

1 State of Alaska
2 Department of Commerce, Community and Economic Development
3 Division of Corporations, Business and Professional Licensing
4

5 Alaska Board of Pharmacy
6

7 **DRAFT MINUTES OF THE MEETING**
8 **May 10, 2018 Teleconference via OnBoard**
9

10
11 By authority of AS 08.01.070(2), and in compliance with the provisions of AS
12 44.62, Article 6, a scheduled meeting of the Board of Pharmacy was held via
13 teleconference at the State Office Building, Conference Room A in Juneau,
14 Alaska on May 10th, 2018.
15

16
17 **Agenda Item 1** **Call to Order/Roll Call** **Time: 9:26 a.m.**
18

19 The **May 10, 2018** meeting day was called to order by Chair, Rich Holt at 9:26 a.m.
20

21 Board members present, constituting a quorum:
22

23 Richard Holt, PharmD #PHAP2008, MBA – *Chair*
24 Leif Holm, PharmD #PHAP1606
25 Phil Sanders, RPh #PHAP776
26 James Henderson, RPh #PHAP1683
27 Lana Bell, RPh #PHAP893 (Absent)
28 Tammy Lindemuth, Public Member
29 Sharon Long, Public Member (Absent)
30

31 Division staff present:
32

33 Donna Bellino, Occupational Licensing Examiner
34 Deborah Roesch, Occupational Licensing Examiner
35 Laura Carrillo, Records & Licensing Supervisor
36 Brian Howes, Investigator
37 Marilyn Zimmerman, Paralegal
38 Melissa Dumas, Administrative Officer
39 Marylene Wales, Accountant
40

41 **Agenda Item 2** **Review/Approve Agenda** **Time: 9:27 a.m.**
42

85 Enhancement Features

86 Ms. Carrillo then addressed enhancement features, including Clinical Alerts and NarxCare. Both
87 enhancement features were previously reviewed by the board during their February – March 2018
88 meeting. Clinical Alerts is an automated alert feature that sends direct messages to prescribers
89 when a patient has met or exceeded the threshold of five (5) prescribers and five (5) pharmacies
90 over a three (3) month period. NarxCare is a feature that provides visual snap shots of risk-scores
91 related to opioid addiction, abuse, and overdose. Chair Holt commented that some pharmacies are
92 already integrating this feature into their business practices. Ultimately, the consensus was not to
93 move forward with providing NarxCare as an enhancement feature. Chair Holt then inquired as to
94 where the 5, 5, 3 threshold came from, to which Donna Bellino indicated was recommended to
95 the board in 2014 and discussed at one of their regularly scheduled board meetings. Ms. Carrillo
96 added that it may have been a recommended threshold based on other states with a similar
97 population size of prescribers and patients.

98

99 **TASK:**

100 Donna Bellino will look for the minutes pertaining to the 5, 5, 3 threshold for the board to assess
101 the context of how this threshold level was determined.

102

103 Chair Holt further inquired about whether practitioners and pharmacists would receive the alerts
104 or if the direct alert would just be pushed to the practitioner. Also of interest was whether the alert
105 would be sent to all practitioners who have a treating relationship with the patient or only the
106 practitioner who prescribed a medication that made the patient meet or exceed the threshold.

107

108 **TASK:**

109 Ms. Carrillo will inquire with Apriss Health as to who would receive the clinical alerts.

110

111 Ms. Carrillo stated that the Clinical Alerts feature would be covered by grant funds obtained by the
112 Alaska Department of Health and Social Services, to which Tammy Lindemuth inquired as to
113 where subsequent funds would come from. Ms. Carrillo speculated that funds would continue to
114 come from grant funding, however, PDMP fees may help to pay for the feature as well. Leif Holm
115 expressed concern about alert fatigue, stating that it can be overwhelming to receive numerous
116 notices on a daily basis, and that practitioners should already be aware of whether a patient might
117 be exceeding threshold levels since mandatory reviewing is already in effect. Ms. Carrillo agreed,
118 stating that PDMP administrators in other states expressed similar concerns with regards to alert
119 fatigue, however, Ms. Carrillo encouraged the board to continue looking into obtaining this
120 feature.

121

122 Awareness and Feedback Questionnaire

123 Ms. Carrillo then addressed the PDMP Awareness and Feedback Questionnaire, which is a CDC-
124 DDPI grant deliverable activity required as a condition of receiving federal funding. The board
125 was informed that the questionnaire would be posted on May 15th and would be open for two
126 weeks. Tammy Lindemuth inquired as to who would evaluate the results and also expressed
127 concern that two weeks wasn't long enough to thoroughly collect responses. Ms. Carrillo

128 responded that external evaluators hired by DHSS could analyze the results. Ultimately, it was
129 decided that the questionnaire would remain open for 4 weeks.

130
131 PDMP Education and Outreach
132 An education and outreach survey was sent out to 188 practitioners and pharmacists in Juneau at
133 the end of March 27, 2018 soliciting participation in PDMP-related training. Ms. Carrillo let the
134 board know that she has since participated in about half a dozen sessions, which include topics
135 such as mandatory reporting and reviewing requirements, PDMP state website resources, PDMP
136 legislative reports, and profession-specific high-level data.

137
138 PDMP Renewal and Forms
139 The board was then informed of the upcoming PDMP renewal, which will coincide with each
140 licensing program's renewal date. Since the Board of Pharmacy is renewing at the end of June, its
141 licensees will be the first to undergo the PDMP renewal process, for which there is a \$25.00 fee
142 and separate renewal form. Ms. Carrillo presented to the board the other forms that were
143 developed for the PDMP, including a DEA registration status and an initial registration form.
144 Chair Holt noticed a typo on the DEA registration status form, 08-4763.

145
146 **TASK:**
147 MS. Carrillo will correct the typo on the DEA Registration Status form #08-4763.

148
149 **Agenda Item 5 Pharmacy Industry Updates Time: 10:32 a.m.**

150
151 FDA Continuing Education – Drug Supply Chain Security Act (DSCSA)
152 Chair Holt indicated to the board that he attended this CE opportunity and directed the board to
153 the DSCSA presentation slides that were included in the board packet. The slides covered an
154 overview of the DSCSA, DSCSA goals, trading partners, products, transactions, reporting,
155 packaging, and product tracing documentation. Chair Holt commented that overall, the
156 presentation was insightful, but that he wished they had expounded more upon wholesale drug
157 distributors and 503(b)s.

