

1 157.12 PROPOSED RULE
2 TEXAS ~~ACCREDITATION PROCESS~~AIR MEDICAL
3 LICENSURE RULE DRAFT
4 MAY 2010
5

- 6 (a) The Air Medical Provider seeking licensure through the State of Texas who does not wish to
7 obtain deemed status through Commission on Accreditation of ~~Air~~ Medical Transport
8 Services (CAMTS) Accreditation must acquire ~~Accreditation, and therefore~~ licensure,
9 through the ~~Texas Accreditation Process~~ Licensure Rule(TAP).
10 (1) Submission of the appropriate application, self assessment and supporting documents
11 must be submitted to DSHS prior to the establishment of a new Air Medical Program.
12 (A) Initial applicants *may* initiate a pre-survey process with a DSHS-approved surveyor.
13 The surveyor and applicant will undertake an evaluation of the applicant's training,
14 resources and plans concerning Air Medical Operations to assist the program in
15 preparation for the initial TAP Licensure.
16 (B) Initial applicants will be licensed with a provisional license upon successful
17 completion of the initial TAP Licensure.
18 (C) A provisional initial license holder must complete a ~~TAP re-accreditation~~ the
19 Licensure survey not less than 12 months or more than 15 months after the initial
20 provisional license issuance.
21 (D) A provisional initial license holder who successfully completes a ~~TAP re-accreditation~~
22 the Licensure survey will be awarded regular license status.
23 (2) Established Air Medical Programs (AMP's) who wish to seek licensure through the
24 ~~Texas Accreditation Process~~ Licensure Rule must complete their survey process and
25 obtain re-licensure within two years after the effective date of the TAP Licensure Rule to
26 remain an Air Medical Provider.
27 (3) The complete self assessment package with supporting documents will be completed and
28 submitted with the application for provider license to DSHS.
29 (A) The self assessment, documentation and application must be submitted in electronic
30 format as acceptable by DSHS.
31 (i) Documentation must include:
32 (aa) Current FAA Part 135 Air Carrier Certificate.
33 (bb) Current individual aircraft FAA Airworthiness Certificate(s).
34 (cc) All other documentation as required to demonstrate evidence of program
35 components.
36 (A) Associated fees must be included with application.
37 (B) All program records that support the ASP process must be on site during the site
38 survey.

- 39 (C) Established Air Medical Providers must provide a minimum of 6 months documented
40 compliance with the ASP requirements prior to the date of application.
- 41 (D) Application for initial provider license must show documentation of protocols,
42 policies, procedures, training, Quality Improvement (QI) and evaluation of outcomes
43 that comply with the ASP requirements.
- 44 (4) Notification of the intent to perform a site visit will be delivered to the AMP 90 days in
45 advance.
- 46 (A) The site visit cannot be delayed by the AMP more than 90 days after intent to visit
47 date established by DSHS.
- 48 (B) The site visit team will be composed of DSHS department representatives along with
49 other AMP Personnel which could include but is not limited to:
- 50 (i) Physician Medical Director
51 (ii) AMP Administrator
52 (iii) AMP Educator
53 (iv) AMP Nurse or Paramedic
54 (v) AMP Pilot
55 (vi) AMP Mechanic
56 (vii) Federal Aviation Administration (FAA) Representative
- 57 (C) The AMP is responsible for reasonable expenses incurred by Non-DSHS Department
58 Members conducting the review.
- 59 (5) The site visit team will establish and provide a schedule to the applicant.
- 60 (A) No personnel or program component may be excluded or exempt from participation
61 in site survey.
- 62 (B) Scheduled activities may include but are not limited to:
- 63 (i) Meeting with the AMP Medical Director and Administrator.
64 (ii) Interviewing staff members.
65 (iii) Reviewing records.
66 (iv) Interviewing hospitals and other appropriate regional personnel.
67 (v) Site visits to bases, offices and communication centers.
68 (vi) Preparation of initial evaluation in the form of a short oral summary of what was
69 found by the survey team to AMP by evaluators prior to completion of survey.
70 (vii) Programs will provide clarification of evaluation points to evaluators.
- 71 (C) A copy of the final written report will be mailed to DSHS and the Air Medical
72 Program Director within 30 days of the completion of the site visit.
- 73 (i) Deficiencies may result in disciplinary action as authorized by §157.16 of this
74 title (relating to Emergency Suspension, Suspension, Probation, Revocation or
75 Denial or a Provider License). The department may grant a reasonable period of
76 time for the provider to correct deficiencies as defined in §157.16 . If the
77 department must reinspect the provider because of noncompliance noted during a

