MDCH Recommendations for CON Standards Scheduled for 2013 Review

Air Ambulance Services			
Should the covered service continue to be regulated?	No.		
Identified Issues	**Does this issue require further review?**	**Recommended Course of Action to Review Issues**	**Other/Comments**
Air Ambulance Standards are preempted by the Federal Aviation Administration (FAA).	Yes	Proposed Action at the March CON Commission meeting to de-regulate this service.	The Commission should consider de-regulation of this service as it is already federally regulated. Currently, the Department is applying the existing Standards and is applying the federal Declaratory Ruling, which doesn't allow states to regulate need.

MDCH Staff Analysis of the Air Ambulance (AA) Services Standards

Pursuant to MCL 333.22215 (1)(m), the Certificate of Need (CON) Commission is to "…review, and if necessary, revise each set of CON standards at least every 3 years." In accordance with the established review schedule on the Commission Work Plan, the AA Services Standards are scheduled for review in calendar year 2013.

Public Comment Period Testimony

The Department held a Public Comment Period to receive testimony regarding the Standards on October 10 - 24, 2012. Testimony was received from three (3) organizations and is summarized as follows:

Sean Gehle, Ascension Health

- Continues to support regulation of these services and does not recommend any changes to the current standards.

Robert Meeker, Spectrum Health

- Continues to support regulation of these services and does not recommend any changes to the current standards.

History of the Covered Service:

At the September 18, 2007 Commission meeting, the Attorney General's office provided division legal advice on the declaratory ruling and the ability to continue regulation of AA Services. This was not a formal opinion from the Attorney General's office. However, at this time, the Commission approved a motion to table the discussion of AA Services until January 28, 2010 when the AA Services Standards were up for review again. The consensus was based on federal actions, need requirements cannot be enforced. On June 10, 2010, the Commission took final action on previously proposed changes. If the federal status regarding need would change in the future, then Michigan's CON review standards would already contain need requirements. The Department has continued to apply the Declaratory Ruling as appropriate.

Summary of FAA Exemption:

The US Department of Transportation (US DOT), in attempting to clarify the limits of federal regulation, has indicated that the while the FAA regulates air safety, states are free to regulate medical safety.

The areas where federal preemption has been asserted are as follows: requirement for 24/7 service, requirement for a CON, regulation of rates, response times, bases of operation, bonding requirements, and accounting and reporting systems, matters concerning aviation safety including equipment, operation, and pilot qualifications, requirements for certain avionics/navigation equipment, requirements for general liability coverage, and safety aspects of medical equipment installation, storage on aircraft and safety training of medical personnel. Court decisions have found in favor of the Helicopter Emergency Medical Service (HEMS) programs when states have required a CON.

Further, the Federal district court in Med-Trans found a State Certificate of Need program requiring an air ambulance provider to obtain a "valid EMS Provider License" and have an "EMS Peer Review Committee" in place to operate as a Specialty Care Transport Program preempted under Federal law. 581 F.Supp.2d at 737. Under the facts of that case, the court found that the challenged regulations could be used to affect entry into the air ambulance market for reasons other than medical ones.

The court stated: The collective effect of the challenged regulations is to provide local government officials a mechanism whereby they may prevent an air carrier from operating at all within the state.... The court therefore finds that the [regulations] are preempted to the extent that they require approval of county government officials which, if denied, would preclude plaintiff from operating within the state. 583 F.Supp.2dat738.[1]

2011 AA Service Data

AA Services are regulated by 7 of the 37 CON States. There have been 9 applications since 2009 to change or provide AA service. The Department collected AA data via the web-based annual survey in 2011. There were nine (9) providers with a total of 11 primary air ambulances. The 2011 data by facility is as follows:

[1] http://proteus.howdyhost.net/pipermail/board_lists.acctforpatients.org/attachments/20120315/536a33ea/attachment-0001.pdf

2011 AA Service Data

Facility Number	Facility Name	Number of Helicopters			Number of Patient Transports			
		Type	Primary	Back-up	Pre-Hospital	Inter-Facility	Advance Life	Total
19.C004	LIFENET OF MICHIGAN	M	1	0	26	174	0	200
28.C001	NORTH FLIGHT, INC	M	1	0	60	101	7	168
39.1013	WEST MICHIGAN AIR CARE	M	1	1	99	427	0	526
41.0040	SPECTRUM HEALTH BUTTERWORTH	H	2	0	112	486	7	605
50.C688	SUPERIOR AIR GROUND	M	1	0	0	201	0	201
73.8653	ST. MARY'S OF MICHIGAN – FLIGHTCARE	M	1	1	34	295	1	330
73.C005	LIFENET	M	1	0	333	46	0	379
81.0060	UNIVERSITY OF MICHIGAN HOSPITALS	H	2	1	73	745	2	820
81.1007	MIDWEST MEDFLIGHT	M	1	1	14	208	0	222
99.0002	PROMEDICA TRANSPORTATION NETWORK	M	1	3	10	197	0	207
99.1006	ST. VINCENT MEDICAL CTR/LIFE FLIGHT	M	2	0	55	28	0	83
STATE TOTAL		**11 Facilities**	**14**	**7**	**816**	**2,908**	**17**	**3,741**

MDCH Staff Recommendations

The Department recommends de-regulation of Air Ambulance Service.

Aviation safety decisions are separate from medical decisions. The decision to conduct a flight with a patient on board does not mean that flight safety will be compromised in any way. Need determination requirements are preempted by FAA regulations. Therefore safety, equipment, and staffing requirements are the only aspects to be regulated by CON within the State of Michigan.

Deregulating this covered clinical service would reduce duplicating AA regulations within State and Federal governments.