158
159 PDMP Conference/Meeting Updates – Nation Rx Drug Abuse and Heroin Summit
160 After attending the summit in Atlanta, Lana Bell and Ms. Carrillo prepared summaries of their
161 experience there. Though Ms. Lana Bell was not able to attend this board meeting, included in the
162 board packet was her overview of the conference reflecting a number of tracks she participated in,
163 including pharmacy, treatment, and law enforcement sessions. To note was that Ms. Bell was
164 impressed at federal, state, and local coordination efforts to respond to the opioid problem. Ms.
165 Bell reiterated the importance of shifting away from the negative stigma surrounding drug
166 addiction, reported on the focus of treatment resources for pregnant women, and shared the need
167 for increased accessibility to medication assisted therapy (MAT) and naloxone resources. Ms.
168 Carrillo also shared her summary on her experience attending the conference, which mainly
169 included participation in PDMP-specific sessions. Topics included Washington's opioid response
170 plan, prescriber report format, public dashboard, and provisions allowing the issuance of facility or

171 group prescriber reports. The latter allows the chief medical officer of a facility to view prescribing
 172 metrics of employees, which is mainly used for quality improvement and to drive adoption of
 173 prescribing guidelines. In comparison, Alaska does not allow direct issuance of prescriber reports
 174 to practitioners other than to those for whom the prescriber report is concerning. Ms. Carrillo also
 175 discussed Wisconsin and Rhode Island’s PDMP programs as well as states implementing e-
 176 prescribing laws to reduce fraudulent prescriptions.

177
 178 PDMP Conference/Meeting Updates – BJA West Regional Meeting
 179 Ms. Carrillo attended the BJA grantee meeting in Albuquerque, where other state PDMP
 180 administrators convened to discuss a number of topics, including prescriber report cards, e-
 181 prescribing to reduce prescription errors, challenges for veterinarians, gateway integration, pre-
 182 criminal intervention programs for doctor shoppers, interstate data-sharing, prescriptive
 183 guidelines, and PDMP fees.

184
 185 **Agenda Item 6 Investigative Report Time: 10:50 a.m.**

186
 187 *Brian Howes joined the room telephonically at 10:49 a.m.*

188
 189 Investigator, Brian Howes joined the room to present to the board the investigative report, which
 190 included activity from February 7th to May 7th, 2018. Mr. Howes informed the board that eight (8)
 191 matters had opened, eleven (11) had closed, and that three (3) matters were ongoing.

192
 193 Case #2017-000557 (license surrender)
 194 Mr. Howes also informed the board of a fraud case that led to the licensee’s voluntary surrender
 195 of his license, which prompted the board to make a motion.

196
 197 **On a motion duly made by Rich Holt and with unanimous approval to accept the**
 198 **voluntary surrender of Alaska Pharmacist License #PHAP2124, case #2017-000557**
 199 **pursuant to AS 08.01.075, AS 08.80.261(a)(2), (a)(9), (a)(11), (a)(14), and 12 AAC**
 200 **52.920(a)(4)(10), it was:**

201
 202 **RESOLVED to accept the voluntary license surrender of license # PHAP2124 by**
 203 **Joshua Fillible.**

204

	APPROVE	DENY	ABSTAIN	ABSENT
205				
206	Leif Holm	x		
207	Richard Holt	x		
208	Phil Sanders	x		
209	James Henderson	x		
210	Tammy Lindemuth	x		

211
 212 The motion passed.

213 *Brian Howes left the room telephonically at 11:00 a.m.*

214

215 **TASK:**

216 Chair Holt will sign the voluntary surrender document and return it to the department.

217

218 **Agenda Item 7 Board Business**

Time: 11:00 a.m.

219

220 Before addressing board business, Ms. Carrillo introduced licensing examiner, Deborah Roesch,
221 who recently transitioned to assisting with administrative duties for the Board of Pharmacy. Ms.
222 Roesch is specifically handling pharmacy technician and intern initial and renewal applications.

223

224 Annual Report

225 Chair Holt moved to discussing the annual report, which he reminded the board is due on an
226 annual basis by June 1st. Chair Holt presented his draft to the board for review. Tammy
227 Lindemuth commented on two typos, which Ms. Carrillo noted to be corrected. Leif also
228 commented that his duty station needed to be corrected to North Pole.

229

230 **TASK:**

231 Ms. Carrillo will correct the last name typo, will capitalize the ‘a’ in Anchorage before forwarding
232 the annual report to the publications specialist, and will update Leif Holm’s duty station from
233 Fairbanks to North Pole.

234

235 **On a motion duly made by Tammy Lindemuth and seconded by Phil Sanders, it was:**

236

237 **RESOLVED to accept the 2018 Annual Report as amended.**

238

239 Review Applications

240 Hearing nothing further on the annual report, Chair Holt addressed the continuing education
241 audit of Rex Malcom, who requested the board to consider accepting college credit to meet CE
242 requirements. Ms. Carrillo commented that 12 AAC 52.340(a) would allow licensees to apply
243 college credit to CE requirements in lieu of other approved programs under 12 AAC 52.340, and
244 Phil Sanders added that this would potentially be the case if the program was specifically
245 accredited by the ACPE and is assigned an ACPE course number. The board discussed this
246 college credit and found no indication that the courses have been accredited by the ACPE.

247

248 *Leif Holm left the room telephonically at 11:30 a.m.*

249

250 **On a motion duly made by Rich Holt and seconded by James Henderson to accept the**
251 **college education classes by Rex Malcom, PHAP1523 as evidence of satisfactory**
252 **completion of required continuing education under AS 08.80.165, 12 AAC 52.320, 12 AAC**
253 **52.340, and 12 AAC 52.350, it was:**

254

255 **RESOLVED** to reject the request by Rex Malcom to apply college education
256 courses to the credit hours required for the 2016 – 2018 renewal cycle.

	APPROVE	DENY	ABSTAIN	ABSENT
258				
259	Leif Holm			x
260	Richard Holt	x		
261	Phil Sanders	x		
262	James Henderson	x		
263	Tammy Lindemuth	x		

264
265 The motion did not pass.

