but the federal government did encourage the State of
147 Alaska to reapply. HHS is lead and they will work on reapplying for this second
148 grant. If successful in getting this second grant for the next fiscal year it would be
149 the augmentation of the AKPDMP program and would be able to institute a state
150 wide comprehensive opioid control program. The funding from this additional
151 grant if awarded would provide another funding source for a dedicated
152 pharmacy/PDMP staff member of some kind. Ms. Giessel asked it these grants
153 sunset and if so, when? Ms. Chambers advised that each grant is for five years and
154 can be reapplied for.

155
156 11:46 Investigator Howes entered the meeting.

157
158 Lunch Break:
159 Off the record at 11:58 am
160 On the record at 1:19 pm

161
162 **Agenda Item10 – Statute/Regulation Review**

163
164 The Board began this portion of the meeting by reviewing and discussing the
165 regulation changes that were sent out for public comment. Jun Maiquis, Regulation
166 Specialist advised Ms. Bellino before leaving for the Board meeting that no
167 comments or questions were received for the three regulation changes. Although no

168 public comments were received, the Board paid special attention to the cost to
169 private persons of the regulatory action being taken.

170

171 **On a motion duly made by Ms. DeVito, seconded by Ms. Giessel and approved**
172 **unanimously, it was**

173

174 **RESOLVED to adopt as public noticed the regulation changes to:**

175

176 **12 AAC 52.080 Internship requirements for a pharmacist license**

177 **12 AAC 52.100 Temporary pharmacist license**

178 **12 AAC 52.991 Disciplinary decision or conviction reporting**
179 **requirement.**

180

181 Ms. Giessel provided the Board with a copy of the working draft of the
182 PBM/Pharmacy Audit bill for the Board to review. This Bill will be introduced by
183 Senator Giessel. Upon the Board's review of the unnumbered Senate bill, the board
184 did not suggest or make any changes, and supports the bill as currently written. The
185 Alaska Pharmacist Association (AKPhA) is the organization that will manage the
186 progress of this Bill.

187

188 **Sterile Compounding Regulations -**

189 Mr. Cotter advised that he did not have any updates at this time. Ms. DeVito
190 provided a brief update to the Board regarding her discussions with Scottie Russell
191 who is NABPS's Government Affairs person about crafting compounding
192 regulations.

193

194 Ms. Russell forwarded Ms. DeVito statutes and information from a few states such as
195 Virginia and Florida. That information was forwarded to Mr. Cotter and Ms. Bellino.
196 Also discussed with Ms. Russell was the requirement to have the Pharmacist-in-
197 Charge hold an Alaska pharmacist license which currently is not a requirement in
198 Alaska. Ms. Russell advised a lot of states do require the PIC to be licensed for an
199 out-of-state pharmacy. Some states require that at a minimum a staff pharmacist
200 working +20 hours per week hold the license versus the PIC. It's less restrictive and
201 may make more sense.

202

203 Ms. Bellino advised the Regulation Specialist is researching if the Board has the
204 authority to require the PIC from an out-of-state pharmacy become licensed in
205 Alaska or if they will have to seek statutory authority to make this change.

206

207 The Board debated the pros and cons of having the PIC vs a staff pharmacist be
208 licensed for an out-of-state pharmacy. A case can be made for either one.

209 Ms. Russell also advised that many states are adopting USP 797 standards and
210 adding items needed. Ms. Russell suggested that Virginia's statutes should provide a
211 good example for drafting compounding regulations.

212

213 Break:

214 Off the record at 2:28 pm

215 On the record at 2:39 pm

216

217 **12 ACC 52.240 Pharmacist Collaborative Practice Authority** – Regulation change
218 discussion continued from previous meetings. CJ Kim led the discussion on
219 developing collaborative practice regulations since the SB71 became law in August.
220 Mr. Kim presented a working draft of regulations for **12 AAC XX.XXX**
221 **Administration of Vaccines and Related Emergency Medications**. The Board
222 reviewed and discussed the example provided. The Board made changes to the
223 draft based on the outcome from the discussion. Mr. Kim will make the
224 changes/revisions discussed and provide the update at the next Board meeting.

225

226 Pharmacy Technician Certification –

227 Mr. Cotter reviewed what was in the state of Idaho's regulations. Idaho's
228 regulations are very similar to what the Board's objectives are in making these
229 changes to the technician license. The Board requested an update on the status of
230 this regulation project and clarity if the Board has the authority to make this change.
231 Mr. Cotter requested that Ms. Bellino provide the Regulation Specialist with a copy
232 of the Idaho regulations.