U.S. Department
of Transportation
Office of the Secretary
of Transportation

GENERAL COUNSEL

1200 New Jersey Avenue, SE
Washington, DC 20590

March 9, 2012

Mr. Thomas Judge, EMTP
Chair, Board of Directors
Association of Critical Care Transport
2099 Pennsylvania Avenue, NW, Suite 600
Washington, DC 20006

Re: *Regulation of Air Ambulance Services*

Dear Mr. Judge:

Thank you for your May 13, 2011 letter addressed to Secretary LaHood and Secretary Sebelius, in which you asked whether the Airline Deregulation Act (ADA) would preempt a series of potential State regulations. Secretary LaHood asked the General Counsel's Office to respond on his behalf. The Department notified you that we would require additional time to respond to your letter, and we thank you for your patience.

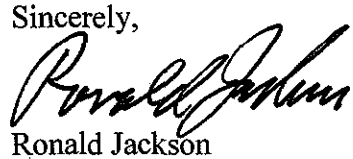
We typically issue advisory opinions on the relationship between the ADA and State regulation of air ambulances based on actual fact scenarios, primarily because legal opinions in this area often depend on the underlying facts, and may cause confusion or prove inadequate if not tied to specific circumstances. Your letter asks us for legal opinions about nine broad "Areas" of potential State regulation, with more than 45 subcategories -- some of which have subparts of their own. Although the breadth and nature of your questions prevent us from responding to each of them, rest assured that we take your inquiries very seriously.

As it turns out, we also received a series of questions on this topic from Senator Patty Murray's office. And as with your questions, we realized that we could not provide definitive legal opinions on all of Senator Murray's questions, outside the context of actual fact scenarios. We thus prepared, instead, a detailed explanation of this area of law, addressing broad categories of potential State regulation (as identified in Senator Murray's questions). We believe that the explanation provides additional clarity on the Department's views regarding the relationship between the ADA and State regulation of air ambulances. We recently provided the explanation to Senator Murray's office, and attach the same write-up as Attachment A to this letter, except for some minor formatting and other non-substantive changes. We hope that your organization will find it useful.

The Department appreciates the invaluable work performed by members of the Association of Critical Care Transport in caring for and transporting patients under very difficult circumstances. We believe that the attached document explains the Department's position on the important role

played by the States in regulating patient care, consistent with the ADA. If you have additional questions, however, please feel free to contact me at (202) 366-9151.

Sincerely,



Ronald Jackson
Assistant General Counsel for Operations

cc: V. Ann Stallion (HHS)
U.S. Department of Justice (Executive Secretariat)

Attachment A
To Letter Dated March 9, 2012
From Ronald Jackson to the Association of Critical Care Transport

Questions and Answers

Question:

Both the Federal government and State governments regulate the air ambulance industry. The Federal Aviation Administration regulates the aviation safety of the industry, and State governments can regulate the medical aspects of air ambulances. The Airline Deregulation Act (ADA) of 1978 preempts States from economic regulation of the air ambulance industry, including the regulation of rates, routes and services.

However, the boundaries between Federal and State regulation are not always well defined, and it is not always clear which regulations may be economic in nature. To date, any clarification of Federal or State regulatory authority has been provided on a case-by-case basis by the courts or opinion letters from the Department of Transportation. This process has left many questions about which aspects of the air ambulance industry States may regulate.

Please indicate whether the requirements listed below may be regulated by a State. If not, please explain the reason. In addition, for anything listed below that the Department interprets as being preempted by the Airline Deregulation Act, please indicate whether the Department of Transportation or the Federal Aviation Administration has exercised any oversight.

General Answer:

The Department of Transportation (DOT) appreciates the questions presented to us. We describe below the legal standards we use to determine the permissibility of State regulation of an air ambulance provider, in light of potential Federal legal restrictions.

DOT recognizes a State's customary role in the regulation of medical care to patients within its borders. A State may act in its:

> traditional role in the delivery of medical services – the regulation of staffing requirements, the qualifications of personnel, equipment requirements, and the promulgation of standards for maintenance of sanitary conditions. Hiawatha Aviation of Rochester v. Minnesota Dep't of Health, 389 N.W.2d 507, 509 (Minn. 1986).

On the other hand, the Federal Aviation Administration (FAA) has plenary authority to regulate safety of aircraft and crew operations. In this regard, courts have found that:

> FAA preemption in the area of aviation safety is absolute. State regulations that require air carriers to provide specific aviation safety related equipment, and to participate in safety related training, are therefore preempted. Med-Trans Corp. v. Benton, 581 F. Supp.2d 721, 740 (E.D.N.C. 2008).

With safety the province of the FAA, and the regulation of patient care the province of the States, the more complex questions concern the Airline Deregulation Act's (ADA) preemption provision, which prohibits State economic regulation of air carriers. Specifically, pursuant to 49 U.S.C. § 41713(b), a State or political subdivision "may not enact or enforce a law, regulation, or other provision having the force and effect of law related to a price, route, or service of an air carrier." Through the ADA, Congress preempted such State regulation in favor of reliance on competitive market forces to provide efficiency, innovation, and low prices in transportation. 49 U.S.C. § 40101(a)(4),(6), and (12).

The courts have broadly interpreted the words "related to" in the ADA preemption provision. For example, a State requirement may "relate to" the price, route, or service of an air carrier even if the impact is "indirect." Rowe v. New Hampshire Motor Transport Ass'n, 552 U.S. 364 (2008) (interpreting the motor carrier deregulation statute, based on the ADA). On the other hand, requirements that impact an air carrier's prices, routes, or services in only a "tenuous, remote, or peripheral manner" are not preempted. Branche v. Airtran Airways, Inc., 342 F.3d 1248 (11th Cir. 2003) (airlines not protected from a whistleblower statute of general applicability passed in Florida). State requirements with a "significant impact" on an air carrier's prices, routes, or services are preempted. Med-Trans, 581 F.Supp.2d at 735 (citing Rowe, 552 U.S. 364 and Morales v. Trans World Airlines, Inc., 504 U.S. 374, 378 (1992)).

In sections 1 through 10 below, we address the specific State standards you hypothesize. Please note, however, that these responses provide general guidance and do not represent a determination of any specific future issue.

1. Medically-related equipment standards (for example, specific standards for design, engine power or electrical systems to support the use of specified medical equipment).