266
267 The board then moved on to discussing the continuing education audit of Jessica LaTourelle, who
268 requested that the board consider accepting 15 hours of participation in an ACLS/PALS course to
269 satisfy the required 30 hours for license renewal. Pointing to 12 AAC 52.340(1), Rich reiterated
270 that any program accredited by the ACPE should be considered acceptable but that the course
271 should also indicate an ACPE-assigned course number. Phil Sanders stated that there needs to be
272 clarification as to what specifically is being accredited; the American Heart Association (AHA) or
273 the courses themselves. The board continued to discuss this and requested the presence of
274 paralegal, Marilyn Zimmerman, as the board didn't immediate have access to the certificates of
275 completion indicating how many hours were included and whether they were accredited by the
276 ACPE or AHA.

277
278 *Marilyn Zimmerman joined the room at 12:06 p.m.*

279
280 Ms. Zimmerman joined the room and provided board staff with the certificates of completion
281 submitted by Ms. LaTourelle, which specified that the ACLS/PALS course was approved under
282 the AHA but was provided by the Alaska Learning Institute and presented by LifeTek, neither of
283 which are currently ACPE accredited. Ms. Zimmerman pointed out that LifeTek is listed as an
284 approved presenter by the AHA, meaning the AHA has authorized them to present courses on
285 their behalf. Ms. Zimmerman added that if the board were to deny this request, the Office of
286 Administrative Hearings (OAH) may find that AHA's authorization of LifeTek to present the
287 course is a valid basis for accepting the credit under current board regulations. Chair Holt stated
288 that the regulations should be amended to accommodate situations in which the AHA authorizes
289 providers to present courses on their behalf.

290
291 **TASK:**

292 Ms. Carrillo will add to the board's agenda for the next meeting the regulation topic of adding
293 language to accommodate authorized presenters of approved providers.

294
295 Phil Sanders prompted the board for clarification on whether the 1 credit hour required for CPR
296 will be accepted and if the 15 hours will be accepted as an AHA presented course. Ms. Carrillo

297 clarified that the 15 will cover the 1 hour for CPR and the remaining 14 hours would satisfy the
298 remaining credits.

299
300 **On a motion duly made by Rich Holt and seconded by James Henderson to accept the**
301 **ACLS/PALS course totaling 15 hours towards Jessica LaTourelle’s continuing education**
302 **requirements under AS 08.80.165, 12 AAC 52.320, 12 AAC 52.340, and 12 AAC 52.350, it was:**
303

304 **RESOLVED to accept the request by Jessica LaTourelle, PHAP1912, to apply the**
305 **15 hours inclusive in the ACLS/PALS course to the 30 credit hours required for the 2016 –**
306 **2018 renewal cycle.**
307

	APPROVE	DENY	ABSTAIN	ABSENT
308 Leif Holm				x
309 Richard Holt	x			
310 Phil Sanders		x		
311 James Henderson	x			
312 Tammy Lindemuth	x			

313
314
315 The motion passed.

316
317 **Agenda Item 8 Lunch Time: 12:41 p.m.**

318
319 Chair Holt called for a lunch at 12:41 p.m.

320
321 *Off record for lunch at 12:41 p.m.*

322 *Back on record at 1:23 p.m.*

323
324 *Melissa Dumas, Administrative Officer, joined the room at 12:41 p.m.*

325
326 **Agenda Item 9 Budget Report Time: 1:23 p.m.**

327
328 Returning from lunch, the board was joined by Melissa Dumas, who presented the board’s FY18
329 3rd quarter budget report. Ms. Dumas reminded the board that as they’re in a renewal year, their
330 revenue as reported is dramatically understated; that the board can anticipate collecting \$700,000 –
331 \$80,000 from this renewal cycle. Ms. Dumas also reviewed the board’s direct and indirect
332 expenditures, and RSAs.

333
334 *Melissa Dumas, Administrative Officer, left the room at 1:32 p.m.*

335
336 **Agenda Item 7 Board Business Time: 1:35 p.m.**

337
338 The board then moved to discussing initial applications for out-of-state pharmacies: Avita Drugs,

339 Entirely Pets, OMRO Pharmacy, and Sterling Specialty Pharmacy, as well as a pharmacy
340 technician application submitted by Elita Cleveland. Due to the new Division-wide policies
341 governing email voting processes using OnBoard, board members had limited voting options and
342 lack of opportunity to explain their vote. As such, the applications were brought to the meeting
343 for board discussion. With more time needed to review these applications, it was ultimately
344 decided to re-open the online voting ballots and to return for discussion on these applications on
345 May 11th.

346

347 **TASK:**

348 Ms. Bellino will re-open the online voting ballots for Avita Drugs, Entirely Pets, OMRO
349 Pharmacy, Sterling Pharmacy, and Elita Cleveland.

350

351 **Agenda Item 10 New Business**

Time: 2:08 p.m.

352

353 Change of Pharmacy Manager Form

354 Hearing nothing further on the budget report, Donna Bellino addressed the need to revise the
355 change of pharmacy manager form. Currently, the change of pharmacy manager or pharmacist-in-
356 charge (PIC) status change form is to be filled out by a new or incoming pharmacist in charge. Ms.
357 Bellino stated, however, that many states require notifications from both the outgoing and
358 incoming PIC, suggesting that there can be a more robust way to accurately capture when a
359 change has taken place. Ms. Bellino added that often times, PIC changes are submitted to the
360 department in a delayed manner that is outside of the required 10-day timeframe. Ms. Carrillo
361 commented that since timely notifications of PIC changes are required in regulation, this is
362 something that needs to be reinforced, to which Chair Holt agreed. Chair Holt expounded on this
363 issue, saying that if a PIC fails to notify the department, the previous PIC will be listed on file as
364 the current PIC indefinitely. Ms. Bellino stated that one PIC was listed as the current PIC even
365 though she had left two years before. Ms. Carrillo stated that moving forward, an investigative
366 memo consistent with our division policies and procedures will be drafted when a PIC fails to
367 notify the department of the change within the required 10 days.

368

369 **TASK:**

370 Staff will route delayed PIC notifications to the Investigations section according to P&P28.

371

372 Inspection Report Forms

373 The board acknowledged a need to update the formatting and context of the in-state and out-of-
374 state inspection reports.