- 78 previous inspection, the provider shall pay a nonrefundable administrative fee, if
79 applicable.
- 80 (ii) Failure to correct identified deficiencies within a period of time determined to be
81 reasonable by the DSHS or if the deficiencies are found to be repeated, the
82 provider shall be subject to disciplinary actions in accordance with §157.16 of this
83 title.
- 84 (6) If a provider changes any part of the originally completed survey process it must be
85 reported to DSHS in writing within (XX) days with an explanation.
- 86 (A) DSHS will evaluate the change and decide if a new site visit is warranted to assure
87 compliance with the ASP.
- 88 (7) DSHS regional office may perform or order an unannounced site visit at any time.
- 89 (8) Program renewal applications must consist of an update to the original program self
90 assessment that addresses and documents all changes and updates to the program.
- 91 (A) DSHS requires an on-site survey to renew a provider license.
- 92 (9) A program may contest, in writing, a site survey result to DSHS no later than 30 days
93 after the receipt of the rejection of application for initial or renewal licensing.
- 94 (A) Appeals must include either supporting documentation to refute the deficiencies or
95 provide an acceptable plan of corrective action to correct the deficiencies.
- 96 (B) Appeals will be reviewed by DSHS with decision delivered within (XX) calendar
97 days after receipt of appeal.
- 98 (b) The AMP must demonstrate a hiring, education and credentialing process.
- 99 (1) The AMP should be able to provide a job description for each clinical and operational
100 position.
- 101 (A) The AMP must document a process by which air medical personnel applicants are
102 screened to insure that they meet the minimum qualifications for the position for
103 which they apply.
- 104 (2) The AMP must administer an employment application process that includes an
105 assessment of the candidate's knowledge, skills and experience.
- 106 (3) After selection for employment, the AMP should have a credentialing process that
107 incorporates the following:
- 108 (A) A defined preceptor selection process.
- 109 (i) That involves the Medical Director in the selection of appropriate preceptors.
- 110 (ii) The Medical Directors approval of the development and training of preceptors.
- 111 (B) The Medical Directors established clinical competencies.
- 112 (C) The Program Director established program competencies.
- 113 (D) New employee proficiency criteria:
- 114 (i) The new employee must attend an initial didactic training session.
- 115 (ii) The new employee must demonstrate understanding of aircraft safety, protocols,
116 procedure manuals, and proficiency in clinical procedures to the agency's
117 standard.

- 118 (aa) In accommodating airframes, new employees will ride as 3rd person until
119 the preceptor establishes that the new employee has met pre-established
120 competencies as defined by the Medical Director and Program Director.
- 121 (aa) In airframes that cannot accommodate a “third” person, new employees
122 will ride as a 2nd person until preceptor establishes that the new employee
123 meets the prerequisites for independent duty as determined by the Medical
124 Director and Program Director.
- 125 (E) New employees must demonstrate proficiency to second evaluator.
- 126 (4) New employee clinical evaluation must be completed using:
- 127 (A) A process that allows the new employee to evaluate the new employee program.
128 (B) A process to promote inter-rater reliability.
- 129 (5) A process for remediation and reeducation must be defined.
- 130 (6) A representative sample of call types (minimum number to be determined by the Medical
131 Director) of critically ill adult patients, pediatric patients and trauma patients will be
132 correctly cared for by the new employee prior to release from new employee.
- 133 (7) Must demonstrate loop closure from preceptor to new employee and from new employee
134 back to preceptor in evaluation.
- 135 (8) The AMP must maintain documentation that employee certifications and/or licensures are
136 verified.
- 137 (9) The AMP must maintain documentation of a system that requires each patient care
138 provider to demonstrate skills appropriate for their level of training to the satisfaction of
139 the Medical Director.
- 140 (10) The AMP must have an established process for reintegration of personnel.
- 141 (11) The AMP must have an established policy for administrative personnel to remain
142 field credentialed.
- 143 (12) The AMP must at a minimum document initial demonstration of patient care
144 skills, scene control skills, program competencies, ethics, compliance, and to include but
145 not be limited to:
- 146 (A) Advanced airway management.
147 (B) Altitude physiology.
148 (C) Stressors of flight.
149 (D) Anatomy and physiology along with assessment of adult, pediatric and neonatal
150 patients, as appropriate, within the programs scope of care.
151 (E) Aircraft and ambulance orientation including safety procedures (for all crew members
152 including specialty team members).
153 (F) Emergency access and egress training.
154 (G) Orientation to all emergency procedures.
155 (H) Air Medical Service Crew Resource Management including human factors, stress
156 recognition and management.
157 (I) Survival training.

- 158 (J) Cardiac emergencies and advanced cardiac critical care.
- 159 (K) Mission specific education for patient populations encountered (i.e. environmental
- 160 emergencies, high risk OB, multi-system trauma, neonatal emergencies, thermal
- 161 related injuries, etc.).
- 162 (L) Disaster and triage including Hazardous Materials (Haz-Mat) recognition and
- 163 response.
- 164 (M) Radio communications.
- 165 (N) Hemodynamic monitoring, pacemakers (invasive and non invasive), automatic
- 166 implantable cardiac defibrillators, intra-aortic balloon pump, central lines, pulmonary
- 167 artery and arterial catheters, ventricular assist devices and extracorporeal membrane
- 168 oxygenation (ECMO), as appropriate, within the programs scope of care.
- 169 (O) Infectious control.
- 170 (P) Mechanical ventilation and respiratory physiology for adult, pediatric and neonatal
- 171 patients, including oxygen therapy in the transport environment.
- 172 (Q) Pediatric medical and trauma emergencies.
- 173 (R) Pharmacology.
- 174 (S) Quality Management education.
- 175 (T) Respiratory emergencies.
- 176 (U) Scene management.
- 177 (c) The AMP must implement and maintain Professional Development Programs that:
- 178 (A) Reinforce and expand the knowledge base of the individual provider.
- 179 (B) Have objectives based upon quality improvement outcomes.
- 180 (C) Are designed to incorporate best practices from industry, Protocol Development
- 181 Review Committee (PDRC), and Quality Improvement Committee (QIC).
- 182 (2) The AMP will maintain minimum professional requirements.
- 183 (A) Hours as required by the professional certifying or licensing authority.
- 184 (B) Consisting of at least 50% in person training.
- 185 (C) Must offer a Professional Development Program on at least a semi-annual basis.
- 186 (D) The Medical Director shall be responsible for defining and approving the objectives
- 187 of the professional development hours.
- 188 (3) The AMP will provide Professional Development Training Programs that annually
- 189 include:
- 190 (A) Hazardous Materials.
- 191 (B) Human Factors and Crew Resource Management (including specialty team
- 192 members).
- 193 (C) Infectious Control.
- 194 (D) State EMS rules and regulations regarding ground and air transport.
- 195 (E) Stress recognition and management.
- 196 (F) Survival Training (including specialty team members).