   Answer:

   In Med-Trans, the U.S. District Court for the Eastern District of North Carolina had occasion to rule on the permissibility of certain State requirements for medical equipment and patient care affecting air ambulance operators. The court held that the ADA did not preempt requirements "specifying medically related equipment, sanitation, [or] supply and design requirements for air ambulances," or a requirement mandating a plan to inspect, repair, and clean medical equipment on board. Med-Trans, 581 F.Supp.2d at 739-40.

   The Department also has provided guidance on the permissibility of State medical requirements related to air ambulance providers. In the context of Hawaii air ambulance medical requirements, for example, the Department wrote that State medical requirements on air ambulance operators for such items as patient oxygen masks, litters, and patient assessment devices on board air ambulance aircraft are permissible. See Apr. 23, 2007 Letter from Rosalind A. Knapp, Acting General Counsel of the Department of Transportation, to Gregory S. Walden, Counsel for Pacific Wings, L.L.C.

Similarly, the Department has opined that State requirements for medical services provided inside an air ambulance, including minimum requirements for medical equipment, are not preempted by the FAA's safety authority (except for their flight safety aspects). See Feb. 20, 2007 Letter from James R. Dann, Deputy Assistant General Counsel for the Department of Transportation, to Donald Jansky, Assistant General Counsel for the State of Texas. Thus, if a State requires particular medical equipment on board air ambulances and that equipment in turn necessitates a certain level of electrical power, there is no preemption so long as applicable FAA standards for installation or operation of the equipment are met (for example, so that there is no interference with safe flight).

Although State medically-related standards for medical equipment have been found permissible, States may not prescribe avionics equipment standards for air ambulances; these are preempted by the FAA's safety authority. Air Evac EMS, Inc. v. Robinson, 486 F.Supp.2d 713, 722 (M.D. Tenn. 2007) (involving a mandated type of altimeter).

In the context of a State regulation of medical equipment that bears on aviation safety, the Department has noted that, to the extent State air ambulance requirements affect matters concerning aviation safety, including air ambulance equipment, operation, and pilot qualifications, these would fall under the purview of the FAA and therefore are preempted by Federal law. 49 U.S.C. §§ 44701, 44703, 44704, 44705, 44711, 44717, and 44722. The FAA has developed and administers an extensive system of aviation safety certification and regulation, which extends to air ambulances. See 14 CFR Part 135 (operating specifications) and 14 CFR Part 119 (air carrier operating certificates). The FAA also regulates the safety aspects of medical equipment installation and storage aboard aircraft. See FAA Flight Standards Information Management System (Order 8900.1, Volume 4, Chapter 5, and Volume 6, Chapter 2, Sections 7 and 32); FAA Advisory Circulars 135-14A and 135-15; see also Apr. 23, 2007 Letter from Acting General Counsel Knapp to Gregory S. Walden, Esq.

2. Requirements related to the patient care environment (such as the design of the medical bay and configuration of the air ambulance for the provision of patient care).

Answer:

Last year, the Department responded to a request for an opinion from the State of Tennessee Department of Health on whether Federal law would preempt a proposed Tennessee State Emergency Medical Services Board rule mandating cabin climate control in air ambulances. We stated that such a requirement would not be preempted by the ADA if it serves primarily a patient care objective and if its installation conforms to the FAA's safety standards. Nov. 12, 2010 Letter from Robert S. Rivkin, General Counsel of the Department of Transportation, to Lucille F. Bond, Assistant General Counsel for the State of Tennessee.

Similarly, we have opined that State of Hawaii requirements for patient care, such as patient oxygen masks, minimum flow rates for a patient's oxygen supply, reporting

requirements as to a patient's condition, litters, blankets, sheets, and trauma supplies are not preempted by the FAA's safety standards, so long as the FAA requirements pertaining to safe installation and carriage aboard an aircraft are met. See Apr. 23, 2007 Letter from Acting General Counsel Knapp to Gregory S. Walden, Esq.

Other State requirements related to the patient care environment, such as the design of the medical bay and configuration of the air ambulance for the provision of patient care, would similarly not be preempted if they serve primarily a patient care objective and meet the FAA's requirements pertaining to safe installation and carriage aboard an aircraft.

3. Requirements for the performance of the air ambulance to maximize patient outcomes, assure timeliness of transport, quality of care and patient safety (such as requiring that air ambulances be able to travel certain distances without refueling, not load a patient with the rotors turning, be able to lift off within a certain time after patient and medical crew are aboard, or provide ventilation without compromising temperature regulation).

Answer:

As indicated above, the general principle is that State regulation that serves primarily "a patient care objective" is properly within the State's regulatory authority. Med-Trans, 581 F.Supp.2d at 738. There, the Federal district court held that the ADA does not preempt a State statute requiring air medical programs to document "[a] written plan for transporting patients to appropriate facilities when diversion or bypass plans are activated." Id. at 738. The court found the requirement had too tenuous a relation to an air carrier's routes to be of concern under the ADA, because it did not define or restrict the service area, but simply required an operator to develop a plan to ensure the patient's medical care. Additionally, the court held that a State requirement that an air ambulance provider document a plan to inspect, repair, and clean medical and other patient care related equipment would not be preempted by the FAA's aviation safety authority. Id. at 740.

In this regard, we note that the Department has opined that an Arizona regulation of an air ambulance operator's "operating and response times" (in addition to regulating an air ambulance operator's entry through a certificate of public convenience and necessity, its rates, base of operations, accounting and report systems, and bonding) was preempted by the ADA's preemption provision. 49 U.S.C. § 41713(b). See June 16, 1986 Letter from Jim J. Marquez, General Counsel of the Department of Transportation, to Chip Wagoner, Assistant Attorney General, Environmental Protection Unit, State of Arizona. See also Feb. 20, 2007 Letter from DOT Deputy Assistant General Counsel Dann to Texas Assistant General Counsel Jansky. Additionally, the Department has opined that a State requirement for 24-hour daily air ambulance availability is preempted by the ADA, because it prescribes particular hours or times of operations. The Department also advised that such a requirement is preempted by the FAA's aircraft and crew operation

safety regulations. See Apr. 23, 2007 Letter from Acting General Counsel Knapp to Gregory S. Walden, Esq.