233

234 Out-of-State Wholesale Drug Distributor Bill –

235 Ms. Giessel emailed a copy of the last version of HB319 that was sponsored by
236 Representative Tami Wilson to Ms. Bellino. Ms. Bellino will print copies and have
237 them ready for the Board to review/discuss the bill as part of Friday's meeting. Time
238 will be added to tomorrow's agenda to discuss this.

239

240 Due to the short time remaining the Board decided to work on Board business.

241

242 **New/Old Business:**

243

244 The Board of Pharmacy elected Board officers for the next year. The following are
245 the new officers for the Board of Pharmacy:

246

247 John Cotter chosen to continue as Board Chair

248 Leif Holm chosen as Board Vice-Chair

249 Anne Gruening chosen to continue as Board Secretary

250 The Board discussed the pros and cons of holding the first quarter BOP meeting in
251 Juneau or having the meeting in Anchorage to participate in AKPhA Convention in
252 February. After spirited discussion and debate the Board decided to not hold the
253 first quarter meeting in Juneau and hold the meeting in Anchorage to coincide with
254 the AKPhA convention.
255

256 **Break:**

257 Off the record at 4:30 pm

258 Back on the record at 4:35 pm

259

260 The Board set 2016 meeting dates as follows:

261

262 1) February 11-12, 2016 – Anchorage

263 Friday 2/12/16 9:00-Noon will be held at Hilton Anchorage/AKPhA Convention

264 2) May 5-6, 2016 – Anchorage

265 3) August 18-19, 2016 – Tentative location Fairbanks

266 4) November 17-18, 2016 – Anchorage

267 The Board recessed until 9:00 a.m. Friday November 13th, 2015

268

269 **Off the record at 4:53 p.m.**

270

271

Friday November 13, 2015

272

273 The meeting was called to order by John Cotter, Board Chair, at 9:06 a.m.

274

275

Call to Order/Roll Call

276

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

278

279 John Cotter RPh, Fairbanks - Chairman

280 CJ Kim RPh, Anchorage

281 Leif Holm Pharm D, North Pole

282 Taryl Giessel Public Member, Eagle River

283

284 Lori DeVito RPh, Soldotna, participated in the meeting telephonically

285

Not present at meeting: Anne Gruening, Public Member, Juneau

286

287

288

289 In attendance from the Division of Corporations, Business & Professional
290 Licensing, Department of Commerce, Community and Economic
291 Development were:

292
293 Donna Bellino, Licensing Examiner – Juneau
294 Brian Howes, Investigator - Anchorage

295
296 Visitors Present –
297 Richard Holt – Walmart
298 Ryan McDonald - Walgreens
299 John Pritchett – ACHC (Accreditation Commission for Health Care)

300
301 **Agenda Item 1 Review/Amend Agenda –**

302
303 The board reviewed the agenda and decided to add time to work on the work on
304 out-of-state wholesale distributor bill.

305
306 **On a motion duly made by Ms. Giessel, seconded by Mr. Kim and approved**
307 **unanimously, it was**

308
309 **RESOLVED to approve the amended agenda with changes for Friday**
310 **November 13, 2015**

311
312 Mr. Cotter Called for Public Comment at 9:15 a.m. No one addressed the Board for
313 the public comment.

314
315 **Agenda Item 1 – Investigative Report/Investigator Howes**

316
317 Investigator Howes presented the Investigative Report for the period of May 6, 2015
318 through October 28, 2015. Including cases, complaints, and intake matters, since
319 the last report, the Division opened Twenty seven (27) files and closed twenty eight
320 (28) Pharmacy Board matters. A total of seven (7) matters remain on-going and
321 under active investigation or are pending litigation.

322
323 Investigator Howes advised the board that he had the following cases to
324 review/discuss with the Board:

325
326 Case No. 2013-000703
327 Case No. 2013-000704
328 Case No. 2015-001355
329 Case No. 2015-000850

330 It was decided the Board go into executive session to investigative matters.

331

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

334

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

337

338 Board staff to remain

339

340 Off the record at 9:25 a.m.

341 On the record at 9:48 a.m.

342

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

345

346 **RESOLVED to accept the Voluntary Surrender of State of Alaska**
347 **Pharmacist License for Jay William Kennelty Case No. 2015-000850.**

348

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

351

352 **RESOLVED to accept the Imposition of Civil Fine for Catamaran (Ohio)**
353 **Case No. 2013-000703.**

354

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

357

358 **RESOLVED to accept the Imposition of Civil Fine for Catamaran**
359 **(Florida) Case No. 2013-000704.**

360

361 **On a motion duly made by Ms. Giessel, seconded by Mr. Holm and approved**
362 **unanimously, it was**

363

364 **RESOLVED to accept the Imposition of Civil Fine for BioRx, LLC**
365 **Case No. 2015-001355.**

366

367 Investigator Howes provided the Board with a year to date report regarding the
368 Alaska Prescription Drug Monitoring Program. This type of report will be provided
369 to the Board when they meet quarterly.