- 197 (G) Medical patient transport considerations (assessment/treatment/preparation
198 handling/equipment)
199 (H) Day and night flight protocols
200 (I) General aircraft safety including (including specialty team members): Emergency
201 shut down and aircraft evacuation procedures.
202 (J) Aviation terminology and communications procedures including emergency
203 frequency uses.
204 (K) In flight and ground fire suppression procedures (fire extinguishers)
205 (L) In flight emergency landing procedures.
206 (M) Safety in and around the aircraft, including FAA rules and regulations pertinent to
207 safety for medical team members, patient(s) and lay individuals.
208 (N) Specific capabilities and limitations for each aircraft used, which includes backup
209 aircraft.
210 (O) Use of emergency locator transmitter (ELT)
211 (P) Scene landing operations.
212 (Q) Hospital landing site changes or special needs review.
213 (R) Patient loading and unloading (including specialty team members)
214 (S) Refueling policy for normal and emergency situations.
- 215 (4) The AMP shall provide outreach professional development:
216 (A) That clearly identifies the FAA Part 135 Certificate Holder as the entity that is
217 operating the aircraft.
218 (B) The Air Medical Provider must provide education regarding safe Ground Operations
219 in and around the aircraft.
220 (C) Safety program consisting of patient preparation criteria and personal safety around
221 the aircraft.
222 (i) Including landing zone (LZ) designation for rotor wing services.
223 (ii) Information on how to initiate a flight.
224 (iii) Hours of operations.
225 (iv) Helicopter shopping dangers.
226 (v) Access to services/services available from the flight program including crew
227 composition and specialty teams.
- 228 (d) An AMP must demonstrate protocol administration and oversight.
229 (1) The AMP must demonstrate that the protocol is annually reviewed and updated.
230 (A) Ensuring that the protocol review incorporates evidence based best practices and data.
231 (B) Must review recommendations as proposed by the PDRC for incorporation.
232 (2) The AMP protocol must be executed/approved by the Medical Director.
233 (3) The AMP must demonstrate a process for assessing relative benefit from protocol
234 revisions.
235 (4) The protocol criteria will be jointly defined by the Medical Director and by the provider's
236 PDRC.

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- 237 (5) The AMP must demonstrate protocol compliance.
- 238 (A) The AMP must demonstrate the level of clinical care provider proficiency as defined
- 239 by the Medical Director.
- 240 (B) The AMP must demonstrate a remediation process for clinical care providers and
- 241 timeline that clearly identifies the criteria for successful completion and for
- 242 revocation of credentials.
- 243 (e) The AMP must demonstrate operational standards:
- 244 (1) The AMP must demonstrate aircraft design and configuration that does not compromise
- 245 patient stability in loading, unloading or in-flight operations.
- 246 (A) The aircraft must have an entry that allows loading and unloading without excessive
- 247 maneuvering (no more than 45 degrees about the lateral axis and 30 degrees about the
- 248 longitudinal axis) of the patient, and does not compromise functioning of monitoring
- 249 systems, intravenous lines, and manual or mechanical ventilation.
- 250 (B) The AMP must demonstrate that aircraft have a minimum of one stretcher/sled.
- 251 (i) The stretcher/sled must be able to be carried to the patient.
- 252 (ii) The AMP must demonstrate ~~aircraft stretchers and~~ the means of securing
- 253 ~~stretchers/sleds that are in-flight must be~~ consistent with FAR's.
- 254 (iii) The AMP must demonstrate a policy that indicates the maximum gross weight
- 255 allowed on the stretcher (inclusive of patient and equipment) as consistent with
- 256 manufacturer's guidelines.
- 257 (iv) The stretcher must be large enough to carry the 95th percentile adult patient, full
- 258 length in the supine position. (The 95th percentile adult American male is 6 ft.
- 259 and 212 lbs.)
- 260 (v) The stretcher should be sturdy and rigid enough that it can support
- 261 cardiopulmonary resuscitation. If a backboard or equivalent device is required to
- 262 achieve this, such device will be readily available.
- 263 (vi) The head of the stretcher must be capable of being elevated at least 30 degrees for
- 264 patient care and comfort.
- 265 (vii) If the stretcher is floor supported by its own wheels, there must be a
- 266 mechanism to secure it in position under all conditions. These restraints permit
- 267 quick attachment and detachment for patient transfer.
- 268 (C) The AMP must demonstrate operational standards that require securing the patient to
- 269 the stretcher/sled.
- 270 (i) Patients transported by air are restrained with a minimum of three cross straps and
- 271 shoulder straps that must comply with FAA regulations including applicable
- 272 STCs. (cross straps are expected to restrain the patient at the chest, hips and
- 273 knees). Belt locations should be adjustable along the length of the stretcher to
- 274 accommodate patients' specific medical situations (Such as pregnant patients or
- 275 specific injury locations)
- 276 (ii) Patients less than 60 pounds (27kg.) ~~should be provided-must be secured~~ with an
- 277 appropriately sized ~~FAA approved~~ restraining device (for patient's height and
- 278 weight), which ~~is further-must be~~ secured by a FAA approved locking device that
- 279 allows good access to the patient from all sides and permits the patients head to be
- 280 raised at least 30 degrees.