4. Requirements related to the quality and acceptability of the medical services provided (such as requiring the use of medical procedures that follow the standard of care, or the use of state-of-the art medical devices, affiliation with health care institutions for clinical training, or reporting on quality of care, outcomes, and patient experience).

   Answer:

   As indicated above, a State regulation on medical standard of care that serves primarily "a patient care objective" is properly within a State's regulatory authority.

   The Med-Trans court made clear that vehicle- or equipment-related training, to ensure proper patient care on board an air ambulance, would not be preempted by the FAA's safety authority. 581 F.Supp.2d at 741. Hence, a State requirement for training about cabin pressurization ("altitude physiology") of an aircraft as it relates to specific medical conditions would not be preempted, nor would requirements that an air ambulance be staffed by a minimum number of medical personnel for patient care. The Federal district court, however, found training or other requirements related to aviation or aircraft safety to be preempted, only to the extent the requirements purport to impose aviation-related requirements on air ambulance providers. Id. at 740.

   We have similarly opined that State training and licensure requirements of an air ambulance medical crew generally would not be preempted by Federal law. We cautioned that the FAA has minimum requirements for medical personnel aboard an aircraft, when in the positions of possible flight crew rather than medical crew. See Feb. 20, 2007 Letter from DOT Deputy Assistant General Counsel Dann to Texas Assistant General Counsel Jansky.

   Although medical affiliation requirements (*e.g.*, participation in and/or coordination with the regional or local EMS programs) are not preempted *per se*, it should be noted that the Federal district court in Med-Trans found a State Certificate of Need program requiring an air ambulance provider to obtain a "valid EMS Provider License" and have an "EMS Peer Review Committee" in place to operate as a Specialty Care Transport Program preempted under Federal law. 581 F.Supp.2d at 737. Under the facts of that case, the court found that the challenged regulations could be used to affect entry into the air ambulance market for reasons other than medical ones. The court stated:

   > The collective effect of the challenged regulations is to provide local government officials a mechanism whereby they may prevent an air carrier from operating at all within the state. . . . The court therefore finds that the [regulations] are preempted to the extent that they require approval of county government officials which, if denied, would preclude plaintiff from operating within the state. 583 F.Supp.2d at 738.

5. Requirements related to the use of air medical services (including criteria for using ground versus air transport, or the use of particular air ambulances based on their ability to fulfill particular medical missions).

   Answer:

   As discussed above, a State may not regulate the entry into the market of air ambulance providers because of the Federal preemption provision of the ADA, 49 U.S.C. § 41713(b). See Med-Trans, 581 F.Supp.2d at 736 (State Certificate of Need law "significantly affects the rates, routes, and services of an air carrier in that it bars [an air ambulance operator] from performing flights [in the State]"; Hiawatha, 375 N.W.2d at 500-501 ("The [State] Department of Health cannot regulate the entry into the market of [an air ambulance operator's] proposed enterprise because this is a matter of aviation services within the jurisdiction and control of the [DOT].)" Id.

   In addition, in response to a question about a State regulation of air carrier economic matters, including rates, insurance requirements, or when and where air ambulances may fly, we opined that the ADA would preempt any State regulation relating to rates, advertising, scheduling, and routing of air ambulances. See Feb. 20, 2007 Letter from DOT Deputy Assistant General Counsel Dann to Texas Assistant General Counsel Jansky.

   This does not, however, preclude States from using medical criteria to determine the proper mode of patient transport or the proper medical facility to which a particular patient should be transported.

6. Requirements related to accessibility and availability of services (including requirements not to discriminate based on a patient's ability to pay, or to be available at specified hours and days, weather permitting).

   Answer:

   In addition to the above discussion, the Department has advised that the ADA would preempt a Texas Subscription Program regulating subscription or membership programs offered by an emergency medical services provider (such as an air ambulance). See Nov. 3, 2008 Letter from D.J. Gribbin, General Counsel of the Department of Transportation, to Texas Attorney General Greg Abbott. Under the program, air ambulance service provided under a subscription program was required to be available to all persons, including paying subscribers and non-subscribers alike. We found that the Texas program impermissibly related to an air carrier's price and service by regulating the terms of service and its availability.

Further, the Department opined that a Hawaii Certificate of Need program requiring the State to determine, among other things, the "reasonableness" of the cost of the air ambulance service was preempted by the ADA. Apr. 23, 2007 Letter from Acting General Counsel Knapp to Gregory S. Walden, Esq. We have also viewed State regulation of air ambulance rates to be similarly preempted. Feb. 20, 2007 Letter from DOT Deputy Assistant General Counsel Dann to Texas Assistant General Counsel Jansky. Finally, as noted previously, the Department has also opined that a State's 24 hours a day service requirement for air ambulance operations is preempted. See Apr. 23, 2007 Letter from Acting General Counsel Knapp to Gregory S. Walden, Esq.

7. Requirements related to dispatching and destination (including requirements that air ambulance services report on their response times or meet specified targets for response times, comply with protocols that govern scene response that prioritize responding air ambulances based upon consideration of medical capabilities for the required medical service and time-to-scene capabilities, or transport patients to particular destinations based on medical protocols).

   Answer:

   In Med-Trans, the court had occasion to rule on the permissibility of State equipment requirements for air ambulances mandating that air ambulances synchronize voice radio communications with local EMS resources. The court found the requirements were not preempted if the equipment was necessary for proper patient care. 581 F.Supp.2d at 739-740. Further, as we indicated above, the Med-Trans court held that the ADA did not preempt a State requirement for written plans on transporting medical patients aboard an air ambulance to appropriate facilities (but that the ADA did preempt requirements to obtain a franchise).

