Guidelines for the Use and Availability of Helicopter Emergency Medical Transport (HEMS)

United States Department of Transportation, April 2015

Introduction

This document describes the regulatory and oversight framework for helicopter air ambulance operations that state emergency medical services (EMS) system planners should consider in developing regulations to help ensure patients receive appropriate medical attention and care. As a general matter, states regulate medical issues and the federal government maintains authority over the aviation industry's economic matters and aviation safety issues. Because economic, medical, and/or safety issues may be involved in any one situation, jurisdictional questions arise that are typically addressed on a case-by-case basis by state or federal courts or in advisory opinion letters from the U.S. Department of Transportation (DOT).

States' Regulatory Authority

The Tenth Amendment to the U.S. Constitution provides that "[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people." States have inherent police powers to protect public health and welfare. Accordingly, states have customarily played the primary role in regulating medical care for patients within their borders. State departments of health usually have rulemaking authority and administrative oversight to establish medical standards of care appropriate to the needs of patients. This state government role is particularly important because of the need to protect the interests of incapacitated patients who cannot provide consent but require pre-hospital medical treatment by EMS personnel. Under the doctrine of implied consent, state laws generally provide legal authorization for medical personnel to provide emergency medical care to incapacitated patients.

The oversight of pre-hospital operations is commonly within the purview of state offices of emergency medical services (OEMS), although the exact nature and authority of an individual state office varies from state to state. Typically, among other things, an OEMS inspects and licenses ground ambulances, provides certification for emergency medical technicians (EMTs) and paramedics, and develops state minimum standards for EMTs and paramedics by approving basic life support and advanced life support protocols. Many states also designate certain hospitals as having special capabilities, such as trauma centers, burn centers, ST Elevation Myocardial Infarction (STEMI) centers, and stroke centers. In addition, states and local jurisdictions may develop triage criteria for EMTs and paramedics to use in the initial assessment of a patient. States also may require routine submission of ambulance run reports, often in a form that is compliant with the National Emergency Medical Services Information System (NEMSIS).¹

Helicopter air ambulance operators provide important services by transporting patients with time-critical injuries and conditions to medical facilities and providing medical care to patients while en route. Courts have held that, in regulating helicopter air ambulance operations, states may act in their "traditional role in the delivery of medical services – the

¹ NEMSIS is a national effort to standardize the data collected by EMS agencies and to establish the National EMS Database. NEMSIS compliant products are currently used by most states to collect standardized data elements, including data about the mode of emergency transport. *See <u>http://www.nemsis.org</u>*. As of October 2012, 38 states submit data to the National EMS Database. In addition, 56 states, territories, and the District of Columbia have signed a memorandum of understanding in support of NEMSIS.

regulation of staffing requirements, the qualifications of personnel, equipment requirements, and the promulgation of standards for maintenance of sanitary conditions."²

For example, a federal court found that a state regulation requiring an air ambulance operator to document its plan for ensuring that patients are transported to an appropriate medical facility in the event of a diversion or bypass served "primarily a patient care objective properly within the state's regulatory authority."³ The same court found that a state may require that air ambulances be equipped with voice communication systems for communication between the flight crew and medical crew, because this "is necessary for proper patient care."⁴ However, the court cautioned that, although aviation safety and emergency medicine may share some of the same goals, a state may not impose aviation safety or other aviation-related operational requirements (including any requirements related to air ambulance avionics equipment) on air ambulance operators, as these types of regulations on air ambulance operators – specifically regulations related to an operator's prices, routes, or services – because these types of regulations are also preempted by federal law.⁶ The source of this federal preemption is discussed in the sections below.

² Hiawatha Aviation of Rochester v. Minn. Dep't of Health, 389 N.W.2d 507, 509 (Minn. 1986).

³ Med-Trans Corp. v. Benton, 581 F. Supp. 2d 721, 740 (E.D.N.C. 2008).

⁴ Id.

⁵ Id.

⁶ *Id.* at 732-733.