- 281 | ~~(ii)~~(iii) Patients less than 40 pounds (18kg) must be secured in a five-point safety
282 | strap device that allows good access to the patient from all sides and permits the
283 | patients head to be raised at least 30 degrees.
- 284 | (2) The AMP must demonstrate operational standards that address the use of an Isolette
285 | when it is part of the AMP's mission profile.
- 286 | (A) There must be a restraining device within the isolette to protect the infant in the event
287 | of air turbulence or poor road conditions.
- 288 | (B) Isolettes must be capable of being opened from its secured position in order to
289 | provide full access to the infant in the event of complicated airway problems or
290 | extrication from the isolette becomes necessary.
- 291 | (3) The AMP must demonstrate an aircraft policy to address the need for supplemental
292 | lighting system installed in any aircraft in which standard lighting is insufficient for
293 | patient care.
- 294 | (A) A self-contained lighting system may be powered by a battery pack or a portable light
295 | with a battery source must be available.
- 296 | (B) In an aircraft, there must be a means to protect the pilot's night adaptation vision
297 | provided for night operations, either through the medical configuration or by a
298 | dividing curtain. (Use of adaptive lighting or low intensity lighting in the patient care
299 | area is acceptable if not able to isolate the patient care area.)
- 300 | (4) The AMP must document that medical equipment complies with the applicable F.A.R. on
301 | avionics interference.
- 302 | (5) The AMP Aircraft must have operational controls and communications equipment that
303 | are physically protected from any intended or accidental interference by the patient,
304 | medical transport personnel, or equipment and supplies.
- 305 | (6) The AMP must demonstrate policies that address storage, maintenance, use and
306 | accessibility of inhaled gases appropriate to the AMP mission profile.
- 307 | (7) The AMP must demonstrate policies that address medication:
- 308 | (A) Storage within the manufacturers recommendations
- 309 | (B) Security that complies with federal and state narcotic laws
- 310 | (8) The AMP must demonstrate policies that require environmental temperature control and
311 | address the effects of hyperthermia and hypothermia extremes on patients and crew.
- 312 | (9) The AMP must demonstrate that it is providing equipment to support patient care such as:
- 313 | (A) Cardiac monitor, defibrillator and external pacemaker that are secured and positioned
314 | so that displays are visible.
- 315 | (B) Ventilator capable of supporting the AMP's mission.
- 316 | (C) ~~3 Chamber~~ Intravenous administration device/pump(s) capable of infusing three
317 | medications simultaneously-
- 318 | (i) May not substitute mechanical metering devices for infusion pump.
- 319 | (D) Vital sign monitoring capable of non-invasive blood pressure, heart rate, external
320 | temperature, pulse oxymetry, exhaled carbon-dioxide, endotracheal end tidal CO2.
- 321 | (E) Additional devices as determined by the AMD.
- 322 | (F) Electric power outlet must be provided with an inverter or appropriate power source
323 | of sufficient output to meet the requirements of the complete specialized equipment
324 | package without compromising the operation of any electrical aircraft/ambulance
325 | equipment. (An extra battery may be the back-up power source for equipment.)

326 (G)AMP must document a program of biomedical support for the devices as required by
327 the device manufacturers.

328 (10) The AMP must demonstrate written operational policies to address personnel
329 staffing:

330 (A) That demonstrates ~~strategies-policies~~ to evaluate fitness for duty including rest prior
331 to duty time, to minimize duty-time fatigue, to monitor length of shifts, number of
332 shifts per week and day-to-night rotations.

333 (B) That documents scheduled clinical personnel shift times that do not exceed 24 hours.

334 (i) Exceeding twenty-four hours in exigent circumstances is permitted on infrequent
335 basis, and must be documented and evaluated by the SMSC.

336 (ii) During exigent shifts beyond twenty-four hours, the AMP must evaluate fitness
337 for duty of personnel on an ongoing basis during the additional hours.

338 (aa) Exigent shifts beyond twenty-four hours will not be permitted to exceed
339 thirty-six hours in total duty time.

340 (iii) That documents clinical personnel twenty-four-hour shifts that:

341 (aa) Do not include any duties beyond those associated with the transport
342 service.

343 (bb) Clinical personnel are provided with access to and permission to
344 uninterrupted rest after daily medical personnel duties are met.

345 (cc) The physical base of operations includes an appropriate place for
346 uninterrupted rest.

347 (iv) That documents communications personnel twelve hour shifts that:

348 (aa) Do not include any duties beyond those associated with the transport
349 service.

350 (bb) A secure environment that is free of non communications essential
351 distractions.

352 (v) The AMP must demonstrate policies that require all personnel must have at least
353 eight hours of rest with no work-related interruptions prior to any scheduled shift
354 of twelve hours or more. Aviation and aircraft maintenance personnel must adhere
355 to the applicable F.A.R.s.

356 (vi) The AMP must demonstrate policies that all personnel have the right to call "time
357 out" and be granted a reasonable rest period if the team member (or fellow team
358 member) determines that he or she is unfit or unsafe to continue duty, no matter
359 what the shift length. There should be no adverse personnel action or undue
360 pressure to continue in this circumstance.

361 (vii) The AMP must demonstrate policies that require management to monitor
362 transport volumes and personnel's use of "time out" policy.