   We note that the FAA maintains authority for the regulation of safety-related aircraft dispatch requirements (as opposed to EMS dispatch requirements) and would likely view State requirements in this aviation safety area to be preempted. See 49 U.S.C. § 44701; 14 CFR §§ 121.591-121.667 (Part 121, Dispatching and Flight Release Rules). Moreover, the pilot in command of an aircraft is "directly responsible for, and is the final authority as to, the operation of that aircraft." 14 CFR § 91.3. Accordingly, while scene response protocols or prioritization may be used to assess whether air ambulance transport is appropriate for a particular patient, the safety of the aviation operation, including a "go" or "no go" decision, is the flight crew's responsibility under FAA regulations.

8. Requirements that would allow State EMS systems to coordinate air ambulance services and oversight (including requirements that would affect the relationships among air ambulances, other providers of other emergency medical services, referring entities, and medical institutions).

   Answer:

State requirements for accreditation by an outside body would not be preempted by the ADA if the accreditation pertained exclusively to medical care. The court in Med-Trans held that a State may not require an air ambulance operator to provide specialty care in "a defined service area," because that impermissibly relates to an air carrier's routes and would be preempted by the ADA. 581 F.Supp.2d at 738.

Additionally, the Department has found a State's broad certification requirement for air ambulances based on the "quality, accessibility, availability and acceptability" of service, or prescription of particular hours or times of operation, to be preempted under the ADA, because those requirements impermissibly relate to an air carrier's service. Apr. 23, 2007 Letter from Acting General Counsel Knapp to Gregory S. Walden, Esq.

9. Requirements for a license based on medical capability (including specific licenses that are limited to an air ambulance's medical capabilities).

Answer:

The Department has opined that licensing requirements that deal exclusively with medical care (as opposed to aviation safety, for example) would not be preempted by the ADA and could be imposed either directly with specific State requirements or indirectly through accreditation requirements. See Feb. 20, 2007 Letter from DOT Deputy Assistant General Counsel Dann to Texas Assistant General Counsel Jansky. This also would be true of licensing standards that strictly relate to matters of patient care, not to an air ambulance's rates, routes, or services. See Apr. 23, 2007 Letter from Acting General Counsel Knapp to Gregory S. Walden, Esq.

10. Requirements for medical accreditation by an entity identified by a State.

Answer:

The Department has provided guidance that State regulations on air ambulance provider training and licensure requirements generally would not be preempted by the ADA when the requirements concern matters of patient care and do not venture into areas of Certificate of Need or other impermissible regulation of air ambulance rates, routes, or services. The Department has found that State requirements for accreditation by an outside body would not be preempted by the ADA if the accreditation pertained exclusively to medical care. See Feb. 20, 2007 Letter from DOT Deputy Assistant General Counsel Dann to Texas Assistant General Counsel Jansky. Similarly, the Department advised that State requirements for accreditation of air ambulance service by a medical professional body would not be preempted to the extent such requirements concern medical standards appropriate to each patient's needs. See Nov. 3, 2008 Letter from DOT General Counsel D.J. Gribbin to Texas Attorney General Greg Abbott.

The Med-Trans court, however, found a State requirement for an air ambulance provider to be affiliated with an EMS system preempted by the ADA to the extent it conditioned

an air carrier's operation in the State on approval by county governmental officials. 581 F.Supp.2d at 742.

	Oversight Bodies			
Areas of Regulation	Federal Aviation Admin. [1]	Michigan Certificate of Need	MI EMS Licensing - MDCH [2]	Other Accreditation(s)
Regulation of Staffing Requirements	X	X	X	
Qualifications of Personnel	X	X	X	
Equipment Requirements	X	X	X	
Maintenance of Sanitary Conditions		X	X	
Safety of the Aircraft & Crew Operations	X			
Regulation of price, route, or service of an air carrier	X			
Flight Safety Aspects		X	X	
Aviation Safety Certification	X			
Patient Care Objective		X	X	Commission on Accreditation of Medical Transport Systems (CAMTS) provides very important benchmark levels for quality and safety within the transport environment
Operating & Response Times	X			
Training	X		X	
Regulate entry into the market of air ambulance providers	X			
Determination of transport	X			Separate medical faculties use medical criteria to determine the proper mode of patient transport
Written plans on transporting medical patients		X	X	
Maintenance of accurate medical flight records		X	X	
Safety Inspections	X		X	CAMTS performs safety inspections
Methodology for projecting need				FAA preempts the need determinations set forth in Michigan's CON law and standards

How do MI's border states regulate Air Ambulance Services?

	Illinois	Indiana	Minnesota	Ohio	Wisconsin
Certificate of Need					
State Licensing program	X	X	X	X	X

1 US Department of Transportation General Counsel RE: Regulation of Air Ambulance Services, March 9, 2012

2 http://www.michigan.gov/documents/FINAL_2001-015__EMS_95428_7.pdf

STATE OF MICHIGAN
DEPARTMENT OF ATTORNEY GENERAL

P.O. BOX 30758
LANSING, MICHIGAN 48909

BILL SCHUETTE
ATTORNEY GENERAL

March 22, 2013

Mr. James B. Falahee, Jr,
CON Commission Chairperson
Bronson Healthcare Group
301 John Street
Kalamazoo, MI 49007

Re: CON Review Standards for Air Ambulance Services and Preemption

Dear Mr. Falahee:

The Commission asked me to provide legal advice regarding preemption and the CON review standards for air ambulance services. The Commission seeks this advice due to the Department's recommendation to consider deleting these services as a covered clinical service and a March 9, 2012 letter regarding this issue from U.S. Department of Transportation (DOT) Assistant General Counsel Ronald Jackson to the Association of Critical Care Transport.

Attached please find a memorandum that provides a legal analysis regarding preemption of CON air ambulance review standards. As you will see, it is highly likely that a Court would find that Federal law preempts much of the current CON review standards regarding air ambulance services. For example, the need methodology outlined in Sections 3-6 would most likely be found to be preempted since they would fall under the broad scope of the Federal laws governing rates, routes and services of air carriers.