375

376 **TASK:**

377 Staff will work towards updating in-state and out-of-state inspection reports in coordination with
378 Chair Holt. Ms. Carrillo will have fillable versions updated by the August 2018 meeting for the
379 board to review.

380

381 Pharmacy Closure Form

382 Included in the board packet was an example form from Kansas that is used by pharmacies to
383 notify the KS Board of Pharmacy when a pharmacy closure has occurred. The board discussed
384 adding language to regulations indicating that pharmacies will need to fill out a pharmacy closure
385 form provided by the department.

386
387 **TASK:**

388 Rich Holt will work on draft language to be added to regulation regarding pharmacy closures.
389

390 Addiction Resources for Pharmacists

391 The board then addressed a letter that was submitted by a former pharmacist who was pursuing
392 licensure in Alaska; however, because of a past history of substance abuse, is unable to resume
393 practice in Alaska for a certain amount of time. Ms. Carrillo cited AS 08.01.050, which allows the
394 department to contract with professional organizations to provide licensed practitioners with
395 treatment resources for substance abuse. The Board of Pharmacy is specifically included in this
396 statute, however, the way it is currently written, the resources only applies to actively licensed
397 pharmacists. Chair Holt agreed with the need to provide such resources, and suggested perusing
398 programs offered by the NABP.

399
400 **TASK:**

401 The board will continue looking at addiction resources offered by the NABP.
402

403 *Leif Holm joined the room at 2:10 p.m.*
404

405 Photo Identification Laws

406 Ms. Bellino commented that she sometimes receives calls from folks concerned that an
407 unauthorized person has picked up a prescription not intended for them, suggesting that this
408 could be an opportunity to add photo identification regulations. Leif Holm commented that the
409 Drug Enforcement Administration has already established guidelines to address these concerns; if
410 a pharmacist is in doubt, s/he has the authority to request a photo ID, so adding language may be
411 redundant to what is federally recommended. Chair Holt agreed, reiterating that it's the
412 pharmacist's prerogative to ask for an ID in questionable circumstances.

413
414 Military PDMP Reporting Agreement

415 The board briefly discussed AS 17.30.200(f), which provides the board with the authority to enter
416 into agreements with dispensers in the state that aren't regulated, e.g.: pharmacists working in VA
417 or IHS pharmacies. Ms. Carrillo informed the board that the VA and IHS facilities have issued
418 directives for all its practitioner and pharmacist employees to register with state PDMPs, so a form
419 based on this agreement may not be necessary.

420
421 Interstate Data-sharing

422 Since the board will be repealing a section of their regulations in 12 AAC 52.855 effective June 7
423 regarding sharing data, new language will need to be added to engage in interstate data sharing.

467 The board then briefly addressed the continuing education audit renewal letter templates and audit
468 complete letters prepared by Ms. Carrillo. Phil Sanders noticed a typo, which will be corrected by
469 Ms. Carrillo before the letters are sent. There were no wall certificates to sign.

470

471 **TASK:**

472 Ms. Carrillo will fix the typo on the continuing education audit letter.

473

474 **Agenda Item**

Recess

Time: 3:33 p.m.

475

476 On a motion duly made by Phil Sanders, seconded by Rich Holt, the board recessed at 3:33 p.m.

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510 State of Alaska
511 Department of Commerce, Community and Economic Development
512 Division of Corporations, Business and Professional Licensing
513

514 Alaska Board of Pharmacy
515

516 **DRAFT MINUTES OF THE MEETING**
517 **May 11, 2018 Teleconference via OnBoard**
518

519 By authority of AS 08.01.070(2), and in compliance with the provisions of AS 44.62,
520 Article 6, a scheduled meeting of the Board of Pharmacy was held via
521 teleconference at the State Office Building, Conference Room A in Juneau, Alaska
522 on May 11th, 2018.
523

524 These are draft minutes that have not yet been approved by the board.
525

526 **Agenda Item 15** Call to Order/Roll Call **Time: 9:07 a.m.**
527

528 The **May 11, 2018** meeting day was called to order by Chair, Rich Holt at 9:07 a.m.
529

530 Board members present, constituting a quorum:
531

532 Richard Holt, PharmD #PHAP2008, MBA – *Chair*
533 Leif Holm, PharmD #PHAP1606 (Absent)
534 Phil Sanders, RPh #PHAP776
535 James Henderson, RPh #PHAP1683
536 Lana Bell, RPh #PHAP893 (Absent)
537 Tammy Lindemuth, Public Member
538 Sharon Long, Public Member (Absent)
539

540 Division staff present:
541

542 Donna Bellino, Occupational Licensing Examiner
543 Deborah Roesch, Occupational Licensing Examiner
544 Laura Carrillo, Records & Licensing Supervisor
545

546 **Agenda Item 16** Review/Approve Agenda **Time: 9:08 a.m.**
547

548 Upon opening the meeting, Chair Holt inquired to the board whether there were any suggestions
549 to amend the written agenda. Phil Sanders expressed a desire to discuss drug disposal regulations,
550 to which Chair Holt responded that he had previously prepared a regulations draft and that this

551 topic could be discussed at the regulations portion of the meeting. Hearing nothing further on
552 amending the agenda, the board motioned to approve the agenda.

553
554 **On a motion duly made by Phil Sanders, seconded by Tammy Lindemuth, and approved**
555 **unanimously, it was**

556
557 **RESOLVED to accept the May 11, 2018 agenda as amended.**

	APPROVE	DENY	ABSTAIN	ABSENT
560 Richard Holt	x			
561 Phil Sanders	x			
562 James Henderson	x			
563 Tammy Lindemuth	x			

564
565 The motion passed with no further discussion.

566
567 **Agenda Item 17 Public Comment **Time: 9:10 a.m.****

568
569 There were members from the public available for public comment.

570
571 **Agenda Item 13 Review of Lost/Stolen Rx **Time: 9:12 a.m.****

572
573 The board reviewed one report from Alaska CVS Pharmacy, LLC, in which the pharmacy
574 reported a loss of \$3,199. Ms. Lindemuth inquired about how the pharmacy recoups this loss, to
575 which Chair Holt stated it may be covered by insurance or may be a cost that they'll have to
576 shoulder. Chair Holt then informed the board that another pertinent part of the form to hone in
577 on is whether the pharmacy has reported numerous losses or thefts, stating that there were no
578 losses previously reported.