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- 363 (viii) AMP must have policies that address crew interface requiring team
364 members to stay alert on all legs of the transport, requiring at least one team
365 member on empty legs, to assist the pilot in staying alert.
- 366 (C) The AMP must demonstrate programs to promote personnel well being through:
367 (i) Wellness programs that promote healthy lifestyles (e.g. balanced diet, weight
368 control, no smoking).
369 (ii) Evidence of an injury prevention program and ergonomic strategies to reduce
370 employee injuries.
- 371 (f) The AMP must demonstrate Program Administrative oversight.
- 372 (1) The AMP must provide an organizational chart that outlines a well defined line of
373 authority.
- 374 (2) This reporting structure should support following chain of command when addressing or
375 handling issues or concerns within the complexity of the air medical program.
376 (A) There should be a clear and direct method in place for reporting information within
377 the organization with rapid communication throughout.
378 (B) There should be a mechanism in place for loop closure.
- 379 (3) The AMP must ensure that a policy manual is available and familiar to all personnel.
380 (A) Policies are dated and signed by the appropriate manager(s).
381 (B) Policies are reviewed on an annual basis.
- 382 (4) The AMP must demonstrate that all disciplines understand their role in aviation
383 operations and Operational Control.
384 (A) Hospital or non-hospital based program director/administrator must be oriented to
385 [Flight Federal](#) Aviation Regulations (FAR's) that are pertinent to the medical service
386 and state ambulance rules.
- 387 (5) The AMP should have a policy in place that documents the employer's disciplinary
388 process.
- 389 (6) The AMP will document formal, periodic staff meetings for which minutes will be kept
390 for four years.
391 (A) Minutes will document attendance, base identification and who is presiding and any
392 discussion items.
393 (B) The AMP must demonstrate a process for disseminating information between
394 meetings.
- 395 (7) The AMP management must demonstrate written guidelines for media issues and
396 marketing activities.
- 397 (8) The AMP must demonstrate a policy that addresses transfers of patient care occur from a
398 lower level of care to an equal or higher level of care, except for elective transfers.
- 399 (9) The AMP must demonstrate an appropriate utilization review process through trending
400 and tracking requests.
401 (A) The AMP must provide evidence of feedback to the requesting agents and feedback
402 from the patient receiving facilities.

- 403 (B) The AMP must demonstrate utilization review that may be prospective, concurrent, or
404 retrospective.
- 405 (C) The AMP's collected data must be tabulated.
- 406 (D) The AMP must establish trigger criteria for utilization review.
- 407 (10) The AMP ~~must establish and demonstrate a practice has a written code~~ of ethical
408 ~~conduct that demonstrates ethical practices in business, clinical operations, marketing and~~
409 ~~professional conduct.~~
- 410 ~~(A) The AMP must provide evidence of use of a written code of ethical conduct.~~
- 411 ~~(i) The AMP must demonstrate ethical practices in business operations.~~
- 412 ~~(ii) The AMP must demonstrate ethical practices in marketing.~~
- 413 ~~(iii) The AMP must demonstrate ethical practices in professional conduct.~~
- 414 ~~(B) The AMP must demonstrate ethical practices in clinical operations.~~
- 415 ~~(C) (A) The AMP must demonstrate a written compliance plan that is in accordance with~~
416 ~~the HHS OIG's "Compliance Guidance for Ambulance Providers".~~
- 417 ~~(D) The AMP Ethical/Compliance (EC) Plan must contain the following elements:~~
- 418 ~~(i) Ethical and Compliance Management Plan (EMP)~~
- 419 ~~(aa) — The AMP must clearly states the policies, objectives and requirements of~~
420 ~~the EMP.~~
- 421 ~~(bb) — The AMP's plan must define each element of the EMP.~~
- 422 ~~(cc) — The plan must clearly identify the responsibilities and authority of key~~
423 ~~individuals for managing the EMP.~~
- 424 ~~(ii) EC Promotion~~
- 425 ~~(aa) — The AMP must clearly demonstrate that EC is a core value through~~
426 ~~procedures, practices and training.~~
- 427 ~~(iii) Document and Data Information Management~~
- 428 ~~(aa) — The AMP must clearly document and publicize the organization's EC~~
429 ~~policies, objectives and EMP.~~
- 430 ~~(bb) — The AMP demonstrates that the organization provides change control for~~
431 ~~all applicable documents and has a process to communicate changes in~~
432 ~~documents to all personnel.~~
- 433 ~~(cc) — The AMP must establish periodic review of all EC documents.~~
- 434 ~~(iv) Occurrence Reporting~~
- 435 ~~(aa) — The AMP must demonstrate procedures for New employeeal reporting of~~
436 ~~EC concerns.~~
- 437 ~~(v) Occurrence Investigation and Analysis~~
- 438 ~~(aa) — Every EC concern must be investigated by the AMP.~~
- 439 ~~(bb) — All investigations must be documented with an analysis by the AMP.~~

- 440 ~~(vi) EC Oversight Programs.~~
- 441 ~~(aa) The AMP must demonstrate oversight programs that evaluate the~~
- 442 ~~effectiveness of the EMP.~~
- 443 ~~(bb) The AMP's oversight programs must include New employeeal and~~
- 444 ~~external assessments.~~
- 445 ~~(cc) The AMP must demonstrate that all oversight programs are integrated.~~
- 446 ~~(vii) EC Training Requirements~~
- 447 ~~(aa) The AMP must document that all personnel are given introductory and~~
- 448 ~~recurrent EC training.~~
- 449 ~~(bb) The training requirements for the AMP must include:~~
- 450 ~~— 1. An EC orientation for all new personnel, stressing the AMP's~~
- 451 ~~commitment to ethics and compliance including everyone's role in the~~
- 452 ~~EMP.~~
- 453 ~~— 2. A tracking mechanism for training requirements.~~
- 454 ~~— 3. Access to conferences, workshops, literature and trade journals.~~
- 455 ~~(viii)(i) Management of Change~~
- 456 ~~(aa) The AMP must have a process to ensure that all personnel are made aware~~
- 457 ~~of and understand any changes in requirements and policies.~~
- 458 ~~(ix)(ii) Key Objectives and Continuous Improvement~~
- 459 ~~(aa) The AMP must identify key Ethics Compliance objectives.~~
- 460 ~~(bb) The AMP must demonstrate Ethics Compliance key objectives which are~~
- 461 ~~tailored to the size, nature and complexity of the organization.~~
- 462 ~~(cc) The AMP must demonstrate proactive and reactive monitoring of key~~
- 463 ~~Ethics Compliance objectives.~~
- 464 ~~(dd) The AMP must demonstrate response to detected offenses and~~
- 465 ~~development of corrective action plans.~~

466 (iii) The AMP must demonstrate a policy that incorporates Just Culture principles.