While there are limited areas that may not be preempted, such as regulations that are exclusively related to the provision of medical services, it appears that these are covered under the State's EMS licensing requirements. As such, CON regulations would provide duplicative oversight.

Please note that the attached memorandum is division level advice and should not be viewed as an Attorney General opinion. If you or any commission member has any questions, please feel free to contact me.

Sincerely,

Joseph E. Potchen
First Assistant Attorney General
Health, Education & Family
Services Division
(517) 373-7700

JEP/sjs
Enclosure
cc: CON Commission
Raymond O. Howd

DEPARTMENT OF

ATTORNEY GENERAL

MEMORANDUM

March 22, 2013

Division Level Advice
Attorney-Client Privilege

TO: Certificate of Need Commission

FROM: Joseph E. Potchen, First Assistant Attorney General
Jonathan S. Ludwig, Assistant Attorney General
Health, Education & Family Services Division

RE: CON Review Standards for Air Ambulance Services and preemption
AG# 2013-0034703-A

This Memorandum represents advice at the division level and is not the opinion of the Attorney General. This Memorandum may be subject to the attorney-client privilege and is not intended to be shared with anyone outside of the Certificate of Need Commission or the Michigan Department of Community Health.

Question

To what extent does the Airline Deregulation Act of 1978 (ADA) and the Federal Aviation Administration Authorization Act of 1994 (FAAAA) preempt CON review standards for air ambulance services in light of the 2012 US DOT General Counsel letter explaining what a state may regulate in this area?

Summary Response

The ADA and FAAAA preempt much of Michigan's CON review standards for air ambulance services. While certain requirements that exclusively relate to medical care are not preempted, they appear to be appropriately regulated through Michigan's Emergency Medical Services licensure requirements.

Background

Under Part 222 of the Public Health Code, no person may initiate a covered clinical service without first obtaining a Certificate of Need (CON) from the Michigan Department of Community Health (DCH). MCL 333.22209(1)(c). A covered clinical service is defined to include air ambulance services. MCL 333.22203(10)(b)(viii). If determined necessary, the CON Commission may delete a covered clinical service listed in the statute. MCL 333.22215 (1)(a).

Air ambulances are helicopters capable of providing treatment or transportation of a patient at or from the scene of an emergency. They are also used for transport of patients between two facilities. Since 1995, there have been CON review standards for air ambulance services.

About thirteen years ago, Rocky Mountain Holding, LLC (Rocky Mountain), proposed to initiate an air ambulance service in Michigan. Since it was a federally certified air carrier with the ability to provide interstate air transportation, Rocky Mountain argued that it should not be subject to the CON review standards. More specifically, Rocky Mountain asserted that the Federal FAAAA preempts the need determination set forth in the Michigan Public Health Code. MCL 333.22225.

Subsequently, in 2002, DCH issued a Declaratory Ruling at Rocky Mountain's request. In the Ruling, DCH determined that the FAAAA preempts only the need determination requirements prescribed under the Public Health Code. However, all other provisions of Michigan law, standards, rules, regulations and guidelines pertaining to air ambulance licensure, certification, standards and services, including but not limited to safety, equipment, and staffing requirements, are not preempted by the FAAAA. DCH Declaratory Ruling 2002/01.

In 2004, the Commission revised the air ambulance CON standards. It is unclear whether there was any discussion regarding the 2002 Declaratory Ruling or the preemption issue being brought up when these changes were made.

In 2007, the CON Commission again took action to change the air ambulance CON standards. At that time, a question was raised as to whether the 2002 Declaratory Ruling has any impact on the proposed air ambulance standards. The question, however, does not appear to have been answered and new standards were approved in 2010.

The air ambulance standards are now up again for review. DCH has asked the Commission to consider deleting air ambulance services as a covered clinical service. According to the Department, since the need determination is preempted, the only aspects being regulated by DCH are the safety, equipment and staffing requirements set out in the standards. The Department suggests that deregulating this covered service would reduce duplicating air ambulance regulations within State and Federal governments.

The Commission seeks advice regarding this recommendation in light of a March 9, 2012 letter from U.S. Department of Transportation (DOT) Assistant General Counsel Ronald Jackson to the Association of Critical Care Transport. Attached to the letter is a detailed explanation of the law in this area. A copy of the letter and attachment has been provided to the Commission.

Analysis

ADA and FAAAA Preemption

In 1978, Congress enacted the ADA, 49 USC 41713(b)(1), as part of an effort to encourage market competition in the airline industry. *Thomas v UPS*, 241 Mich App 171, 175 (2000). The act contains a broad provision that expressly preempts any state "law, regulation, or other provision . . . related to a price, route, or service of an air carrier that may provide air transportation under" a federal certification. 49 USC 41713(b)(1). This law applies to helicopters.

Fifteen years later, Congress passed the FAAAA to limit state regulatory authority over air and motor carriers. *See City of Columbus v Ours Garage and Wrecker Service, Inc*, 536 US 424, 429 (2002). The FAAAA preemption language is essentially the same as the language set forth in the ADA. 49 USC § 14501(c)(1). In fact, the US Supreme Court has held that judicial interpretation of the preemption language contained in the ADA can be used to interpret the preemption language of the FAAAA. *Rowe v New Hampshire Motor Transport Association*, 552 US 364, 370 (2008).

In *Med-Trans Corp v Benton,* 581 F Supp 2d 721 (ED NC, 2008), a case that closely resembles the issues now facing the CON Commission, the Fourth Circuit held that the ADA expressly preempts a significant portion of a North Carolina state law requiring air ambulance operators to obtain a CON in order to operate within the state. According to the court, the state could not require that prospective health-service providers obtain a CON that required the provider to demonstrate that it had a documented service population, that it had proposed the least costly or most effective alternative, and that the proposed project would not unnecessarily duplicate available health-services. *Med-Trans,* 581 F Supp 2d at 735-736. The court found that the CON requirement directly contravened the pro-competition purposes underlying the ADA. *Med-Trans,* 581 F Supp 2d at 736.