579
580 **Agenda Item 7 Board Business **Time: 9:18 a.m.****

581
582 The board then resumed their discussion on review of applications from the previous day.

583
584 Avita Drugs

585 This application had one 'abstain', one 'yes', and one 'no' which was being opened up for
586 discussion and re-voting because the reasons for voting 'no' and 'abstain' were unclear. Mr.
587 Sanders commented that he indicated an 'abstain' vote due to the applicant's employer having
588 previously been convicted of a felony charge. Of particular concern to Mr. Sanders was that the
589 employee who had been convicted of a felony was allowed to work with the pharmacy. Chair Holt
590 also commented that in reviewing the application, he noticed that the owners of the pharmacy
591 were not licensed pharmacists. It was also added that one of the owners was put on probation, but
592 that eventually was no longer working as an officer with the pharmacy.

593 On a motion duly made by Rich Holt and seconded by Tammy Lindemuth to approve the
594 registration application for out-of-state pharmacy, Avita Drugs in accordance with AS
595 08.80.158 and 12 AAC 52.130, it was:

596
597 **RESOLVED** to approve the out-of-state pharmacy registration application for Avita
598 **Drugs.**

599

	APPROVE	DENY	ABSTAIN	ABSENT
600				
601	Richard Holt	x		
602	Phil Sanders	x		
603	James Henderson	x		
604	Tammy Lindemuth	x		

605
606 The motion passed with no further discussion.

607
608 Entirely Pets
609 This application had one ‘abstain’, two ‘yes’ votes, and was reopened for board discussion to more
610 clearly understand the reason for the abstain vote. The board reviewed the four major citations
611 against the pharmacy to determine a timeline of events. It was noted that the home state license
612 was suspended, but had since been reinstated. Seeing that the pharmacy was currently in good
613 standing in its home state, the board prepared a motion.

614
615 **On a motion duly made by Tammy Lindemuth and seconded by James Henderson to**
616 **approve the registration application for out-of-state pharmacy, Entirely Pets in accordance**
617 **with AS 08.80.158 and 12 AAC 52.130, it was:**

618
619 **RESOLVED** to approve the out-of-state pharmacy registration application for
620 **Entirely Pets.**

621

	APPROVE	DENY	ABSTAIN	ABSENT
622				
623	Richard Holt	x		
624	Phil Sanders	x		
625	James Henderson	x		
626	Tammy Lindemuth	x		

627
628 The motion passed with no further discussion.

629
630 OMRO Pharmacy
631 The board then reviewed the out-of-state pharmacy registration application of OMRO Pharmacy,
632 with which the board had concerns regarding the criminal history of the owner who is also the
633 pharmacist-in-charge. In his review, Chair Holt came across a previous case of a pharmacy the

634 board had denied and provided a brief synopsis of this case and why the board had denied this
635 application.

636
637 **On a motion duly made by Rich Holt, and upon review of the out-of-state pharmacy**
638 **registration application from OMRO Pharmacy applying under the authority of AS**
639 **08.80.158 and 12 AAC 52.130, it was moved to accept the application in consideration of**
640 **case number 2659-01-001 OAH #08-0344-PHA, AS 08.80.261(a), and AS 08.80.157(d)((h)(2),**
641 **which grants the board the authority to evaluate out-of-state pharmacies applications**
642 **based on convicted felonies of owners and officers of the company, and demonstrated**
643 **proof of providing specific needs to patients in Alaska. It was with unanimous consent:**
644

645 **RESOLVED to deny the out-of-state pharmacy registration application for**
646 **OMRO Pharmacy per AS 08.80.261(a) and AS 08.80.157(d) which authorizes the board to**
647 **deny a registration if approving the registration would not be in the public interest, and**
648 **per AS 08.80.157(h)(2), which authorizes the board to deny a registration if an owner of the**
649 **pharmacy has been convicted of a felony.**
650

	APPROVE	DENY	ABSTAIN	ABSENT
651				
652	Richard Holt	x		
653	Phil Sanders	x		
654	James Henderson	x		
655	Tammy Lindemuth	x		

656
657 The motion did not pass.
658

659 Sterling Pharmacy

660 This application previously resulted in one ‘yes’ and two ‘no’ responses, for which the reasons for
661 the latter were unclear. Mr. Sanders commented on his concerns regarding one of the pharmacy
662 owners being cited for diverting controlled substances, in which the owner was making available a
663 controlled substance to himself without a valid prescription. Ms. Lindemuth commented that the
664 owner had surrendered the license and entered an agreement to address the issue. Mr. Sanders
665 added that after meeting the conditions of probation, the license was subsequently reinstated in
666 2009; however, Chair Holt commented that having the license reinstated, the individual was then
667 convicted of a DUI.
668

669 **On a motion duly made by Tammy Lindemuth and seconded by Rich Holt to approve the**
670 **registration application for out-of-state pharmacy, Sterling Pharmacy in accordance with**
671 **AS 08.80.158 and 12 AAC 52.130, it was:**
672

673 **RESOLVED to approve the out-of-state pharmacy registration application for**
674 **Sterling Pharmacy.**
675

	APPROVE	DENY	ABSTAIN	ABSENT
676				
677	Richard Holt	x		
678	Phil Sanders	x		
679	James Henderson	x		
680	Tammy Lindemuth	x		

681
682 The motion passed with no further discussion.
683
684 After completing discussion and voting for the out-of-state pharmacy registrations, the board then
685 moved to discussing the pharmacy technician application for Elita Cleveland.
686

687 **On a motion duly made by Rich Holt in accordance with AS 44.62.310(c)(2), the board**
688 **unanimously moved to enter executive session for the purpose of discussing subjects that**
689 **tend to prejudice the reputation and character of any person, provided the person may**
690 **request a public discussion.**

691
692 Staff members, Donna Bellino, Laura Carrillo, and Deborah Roesch were authorized to remain in
693 the room.
694

695 *Off record for executive session at 10:35 a.m.*
696 *On record for public discussion at 10:51 a.m.*
697

698 Upon return from executive session, Chair Holt clarified for the record that no motions were
699 made under executive session.
700

701 **On a motion duly made by Rich Holt to accept the pharmacy technician application of**
702 **Elita Cleveland pursuant to 12 AAC 52.140 and AS 08.80.030(b)(9), and in consideration of**
703 **AS 08.80.261(a)(1) that the non-disclosure of criminal information was unintentional, it**
704 **was with unanimous consent:**
705

706 **RESOLVED to deny the pharmacy technician license application of Elita**
707 **Cleveland pursuant to 12 AAC 52.140, AS 08.80.030(b)(9), and AS 08.80.261(a)(1) which**
708 **authorizes the board to evaluate competency and qualifications, and to deny a license**
709 **based on intentional misrepresentation.**
710

	APPROVE	DENY	ABSTAIN	ABSENT
711				
712	Richard Holt	x		
713	Phil Sanders	x		
714	James Henderson	x		
715	Tammy Lindemuth	x		

716
717 The motion did not pass.