467 (B) The AMP must demonstrate specific guidelines for transport requests that are not

468 performed directly by the AMP for referring flights, subcontracting flights or outsourcing flights

469 to Texas Licensed AMPs.

470 (i) Brokering of flight requests is not permitted.

471 (C) The AMP will know the capabilities and resources of receiving facilities and will

472 transport patients to appropriate facilities within the service region based on direct referral,

473 approved EMS plan, or services available.

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476 (g) The AMP will have a center to receive and coordinate all requests for the medical transport
477 service.

478 (1) The center will be staffed by Communication Specialists.

479 (A) Communication Specialists will be utilized to maintain contact with the medical
480 personnel for response ready status and/or patient coordination and communication of
481 patient status change.

482 (2) The Communication Center shall be equipped with communication capabilities
483 appropriate to the mission profile.

484 (A) The AMP should have a backup emergency power source for communications
485 equipment, or a policy delineating methods for maintaining communications during
486 power outages and in disaster situations.

487 (3) The AMP must retain paperwork/database information regarding transport requests for a
488 period of four years.

489 (A) The AMP must have a method of audio recording or documenting call taking and
490 radio traffic.

491 (4) The AMP will demonstrate written policies concerning communications.

492 (A) The Communications Specialist must document all aspects of the transport.

493 (B) The AMP shall have a written policy requiring that all transport requests are screened
494 for turn downs by other agencies.

495 (i) Information obtained from flight screening shall be communicated internally and
496 externally.

497 (C) The AMP shall have written policies outlining Visual Flight Rule (VFR) flight
498 following requirements.

499 (D) The AMP must demonstrate policies that address post flight debriefings and shift
500 briefings with Communication Specialist.

501 (E) The AMP must maintain written records collecting data as required by Federal, State
502 and Local requirements.

503 (5) The AMP will provide initial training and annual competencies for Communication
504 Specialists.

505 (A) Initial and recurrent training ~~shall include:~~

506 (i) Navigation techniques and map reading skills.

507 (ii) Radio operations.

508 (iii) Telephonic equipment training.

509 (iv) Hazardous materials protocols and procedures.

510 (v) Weather interpretation training.

511 (vi) Stress recognition and management.

512 (vii) Customer service/public relations/phone etiquette.

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- 513 (viii) Computer literacy and skills.
- 514 (ix) Current Post Accident/Incident Plan (PAIP).
- 515 (6) The AMP shall demonstrate participation in weather turn-down notification systems and
- 516 other reporting mechanisms appropriate to your region.
- 517 (7) The AMP shall have written policies regarding communication center operations during
- 518 IFR flights.
- 519 (8) The AMP should have a backup system in place for the computerized systems utilized for
- 520 flight following and mapping.
- 521 (h) The AMP must demonstrate an appropriate and safe work environment for all personnel.
- 522 (1) The facility must have adequate lighting, ventilation, work and rest space commensurate
- 523 to mission profile and scheduled duty hours.
- 524 (2) The facility will have allocated location for storage of equipment required for patient care
- 525 and care of the aircraft.
- 526 (A) The crew quarters must be in a quiet, secure, environmentally safe area away from the
- 527 public.
- 528 (B) The crew quarters must accommodate:
- 529 (i) Flight planning.
- 530 (ii) Crew briefings.
- 531 (iii) Access to a weather reporting system.
- 532 (iv) Computer and internet access.
- 533 (v) Proper rest quarters with chairs, beds, tables and desks as appropriate for the Air
- 534 Medical assignment.
- 535 (3) The AMP must demonstrate a designated medical oxygen storage location with policies
- 536 for safe handling and storage.
- 537 (A) The AMP must demonstrate training on available medical oxygen systems, safe
- 538 storage and handling.
- 539 (4) The AMP must demonstrate a designated biohazard storage location with policies for safe
- 540 handling and disposal.
- 541 (5) The AMP must demonstrate Material Safety Data Sheets (MSDS) is accessible at every
- 542 base and operational facility as appropriate.
- 543 (A) The AMP must demonstrate training on MSDS awareness and use.
- 544 (6) The AMP must demonstrate a policy to address the control of foreign object debris
- 545 (FOD).
- 546 (i) An Air Medical Provider must demonstrate Safety initiatives in the workplace.
- 547 (1) The AMP must provide evidence of a Safety Management System with the following
- 548 elements:
- 549 (A) SMS Management Plan
- 550 (i) The organization clearly states the policies, objectives and requirements of the
- 551 SMS.
- 552 (ii) The plan defines each element of the SMS.

Comment [ALW1]: Should be moved to (h)(1).

Comment [ALW2]: Should be moved to (h)(2)

Comment [ALW3]: Change all wording related to Safety Management System to Safety Management Program.

553 (iii)The plan clearly identifies the responsibilities and authority of key individuals for
554 managing the SMS.

555 (B) Safety Promotion

556 (i) The organization clearly demonstrates that safety is a core value through
557 procedures, practices, training and allocation of resources.

558 (C) Document and Data Information Management

559 (i) The organization clearly documents and publicizes the organization’s safety
560 policies, objectives and SMS procedures.

561 (ii) Demonstrates that the organization provides change control for all applicable
562 documents and has a process to communicate changes in documents to all
563 personnel.

564 (iii) The organization establishes annual review of all SMS documents.

565 (D) Hazard Identification and Risk Management

566 (i) The organization demonstrates a process to identify hazards and to manage risks.

567 (ii) The organization demonstrates a process to prioritize risk management.

568 (iii)The organization demonstrates a method to track identified hazards.

569 (E) Occurrence and Hazard Reporting

570 (i) The organization demonstrates procedures for internal reporting of hazards.