370

371 Investigator Howes and Mr. Kim participate in the Controlled Substance Advisory
372 Committee meetings addressed the Board in regard to approaching other
373 prescribing boards to write letters of support for the AK PDMP. The Board is in
374 agreement that this would be a good time in conjunction with the new AK PDMP
375 vendor taken over in January 2016. Mr. Kim will work on a draft of the letter for the
376 Board to review.

377

378 **Break:**

379 Off the record at 10:07 a.m.

380 Back on the record at 10:14 a.m.

381

382 **Agenda Item 2 - ACHC Inspection & Accreditation Presentation**

383

384 John Pritchett, Associate Director of Pharmacy with ACHC gave a PowerPoint
385 presentation to the Board regarding ACHC Inspection Services (AIS) and PCAB
386 Accreditation.

387

388 Recent developments with ACHC's Pharmacy service offerings include the release of
389 ACHC Inspection Services (AIS) and the integration of PCAB accreditation for non-
390 sterile and sterile compounding pharmacies. The range of compliance solutions are
391 designed to offer regulatory bodies and providers flexibility without compromising
392 quality.

393

394 State boards of pharmacy face challenges in their effort to ensure the safety of its
395 residents. The high risk associated with compounding medications necessitates the
396 inspection of each facility and resources to perform inspections are often strained
397 due to the fragmented nature of the industry. ACHC compliance solutions allow state
398 boards of pharmacy to outsource the inspection process to a highly qualified
399 organization at no cost to the boards or the public.

400

401 By requiring compounding pharmacies to undergo PCAB accreditation, boards of
402 pharmacy can be assured that compounding pharmacies have demonstrated
403 continuous compliance with applicable USP standards.

404

405 There was a brief Q & A period. The Board thanked Mr. Pritchett for taking the time
406 to come to Alaska to make this presentation to the Board.

407

408 Bill Altland provided a brief update to the Board about is trip to Idaho State
409 University to speak to pharmacy students. Mr. Altland spoke to the students about
410 pharmacy ownership, Alaska, rural pharmacy, and medical missions. Mr. Altland
411 was invited to speak by NCPA.

412 Mr. Altland advised that he spoke to Tom Wadsworth who is the Assistant Dean of
413 Alaska Programs but works for Idaho State College of Pharmacy. He sent Mr. Altland
414 a one page recap of program that will begin in the fall of 2016. Mr. Altland will
415 forward the information to Ms. Bellino who will forward it the Board.
416

417 **Out-of-State Wholesale Drug Distributor Bill -**
418

419 The Board spent the majority of the remaining time going through HB319 that was
420 to be submitted last legislative session by Representative Tammie Wilson, but ended
421 up not being submitted. For the upcoming 2016 legislative session Senator Kathy
422 Giessel will sponsor the bill in the senate and Representative Dan Saddler is
423 interested in sponsoring the bill in the house.
424

425 The Board looked at the items that are necessary to remain in the bill and added
426 some new items to be included since the passage of DQSA to ensure the aim of this
427 bill is accurate. The goals of this bill are to get statutory authority to license out-of-
428 state wholesaled drug distributors and for the authority to employ a person who is
429 not a member of the board to serve as the executive administrator of the board.
430

431 **AGENDA ITEM 4 - New/Old Business -**
432

433 The Board reviewed and updated the Project Tracking spreadsheet Mr. Cotter put
434 together to assist in keeping track of the various stages for all of the regulation
435 projects the Board is working on. Ms. Bellino will update the spreadsheet based on
436 the discussion and add in any dates for tracking purposes and forward it to Mr.
437 Cotter for review.
438

439 The Board signed Wall Certificates
440

441 **On a motion duly made by Ms. Giessel, seconded by Mr. Kim and approved**
442 **unanimously, it was**
443

444 **RESOLVED to adjourn the meeting.**
445
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453 The board adjourned at 12:18 p.m.

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Respectfully Submitted:



Donna Bellino
Licensing Examiner

Approved:



John Cotter, RPh., Chair

Date: 11/16/16