The court further found, "To the extent that CON prescribed the behavior necessary to operate in state, it is clearly 'related to' [the air ambulance operator's] price, route, or service under the ADA." *Med-Trans,* 581 F Supp 2d at 736. The court added that CON requirements applied to air ambulance services constituted a substitution of the state's rules for competitive market forces, which contravened *Rowe*. *Med-Trans*, 581 F Supp 2d at 736. According to the court, the state law significantly affected the rates, routes, and services of an air carrier because it barred the air ambulance operator from performing intrastate flights in violation of both Congress's original intent in enacting the ADA and the Act's remedial intent to preempt such state action. *Med-Trans*, 581 F Supp 2d at 736. It also found that CON requirements generally limited an operator's ability to enter the market of providing air services, so they were preempted. *Med-Trans*, 581 F Supp 2d at 736.

But the court found one aspect of North Carolina's regulations too tenuous to be preempted under the ADA. That regulation mandated that Air Medical Programs have a "written plan for transporting patients to appropriate facilities when diversion or bypass plans are activated." 10A

NCAC 13P.0302(a)(3). Apparently, this requirement ensures that operators have a plan for transporting patients to alternative medical facilities when the original destination becomes unavailable. The Court held that "[t]his is primarily a patient care objective properly within the state's regulatory authority." *Med-Trans*, 581 F Supp at 738.

In *Med-Trans*, the court also analyzed Plaintiff's field preemption argument. The court found that, because the Act's field preemption in the area of aviation safety is absolute, state regulations requiring that air carriers provide specific aviation safety-related equipment and participate in safety-related training were preempted. *Med-Trans,* 581 F Supp 2d at 740, citing, among other authorities, *Greene v BF Goodrich Avionics Sys Inc*, 409 F3d 784, 795 (6th Cir 2005). The Court, however, clarified that although the FAA has preemptive control of aviation safety measures, regulations regarding EMS related equipment would not intrude on its domain:

> For example, the two way radio required under 10A N.C.A.C. 13P.0209(6) . . . , which is necessary for communication with various public safety entities in order to facilitate patient care, is not preempted, while the VHF aircraft frequency transceivers required by 10A N.C.A.C. 13P.0209(7)(a) relate primarily to aviation safety and would be preempted by the federal scheme. The court therefore clarifies that only those regulations governing equipment or training directly related to aviation safety are preempted.
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> N.C. Gen. Stat. § 131E-157, however, remains unaffected to the extent that it does not stray into the field of aviation safety. The Commission may still, for example, adopt rules specifying medically related equipment, sanitation, supply and design requirements for air ambulances, and the DHHS may still inspect air ambulances for compliance with these medically-related regulations. Likewise, HN3510A N.C.A.C. 13P.0209(3), which requires air ambulances be equipped with voice communication systems for communication between the flight crew and medical crew, is necessary for proper patient care and does not run afoul of the federal scheme. 10A N.C.A.C. 13P.0204(a)(5) is preempted only to the extent that it purports to impose aviation safety inspections and other aviation related requirements on air carriers. To the extent it merely requires air carriers to document a plan for inspecting, repairing, and cleaning medical and other patient care related equipment, it remains unaffected. Finally, 10A N.C.A.C. 13P.0209(10) is preempted only to the extent that it prohibits structural or functional defects affecting the "safe operation of the aircraft". [*Med-Trans*, 581 F Supp 2d at 740.]

Therefore, courts have acknowledged that the FAAAA did not wholly eliminate a state's regulatory powers. See also *Westlake Transportation, Inc v Public Service Com'n*, 255 Mich App 589, 592 (2003), aff'd on other grounds, 545 US 440 (2005) (state regulatory agencies retained extensive regulatory authority, justifying a regulatory fee).

The above analyses comports with advice provided from the federal agency empowered with administering the ADA and FAAAA, the U.S. Department of Transportation. In the March 9, 2012 letter, the US DOT opined that regulations that concern aviation safety, including air ambulance equipment, operation, and pilot qualifications would be preempted by Federal law. (DOT Jackson Letter, 3/9/12, attachment A p 2-3.) Requirements that relate solely to patient care, however, would not be preempted. For example, the design of the medical bay for the provision of medical services is not preempted as long as it meets the FAA requirements pertaining to safe installation and carriage aboard an aircraft. (DOT Jackson Letter, 3/9/12, attachment A p 5-6.) Perhaps, most significantly, state licensing requirements that deal exclusively with medical care would not be preempted. But when they venture into a need determination or other impermissible regulation of air ambulance rates, routes, or services, the regulation is preempted. (DOT Jackson Letter, 3/9/12, p 8,) "Certificates of need" have also been found expressly preempted in a September 2010 Report from the U.S. Government Accountability Office. See GAO-10-907, Table 3, p 23. Therefore, no matter how closely the regulation may pertain to patient care, if the regulation relates to a determination of need, as opposed to licensure, or otherwise seeks to limit participation in the marketplace, it risks being struck down as preempted. See *Med-Trans*, 581 F Supp 2d at 736 ("CON law is preempted as applied to air carriers . . . .").

Michigan's Air Ambulance CON Standards

It appears that the ADA and FAAAA preempt many aspects of the current CON air ambulance review standards. For example, under the current standards, to obtain a CON for air ambulance services in Michigan, an applicant must use a defined methodology to show that the service will transport at least 275 patients in the second 12 months after beginning operation and must demonstrate that all existing air ambulance services with a base of operations within a 75-mile radius have been notified of the applicant's intent to initiate an air ambulance service. CON Review Standards, Section 3 (5) and (6). To expand an air ambulance service, the applicant must show either (A) 600 patient transports and organ transports expanding to two air ambulances, of which 275 must be patient transports, (B) 1,200 patient transports and organ transports expanding to three air ambulances, of which 550 must be patient transports, or (C) 1,800 patient transports and organ transports expanding to four air ambulances, of which 825 must be patient transports patient transports. CON Review Standards, Section 4 (1); see also Section 5 (Requirements for approval to replace an air ambulance) and Section 6 (Requirements for approval to acquire an existing air ambulance service). These requirements relate to the services of the air carrier and under the broad scope of the ADA and FAAAA's preemption language, it is highly likely that a Court would find these regulations to be preempted.