571 (ii) The organization demonstrates a hazard reporting form available to all employees.

572 (iii)The organization demonstrates timely collection of occurrence and hazard
573 information.

574 (F) Occurrence Investigation and Analysis

575 (i) Every hazard, incident or accident must be investigated by the organization.

576 (ii) All investigations shall be documented with an analysis by the organization.

577 (G) Safety Assurance Oversight Programs

578 (i) The organization demonstrates oversight programs that evaluate the effectiveness
579 of the SMS.

580 (ii) The organization’s oversight programs must include internal and external
581 assessments.

582 (iii)The organization’s oversight programs must proactively seek out potential
583 hazards based on available data as well as evaluating the organization’s safety
584 program.

585 (iv)The organization must demonstrate that all oversight programs are integrated.

586 (H) Safety Management Training Requirements

587 (i) Organization must document that all personnel are given introductory and
588 recurrent SMS training.

589 (ii) Training requirements for the organization must include:

590 (aa) A safety orientation for all new personnel, stressing the organization’s
591 commitment to safety and everyone’s role in the SMS.

592 (bb) Document SMS competency requirements for personnel.

Comment [ALW4]: Safety Management Program elements.

Comment [ALW5]: The first sentence should summarize all three points.

Comment [ALW6]: The first sentence should summarize all three points.

Comment [ALW7]: The first sentence should summarize both points.

Comment [ALW8]: Could be condensed to two sentences under (G)

Comment [ALW9]: Could be condensed to one sentence.

- 593 (cc) Track training requirements
- 594 (dd) Provide access to conferences, workshops, literature and trade journals.
- 595 (I) Management of Change
- 596 (i) The organization must have a process to ensure that all personnel are made aware
- 597 of and understand any changes in requirements, procedures and applicable
- 598 maintenance and operator manuals.
- 599 (J) Emergency Preparedness and Response
- 600 (i) Organization must have a written Emergency Response Plan (ERP).
- 601 (aa) Plan must outline what should be done when an emergency occurs.
- 602 (bb) Plan must outline what to do after an accident happens.
- 603 (cc) Plan must define roles that are responsible for each action.
- 604 (ii) The organization's ERP must be readily available to staff on duty.
- 605 (iii) Organization must demonstrate that the plan is updated when information
- 606 changes.
- 607 (iv) Organization must document at least annual training, review and practiced.
- 608 (K) Performance Measurement and Continuous Improvement
- 609 (i) Organization must identify key safety goals.
- 610 (ii) Organization must demonstrate proactive and reactive monitoring of key safety
- 611 goals.
- 612 (iii) Demonstrates performance measurements that are tailored to the size, nature and
- 613 complexity of the organization.
- 614 (2) The AMP must demonstrate the implementation of Personal Protective Equipment (PPE)
- 615 appropriate to the environment and provider mission profile.
- 616 (A) The AMP must demonstrate appropriate outerwear for Rotor-Wing Operations
- 617 (i) Boots or sturdy ankle supporting footwear
- 618 (ii) Flame retardant clothing
- 619 (iii) Clothing must have reflective material or reflective striping on uniforms for
- 620 nighttime operations
- 621 (iv) Flight helmets with visor(s) and appropriate communications capabilities.
- 622 (v) Appropriate outerwear pertinent to survival in the environment
- 623 (vi) Personnel must wear only natural fibers (i.e. cotton) under flight uniforms.
- 624 (vii) Other clothing or personal protective equipment as required for mission
- 625 profile (i.e. rescue, extrication, law enforcement assist)
- 626 (viii) AMP must document a program of ongoing maintenance and replacement
- 627 as required by manufacturer's recommendation for all PPE.
- 628 (3) The AMP must demonstrate an Exposure Control Plan consistent with Federal OSHA
- 629 Guidelines.
- 630 (4) The AMP must demonstrate policies regarding:

Comment [ALW10]: Make part of (I)

Comment [ALW11]: Should be deleted, stated elsewhere.

Comment [ALW12]: Could be combined.

Comment [ALW13]: Section needs to be deleted. Redundant.

- 631 (A) Dress codes.
- 632 (B) PPE use including the use of eye protection.
- 633 (C) Crew rest for medical staff that addresses maximum duty time and assurance for
- 634 adequate crew rest.
- 635 (D) Safety complaint and feedback system.
- 636 (E) Fitness for duty status:
- 637 (i) Duty status during illness (i.e. sinusitis, otitis media, etc.).
- 638 (ii) Medical conditions, including pregnancy, which may cause an employee to be
- 639 unable to perform job function that requires clearance to return duty by personal
- 640 physician.
- 641 (iii) Duty status while taking medications which may cause drowsiness.
- 642 (j) The AMP must have a Quality Improvement (QI) Program which demonstrates an ongoing
- 643 system that includes retrospective review, concurrent review, and prospective forecasting of
- 644 clinical care.
- 645 (1) The AMP QI Program must be overseen by the Medical Director.
- 646 (2) The AMP QI Program must demonstrate that it is designed to be a source of Clinical
- 647 Practice improvement.
- 648 (3) The AMP QI Program must demonstrate that it is designed to be non punitive.
- 649 (A) The QI program must include a remediation process.
- 650 (B) The AMP QI Program must demonstrate inclusion of disciplinary action as a last
- 651 resort or in extreme instances of violations of protocol or policy.
- 652 (4) The AMP should be able to demonstrate an appropriate method of chart review given
- 653 their resources and abilities.
- 654 (5) The AMP must demonstrate the methods used to define the review process, including the
- 655 sampling methodology, filters, and triggers.
- 656 (6) The AMP must demonstrate ongoing performance improvement through direct
- 657 observation and retrospective review
- 658 (A) Retrospective audits should be accomplished through chart audits or patient care
- 659 records reviews.
- 660 (B) Direct observation of performance.
- 661 (7) The AMP shall demonstrate a customer service process which addresses complaints,
- 662 concerns, comments, and service inquiries.
- 663 (A) The AMP shall document investigation.
- 664 (B) The AMP must document written closure.
- 665 (k) An AMP must provide evidence of Oversight Committees with the following elements:
- 666 (1) The AMP shall demonstrate the ability of all personnel to report and direct information to
- 667 its committees
- 668 (A) In a defined and easily accessible method.
- 669 (B) Anonymously if the respondent so desires.
- 670 (C) That provides a recording and tracking mechanism for the report.