718 Chair Holt called for a short break.

719

720 *Off record at 11:01 a.m.*

721 *On record at 11:17 a.m.*

722

723 **Agenda Item 18 Regulation Projects**

Time: 11:17 a.m.

724

725 Chair Holt informed the board that the regulation workflow was included in the board packet for
726 the review and reference. To note was that the PDMP regulations had been signed by the Lt.
727 Governor on May 8th and are to take effect on June 7th, 2018.

728

729 Chair Holt added that the provisions enacted under SB 37 will go into effect on January 1, 2017,
730 and indicated to the board that he started the draft of wholesale drug distributors, third-party
731 logistics providers, outsourcing facilities, and the executive administrator position on this day. The
732 draft was sent to Ms. Bellino for distribution to the board.

733

734 Discussion: Gross Immorality and Moral Turpitude (12 AAC 52.995)

735 Chair Holt stated that new regulations relating to these topics are being introduced because the
736 board's investigator had previously brought a matter to his attention which involved immorality
737 and moral turpitude, but that the board ultimately couldn't take a disciplinary action against a
738 license based on this because it had not been incorporated into regulation. Ms. Bellino prompted
739 the board to clarify if their intent is to create a new section relating to these topics so as to provide
740 a basis for the board to deny or discipline a license. Mr. Henderson inquired as to whether there
741 was current authority to discipline a license based in AS 08.80.261(8); however, these terms are not
742 defined, which would be provided in regulation. Mr. Sanders expressed his concerns about the
743 wording of the proposed language to be amended from "moral turpitude means" to "moral
744 turpitude may mean", so that the language isn't so absolute. Ms. Carrillo suggested that the board
745 incorporate timelines to consider whether an aged crime is significant enough to be considered in
746 weighing the individual's application. Tammy Lindemuth also suggested that the board consider
747 adding language to specify that the crime is a conviction rather than a charge.

748

749 The board discussing establishing a matrix to guide the board in making determinations on
750 applications based on immorality. Ms. Lindemuth inquired whether the matrix would have to be
751 sent to the board, to which Ms. Carrillo stated it could be sent to LAW at the time the regulations
752 draft is reviewed. Chair Holt reiterated that the board historically has sent drafts to law for
753 precursory review; although not required, the board prefers this so they have immediate feedback
754 as to whether they have the statutory authority to implement desired regulations.

755

756 Discussion: Prescription Thresholds

757 Chair Holt indicated that they'll hold off until the board receives clarification on where the 5, 5, 3
758 threshold came from.

759

760 Discussion: Pharmacist-in-Charge (12 AAC 52.200)

761 Chair Holt then moved to the proposed language for 12 AAC 52.200 (pharmacist-in-charge) and
762 inquired why a pharmacist-in-charge would have to practice at a specific location if they've allowed
763 one particular PIC to be in charge at several different pharmacy locations. Mr. Henderson
764 suggested striking the phrase, "must designate a pharmacist who practices in that pharmacy
765 location". Mr. Sanders commented that it doesn't make sense to him to allow one particular PIC
766 over several pharmacies, but is still unsure on how to change the wording. Chair Holt stated that
767 in New York, you have to work a certain number of hours per week to be considered a PIC at a
768 pharmacy. Mr. Sanders agreed that the number of hours or percentage of time could be defined in
769 regulation. Ms. Carrillo inquired as to whether the board was aware of other states allowing for an
770 alternative PIC, to which Ms. Bellino affirmed, stating that some states do allow for an interim
771 PIC. Chair Holt suggested adding language regarding limitations of pharmacies in which a PIC can
772 be in charge over; e.g.: not be a PIC in more than two locations.

773

774 Discussion: Prescription Thresholds

775 Returning back to the discussion on the 5,5,3 threshold, Ms. Bellino informed the board that this
776 was determined during their January 29 - 31, 2014 board meeting. Thresholds are used as a
777 ballpark for a basis of issuing unsolicited reports, and most states use 5>5>3 as a guideline.

778

779 Discussion: Pharmacist-in-Charge (12 AAC 52.200)

780 The board then continued their discussion on change of PIC notifications. Ms. Bellino reiterated
781 the need to improve the formality of the process, and Ms. Carrillo added that these changes need
782 to be closely followed and reinforced. Mr. Henderson stated that there needs to be protection for
783 the out-going PIC if the incoming PIC fails to submit the required form. Ms. Carrillo reiterated
784 the significant responsibilities that pharmacists in charge shoulder. Ms. Carrillo stated for example
785 that in HB 159, all pharmacists are required to report, however, in the board of pharmacy's
786 statutes, the pharmacist-in-charge is specifically responsible for all data reporting. Mr. Henderson
787 suggested having the in-coming and out-going PIC status be on one form. The board continued to
788 discuss whether we should have separate forms for ingoing and ongoing, or if they should be
789 consolidated onto one form. The board also discussed appropriate disciplinary actions for failing
790 to report PIC changes.

791

792 **TASK**

793 Ms. Carrillo will consult with Investigations as to whether boards have fines for similar situations
794 involving failure to notify the department of a required change.

795

796 Mr. Henderson commented on the language in 12 AAC 52.200(a), which states that a pharmacy
797 must have a PIC before the license is issued, but was wondering what would be the case if one was
798 not assigned after the license was issued. Chair Holt stated that a new section could be added
799 stating that the pharmacy could not remain open if there was no active PIC. Ms. Carrillo inquired
800 to the board whether it would be more appropriate to add the language to the section pertaining
801 to the pharmacy, to which Mr. Henderson agreed it could be added to both the 12 AAC 52.200
802 and the section on facilities. Chair Holt added that the language could be added 12 AAC 52.020 in
803 the section relating to facility licenses.