Additionally, to the extent that any regulations require an air ambulance to carry certain equipment for *air safety reasons,* those regulations are also preempted. See *Air Evac EMS, Inc v Robinson*, 486 F Supp 2d 713 (MD Tenn, 2007). Basically, any CON standard that has a potential to regulate the air ambulance services in the marketplace may be preempted by Federal law. *Med-Trans*, 581 F Supp 2d at 736.

There does appear to be some aspects of the current standards, however, that may not be preempted. For example, Section 8 of the CON Review Standards sets forth certain project delivery requirements that include various quality assurance standards. These quality assurance requirements are deemed met if the Commission on the Accreditation of Air Medical Transport Systems accredits the applicant as an air medical service (which the DOT has determined is acceptable) or if the applicant meets a series of requirements—some of which are more closely related to patient care than others. CON Review Standards, Section 8. Many of these medical and health-related requirements appear too remote to the operation of prices, routes or services and likely would survive a preemption argument. To the extent that a court would find these requirements related to a CON, however, the state runs the risk of a court determining that the rules block entry into the marketplace and are preempted outright.

Additionally, while it appears the Commission may adopt limited standards for air ambulance services that solely relate to patient care, such as equipment or other medically-related regulations, it appears that these areas are already regulated by DCH Emergency Medical Services. DCH EMS administrative rules for life support agencies have specific regulations for ambulance operations. R 325.22131, *et seg.* Those rules cover air ambulances and require that such services meet established patient care and safety equipment standards prescribed by DHS and approved medical control authority protocols. See R. 325.22132 and 325.22133. Since EMS licensing covers those areas of an air ambulance service that may be outside ADA and FAAAA preemption, it appears unnecessary to also regulate these services through CON regulation.

CON Standards for Air Ambulance Services in Other States

As of 2011, only five states still require a CON for air ambulance services: Alabama, Maine, Massachusetts, Michigan, and Vermont. See Summary Chart from AHPA's 2011 National Directory of State Certificate of Need Programs Health Planning Agencies. But, as cited in *Med-Trans*, 581 F Supp 2d at 736, an Alabama state court ruled that federal law preempted Alabama's CON law and any other statute or regulation which required air ambulance providers to obtain a CON prior to conducting air ambulance operations within the state. See *Baptist Hospital, Inc v CJ Critical Care Transportation System of Florida*, CV-07-900193 (Circuit Court of Montgomery County, Alabama, August 3, 2007). Also, as discussed in *Med-Trans*, a federal District Court enjoined enforcement of a majority of North Carolina's CON laws due to preemption. see also *Rocky Mountain Holdings, LLC v Cates*, 97-4165-CV-C-9 (WD Mo, September 3, 1997) (Missouri's ambulance licensure law, which required a state official to determine that "public convenience and necessity require the proposed ambulance service" before issuing a license, was preempted by the ADA). Other states, like Hawaii and Arizona have eliminated or limited their CON programs for air ambulances on the basis of advice issued by the DOT. See GAO-10-907, Table 5, p 39. New Jersey, despite having a publication that appears to indicate that emergency medical service helicopters must have a CON, does not require entities to obtain a CON before issuing an air ambulance license. See *Virtua Health, Inc. v. Alaigh*, 2011 N.J. Super. Unpub. LEXIS 2802 (2011). Per DHS, Illinois, Indiana, Minnesota, Ohio and Wisconsin regulate air ambulance services through their state licensing programs.

Conclusion

The ADA and FAAAA preempt Michigan's CON review standards for air ambulance services that relate to price, route or service of an air carrier, including the need determination. Further the Commission should not create any standards that require an air ambulance service to comply with regulations that are related to general aviation safety standards. While certain requirements that deal exclusively with medical care are not preempted, they appear to be appropriately regulated through Michigan's EMS licensure requirements.

Reviewed and Approved:

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Listing of Michigan CON Air Ambulance Applications since 2009

05/05/2009	09-0126	73-8653	ST. MARY'S OF MICHIGAN FLIGHTCARE	SAGINAW	SAGINAW	ACQ AIR AMBULANCE BY ST. MARY'S OF MICHIGAN	0
07/07/2009	09-0192	81-1007	MIDWEST MEDFLIGHT	YPSILANTI	WASHTENAW	REPLACE AIR AMBULANCE	3564000
07/10/2009	09-0196	50-C688	SUPERIOR AIR GROUND AMBULANCE SERV	WARREN	MACOMB	INITIATE AIR AMBULANCE SERVICE	743331
11/03/2009	09-0298	99-C012	ASPIRUS MEDEVAC	WAUSAU	OUT OF STATE	INITIATE AIR AMBULANCE SERVICE	0
02/09/2011	11-0079	99-C012	ASPIRUS MEDEVAC	WAUSAU	OUT OF STATE	INITIATE AIR AMBULANCE SERVICE	14066
02/17/2011	11-0087	81-0060	UNIVERSITY OF MICHIGAN HLTH SYSTEM	ANN ARBOR	WASHTENAW	REPLACE 2 AIR AMBULANCES & 1 BACK-UP	26258519
10/31/2011	11-0374	63-C003	PHI AIR MEDICAL, L.L.C.	ROYAL OAK	OAKLAND	INITIATE AIR AMBULANCE SERVICE	449700
01/25/2012	12-0042	99-0002	PROMEDICA AIR	TOLEDO, OH	OUT OF STATE	REPLACE AIR AMBULANCE	3607716
11/16/2012	12-0373	41-0040	SPECTRUM HEALTH HOSPITALS	GRAND RAPIDS	KENT	REPLACE 1 AIR AMBULANCE	3700000