Comment [ALW14]: Needs to be moved to (2)(A)

Comment [ALW15]: Need to be moved to Safety Section under Fitness for Duty.

Comment [ALW16]: QI should include business areas other than clinical. The Medical Director must be actively involved in the process but other management may oversee the program.

Comment [ALW17]: Move up to (j)

Comment [ALW18]: Delete, redundant with just culture.

Comment [ALW19]: Combine

Comment [ALW20]: delete, redundant.

Comment [ALW21]: Add into (7)

- 671 (2) The AMP shall demonstrate that its oversight committees publish and disseminate their
672 meeting minutes and provide information to all levels of the organization.
- 673 (3) The AMP committee's must:
- 674 (A) Have a charter that clearly states the policies, objectives and requirements of the
675 committee.
- 676 (B) Have representatives from all disciplines with the AMP.
- 677 (C) Must review and oversee each element of its charter.
- 678 (4) An Air Medical Provider must provide evidence that it has Oversight Committees
679 encompassing:
- 680 (A) Safety Management Systems Committee (SMSC)
- 681 (B) Quality Improvement Committee (QIC)
- 682 (C) Education Committee (EC)
- 683 (i) The EC includes external representatives as required to review education
684 processes.
- 685 (D) Communications Committee (CC)
- 686 (i) The CC includes external representative customers for review of external
687 relationships as required.
- 688 (E) Public Information & Outreach Committee (PIOC) [Optional]
- 689 (i) The PIOC incorporates external representatives for review as required.
- 690 (F) Product Review Committee (PRC) [Ad Hoc]
- 691 (G) Protocol Development and Review Committee (PDRC)
- 692 (i) The PDRC reviews and oversees each element of the Protocol based on QIC
693 reports and best practices within the pre-hospital environment.
- 694 (H) Customer Service Committee (CSC)
- 695 (i) The CSC incorporates external representative stakeholders as indicated by
696 program needs.
- 697 (5) An Air Medical Provider must demonstrate its active participation with all required
698 external committees.
- 699 (1) The AMP shall designate or employ a medical director who shall meet the following
700 qualifications:
- 701 (1) A physician who is currently licensed in the state of Texas, in good standing with the
702 Texas Medical Board, in compliance with the Texas Board of Medical Examiners Rules,
703 particularly regarding Emergency Medical Services as outlined in 22 TAC 197, and in
704 compliance with Subtitle B of Title 3 of the Texas Occupations Code;
- 705 (2) Have knowledge and experience consistent with the transport of patients by air;
- 706 (3) Be knowledgeable in aeromedical physiology, stresses of flight, aircraft safety, patient
707 care, and resource limitation of the aircraft, medical staff and equipment;
- 708 (4) Have access to consult with medical specialists for patient(s) whose illness and care
709 needs are outside the medical director's area of practice; and

Comment [ALW22]: Could become (D) above.

Comment [ALW23]: The following encompassing:

Comment [ALW24]: Safety Management Program. Remove word Committee

Comment [ALW25]: Could have a blanket statement at the end to consider external representation as needed to review the above mentioned categories.

- 710 (5) The physician shall fulfill the following responsibilities:
- 711 (A) Ensure that there is a comprehensive plan/policy to address selection of appropriate
- 712 aircraft, staffing and equipment;
- 713 (B) Be involved in the selection, hiring, training, and continuing education of all medical
- 714 personnel;
- 715 (C) Be responsible for overseeing the development and maintenance of a QI program;
- 716 (D) Participate in any administrative decision making processes that affect patient care;
- 717 (E) Ensure that there is an adequate method for on-line medical control, and that there is a
- 718 well defined plan or procedure and resources in place to allow off-line medical
- 719 control.
- 720 (F) Oversee the review, revision and validation of written medical policies and protocols
- 721 annually.
- 722 (G) Knowledgeable about laws and regulations affecting local, regional, and state EMS
- 723 operations.
- 724 (H) Actively involved in administrative and legislative environments affecting regional
- 725 and/or state pre-hospital organizations.
- 726 (m) The AMP will be assessed as a part of the licensure process in demonstrating program
- 727 components and compliance with law.
- 728 (1) Failure to address any of the following program components shall be considered a
- 729 Critical Failure and result in loss of or denial of license.
- 730 (A) Program for credentialing of providers
- 731 (B) Program for Professional development
- 732 (C) Protocols or Standards of Care
- 733 (D) Established Operational Standards
- 734 (E) Administrative Oversight
- 735 (F) Communications Center
- 736 (G) Base or Facility Standards
- 737 (H) Program for Safety Standards
- 738 (I) Program for Quality Improvement
- 739 (J) Established Committees
- 740 (K) Medical Direction
- 741 (2) Convictions of any of the following:
- 742 (A) Violations of law regulating healthcare provider fraud, abuse, kickbacks.
- 743 (B) Management/Operator convictions of violation of laws of moral turpitude.

Comment [ALW26]: Revisit with QI section revisions as needed.

Comment [ALW27]: Needs to have a statement regarding the responsibility of the Medical Director over Associate and online MD Training.

DRAFT