804
805 Discussion: Transfer of a Prescription Drug Order (12 AAC 52.500)
806 The board discussed removing the wording ‘refill’, and Chair Holt stated that at present, patients
807 can take their refill bottle to any pharmacy as long as the pharmacy that is refilling the prescription
808 calls the originating pharmacy to verify the refill prescription. Ms. Lindemuth inquired to the
809 whether this would allow for a transfer of an initial prescription, to which Chair Holt stated that
810 this could be fulfilled if the language relating to “refills” is removed. Ms. Bellino stated that in this
811 case, a pharmacy that does not have the prescription in stock could refer the patient to another
812 pharmacy to have the prescription filled based on that one prescription drug order. James stated
813 this would allow for transfer of orders to different pharmacies for both the initial fill and for
814 refills.

815
816 Discussion: Generic Drugs and Biologics Substitutions (Senate Bill 32; 12 AAC 52.210)

817
818 This bill effectively changed the statutory definition of equivalents and included biosimilar
819 interchangeable; it created a definition that contained language relating to generic drugs and
820 biosimilars. The new changes were as follows:

821
822 * *Sec. 6. AS 08.80.480(34) is amended to read: (34) "substitute" ["SUBSTITUTION"] means to dispense,*
823 *without the prescriber's expressed authorization,*

824 *(A) an equivalent drug product in place of the prescribed drug; or*

825 *(B) an interchangeable biological product in place of the prescribed biological product;*

826
827 Looking at the draft regulations in 12 AAC 52.210, Mr. Henderson commented that mentioning
828 the cost doesn’t seem to fit well in regulation and was concerned that this would be stipulating
829 what can and cannot be dispensed based on the cost of the drug. Mr. Henderson suggested that
830 the intention may have been to protect consumers from unscrupulous prescribers from
831 prescribing high drug prices. Chair Holt stated he reviewed the statutes and regulations to see if
832 there is mention of drug prices, to which there was not. Mr. Henderson suggested striking (a)(3) of
833 12 AAC 52.510.

834
835 Chair Holt called for lunch.

836
837 *Off record for lunch at 1:23 p.m.*

838 *Back on record at 1:49 p.m.*

839
840 Break for a short lunch at 1:23 a.m.

841 Back on record from 1:49 p.m.

842
843 The board resumed discussion on regulations, returning to 12 AAC 52.510(a)(3), which states “the
844 substitute drug product costs the patient less than the prescribed drug product; and”; the board is
845 leaning towards removing this line.

846

847 Discussion: Senate Bill 37 Regulations

848 The board discussed what qualifications the executive administrator (EA) and what duties they
849 would perform. Not having a clear guidance on how to proceed the board will review other EA
850 position descriptions for direction on the best way to proceed.

851
852 Discussion: Drug Disposal Regulations
853 Chair Holt advised that Alaska is one of the few states that does not have regulations regarding
854 this. The board was in consensus this is an important issue and Mr. Sanders was happy to take this
855 project on and will create draft regulations regarding drug disposal.

856
857 **TASK**

858 Mr. Sanders will begin draft regulations on drug disposals.

859
860 The board moved to making a motion on approving the regulations draft:

861 **12 AAC 52.995 DEFINITIONS**

862 **(36) In AS 08.80.261(8),**

863 **“gross immorality” means conduct that goes flagrantly beyond accepted standards of what is**
864 **right or just in behavior or is unmitigated in any way.**

865 **“moral turpitude” means**

866 **(a) conduct that is considered contrary to community standards of justice, honesty, or**
867 **good morals,**

868 **(b) conduct that is wrong in itself even if no statute were to prohibit the conduct, or**

869 **(c) a crime that includes a conviction or indictment of**

870 **(1) homicide;**

871 **(2) manslaughter;**

872 **(3) assault;**

873 **(4) stalking;**

874 **(5) kidnapping;**

875 **(6) sexual assault;**

876 **(7) sexual abuse of a minor;**

- 877 **(8) unlawful exploitation of a minor, including possession or distribution of child**
878 **pornography;**
- 879 **(9) indecent exposure;**
- 880 **(10) unlawful distribution or possession for distribution of a controlled substance;**
- 881 **(11) prostitution;**
- 882 **(12) sex trafficking.**
- 883 **(13) murder;**
- 884 **(14) human trafficking;**
- 885 **(15) criminal sexual conduct;**
- 886 **(16) incest;**
- 887 **(17) robbery;**
- 888 **(18) extortion;**
- 889 **(19) forgery;**
- 890 **(20) theft;**
- 891 **(21) endangering the welfare of a child;**
- 892 **(22) endangering the welfare of a vulnerable adult; or**
- 893 **(23) reckless endangerment.**

894 **12 AAC 52.200. PHARMACIST-IN-CHARGE.**

895 (a) Before the board will issue a license to a pharmacy, the owner of the pharmacy must designate a
896 pharmacist who practices in that pharmacy location as the pharmacist-in-charge of the pharmacy in
897 accordance with AS 08.80.330. For a remote pharmacy, the owner of the central pharmacy must
898 designate a pharmacist in the central pharmacy as the pharmacist-in-charge of the remote pharmacy.
899 The board will indicate the name of the pharmacist-in-charge on the face of the pharmacy license.

900 (b) The responsibilities of the pharmacist-in-charge include

- 901 (1) compliance with all laws and regulations governing the activities of the pharmacy;
- 902 (2) training of all pharmacy personnel;

- 903 (3) establishing policies and procedures for pharmacy operations;
- 904 (4) maintaining required records;
- 905 (5) storage of all materials, including drugs and chemicals;
- 906 (6) establishing and maintaining effective controls against theft or diversion of prescription
907 drugs; and
- 908 (7) on request, reporting to the board the names of all pharmacists employed by the pharmacy.
- 909 (c) A pharmacist designated to replace the pharmacist-in-charge of a pharmacy shall notify the board
910 within 10 days of that designation **on a form provided by the department.**
- 911 **(d) An out-going pharmacist-in-charge shall notify the board within 10 days when they are no**
912 **longer the current pharmacist-in-charge of the licensed facility on a form provided by the**
913 **department.**
- 914 **(e) In accordance with AS 08.80.330, a pharmacy cannot be open for business without a**
915 **pharmacist-in-charge on the license.**
- 916 **12 AAC 52.020. FACILITY LICENSE.** (a) An applicant for a facility license shall submit
- 917 (1) the fees required in 12 AAC 02.310;
- 918 (2) a completed application on a form provided by the department;
- 919 (3) within 14 days after commencement of business, a completed self-inspection of the premises
920 questionnaire on a form provided by the department; and
- 921 (4) the name of the pharmacy or pharmacist that will provide consultant pharmacist services as
922 required in AS 08.80.390, if applicable.
- 923 (b) *Repealed 1/17/2007.*
- 924 (c) An application for a remote or other pharmacy license must include the name of the pharmacist
925 designated to be the pharmacist-in-charge as required in AS 08.80.330 and 12 AAC 52.200.
- 926 (d) An application for a pharmacy license must include the name and specific location of each remote
927 pharmacy that will be under that pharmacy's control.

