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.

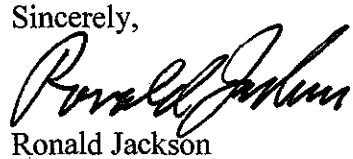
We typically issue advisory opinions on the relationship between the ADA and State regulation of air ambulances based on actual fact scenarios, primarily because legal opinions in this area often depend on the underlying facts, and may cause confusion or prove inadequate if not tied to specific circumstances. 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.