928 (e) An application for a remote pharmacy license must include the name and, if it has been issued, the
929 license number of the pharmacy that is the central pharmacy.

930 **(f) In accordance with AS 08.80.330, a pharmacy cannot be open for business without a**
931 **pharmacist-in-charge on the license.**

932 **12 AAC 52.050. CLOSED PHARMACIES.**

933 (a) When a pharmacy ceases operations, the pharmacist-in-charge of that pharmacy shall

934 (1) **submit to notify** the board **on a form provided by the department a written notice** of the
935 cessation of pharmacy operations; the **written notice form** must be submitted within 10 days
936 after the cessation of operations and include

937 **12 AAC 52.500. TRANSFER OF A PRESCRIPTION DRUG ORDER.**

938 (a) For the purpose of dispensing **a refill of** a prescription drug order, original prescription drug order
939 information may be transferred between pharmacies if the requirements of 12 AAC 52.460 and this
940 section are met.

941 **12 AAC 52.510. SUBSTITUTION.**

942 (a) A pharmacist may dispense **an equivalent drug a substitute drug** product instead of the prescribed
943 drug if

944 (1) the prescribing practitioner does not hand write or electronically note on the prescription drug
945 order that a specific brand must be dispensed, using language such as “brand medically necessary”
946 or similar wording;

947 (2) the patient is notified and consents to the substitution;

948 (3) **repeal.** the equivalent drug product costs the patient less than the prescribed drug product; and

949 (4) for the **substitute** drug product actually dispensed, the pharmacist notes on the prescription drug
950 order one of the following:

951 (A) the drug product’s manufacturer or distributor;

952 (B) national drug code number;

953 (C) short name code; or

954 (D) trade name.

955 (b) The determination of the **substitute** drug product to be dispensed for a prescription drug order is a
956 professional responsibility of the pharmacist. A pharmacist may not dispense any product that in the
957 pharmacist's professional opinion is not ~~an equivalent drug product a substitute~~ as the term
958 "~~equivalent drug product substitute~~" is defined in AS 08.80.480.

959 **(c) In AS 08.80.295(e), "Entry into an electronic records system" means creating an electronic**
960 **dispensing record in the patient profile of the pharmacy computer system regardless if the**
961 **practitioner has direct electronic access to the pharmacy computer system.**

962 **Authority:** AS 08.80.005 AS 08.80.030 AS 08.80.295

963 **12 AAC 52.340 APPROVED PROGRAMS.**

964 (a) The following programs will be accepted by the board as continuing education for pharmacists and
965 pharmacy technicians under 12 AAC 52.320 and 12 AAC 52.325:

966 (1) any program presented by a provider accredited by the ACPE **and results in a continuing**
967 **education certificate showing the date of the course and the ACPE Universal Activity**
968 **Number associated with the program;**

969 (2) cardiopulmonary resuscitation (CPR) courses presented by the American Red Cross or the
970 American Heart Association that lead to CPR certification; the board will accept no more than
971 one contact hour of continuing education credit in a 24 month period for completion of a CPR
972 course.

973 (b) The following programs will be accepted by the board as continuing education under 12 AAC
974 52.325, when the subject contributes directly to the professional competency of a pharmacy technician
975 and is directly related to pharmacy principles and practice:

976 (1) any program presented or approved by the Alaska Pharmacists Association;

977 (2) any program presented or approved by the Pharmacy Technician Certification Board
978 (PTCB) or the National Pharmacy Technician Association (NPTA).

979 (c) An individual who presents an approved continuing education program may receive credit for the
980 time spent during the actual presentation of the program. An individual may not receive credit for the
981 same presentation more than once during a licensing period.

982 **On a motion duly made by Rich Holt to accept the amended changes and additions to the**
983 **drafted regulations, and seconded by Tammy Lindemuth with unanimous consent, it was:**

984

985 **RESOLVED** to approve the draft regulations and to send the draft to the
986 regulations specialist for cursory review by the department of law.

987

	APPROVE	DENY	ABSTAIN	ABSENT
988				
989	Richard Holt	x		
990	Phil Sanders	x		
991	James Henderson	x		
992	Tammy Lindemuth		x	

993
994 The motion passed.

995
996 Agenda item #s 19 and 20 related to regulation projects; however, the board did briefly return to
997 discussing PDMP fees. It was clarified for that only pharmacists who are dispensing federally
998 scheduled II – IV controlled substances in Alaska are required to register and pay the fee.
999

1000 **TASK**

1001 Ms. Carrillo will create a PDMP pharmacist dispensing status form for Chair Holt to review.

1002
1003 **Agenda Item 21 Set Meeting Dates Time: 2:45 p.m.**

1004
1005 Ms. Bellino reminded the board that the August 16 – 17, 2018 meeting date was already set and
1006 that it would be held in Anchorage. Ms. Bellino stated she would send an email survey to the
1007 board to establish a date for the November 2018 meeting.

1008
1009 **TASK**

1010 Ms. Bellino will send out a survey to gauge board member availability for the November 2018
1011 meeting.


1012
1013 **Agenda Item Adjourn Time: 3:08 p.m.**

1014
1015 On a motion duly made by Phil Sanders and seconded by James Henderson, the board decided to
1016 adjourn at 3:08 p.m.

1017
1018 *Laura Carrillo 09/05/2018*

1019
1020

Laura Carrillo, Records & Licensing Supervisor

1021
1022 
1023

1024 Rich Holt, Chair

1025