Supremacy Clause of the U.S. Constitution

The preemption doctrine derives from the Supremacy Clause of the U.S. Constitution, which makes federal law the supreme "Law of the Land."⁷ Courts have held that state law is preempted under the Supremacy Clause in three circumstances: "(1) when Congress has clearly expressed an intention to do so ('express preemption'); (2) when Congress has clearly intended, by legislating comprehensively, to occupy an entire field of regulation ('field preemption'); and (3) when a state law conflicts with federal law ('conflict preemption')."⁸

In the case of helicopter air ambulance operations, courts have held that (1) Congress intended to occupy the field of aviation safety under the Federal Aviation Act of 1958 (Federal Aviation Act), 49 U.S.C. §§ 40101 *et seq.*, and, accordingly, any state law purporting to regulate air ambulance safety is preempted under the doctrine of field preemption; and (2) any state law related to an air ambulance operator's prices, routes, or service is expressly preempted by the Airline Deregulation Act of 1978 (ADA), 49 U.S.C. § 41713(b)(1). While this document does not specifically address conflict preemption, certain other state laws may be preempted where "compliance with both federal and state regulations is a physical impossibility," or where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."⁹

⁷ U.S. Const. Art. VI, cl. 2, which states "This Constitution, and the Laws of the United States which shall be made in Pursuance thereof ... shall be the supreme Law of the Land; ... any Thing in the Constitution or Laws of any state to the Contrary notwithstanding." See also Gibbons v. Ogden, 22 U.S. 1 (1824).

⁸ Med-Trans Corp., 581 F. Supp. 2d at 730 (quoting College Loan Corp. v. SLM Corp., 396 F.3d 588, 595-596 (4th Cir. 2005)). See also Abdullah v. Am. Airlines, Inc., 181 F.3d 363, 367 (3rd Cir. 1999) (quoting Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992)).

⁹ Gade v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 98 (1992).

(1) Federal Preemption of the Field of Aviation Safety¹⁰

The Federal Aviation Act created the Federal Aviation Agency (now the Federal Aviation Administration or FAA), and gave the FAA authority to oversee and regulate safety in the airline industry and the use of United States airspace by both civil and public aircraft.¹¹ As air carriers, helicopter air ambulances are subject to regulation under the Federal Aviation Act, including FAA aviation safety rules and regulations, and the requirement under 49 U.S.C. §§ 41101 *et seq.* that air ambulance operators obtain economic authority from the DOT Office of the Secretary in the form of a certificate of public convenience and necessity (PC&N certificate) or in the form of an exemption before providing air transportation of persons or property for compensation or hire.¹²

In examining the legislative history of the Federal Aviation Act, federal courts have found that "Congress intended to rest sole responsibility for supervising the aviation industry with the federal government."¹³ Supreme Court Justice William Rehnquist wrote that the "Act was intended to consolidate in one agency in the Executive Branch the control over aviation that had previously been diffused within that branch. The paramount substantive concerns of Congress were to regulate federally all aspects of air safety . . . and, once aircraft were in 'flight,' airspace management."¹⁴ The Federal Aviation Act thus gave the FAA plenary authority

¹⁰ The guidance in this paper is focused on entities that are required to hold air carrier certificates from the FAA. It does not address public aircraft operations.

¹¹ See generally, Part A of Subtitle VII of Title 49, United States Code; FAA regulations set forth in Title 14, Code of Federal Regulations; and operation specifications and notices to airmen issued by the FAA.

¹² See 49 U.S.C. § 41102; 14 CFR Part 204; and 14 CFR Part 298.

¹³ Abdullah, 181 F.3d at 368.

¹⁴ City of Burbank v. Lockheed Air Terminal Inc., 411 U.S. 624, 644 (1973).

to regulate the safety of aircraft and crew operations,¹⁵ and federal law alone "establishes the applicable standards of care in the field of air safety."¹⁶

The doctrine of field preemption recognizes that "Congress implicitly may indicate an intent to occupy a given field to the exclusion of state law . . . where the pervasiveness of the federal regulation precludes supplementation by the states, where the federal interest in the field is sufficiently dominant, or where 'the object sought to be obtained by the federal law and the character of obligations imposed by it . . . reveal the same purpose."¹⁷ Because the FAA's authority in aviation safety is plenary, courts have found that "FAA preemption in the area of aviation safety is absolute."¹⁸ State regulations, therefore, cannot "stray into the field of aviation safety."¹⁹ For instance, states cannot require that air ambulance operators provide specific aviation safety equipment or require that operators participate in aviation safety training.²⁰ DOT has noted that, to the extent state air ambulance requirements affect matters concerning aviation safety, including air ambulance aviation equipment, operation, and pilot

¹⁵ Even prior to the passage of the Federal Aviation Act, Supreme Court Justice Jackson stated, concurring in Northwest Airlines, Inc. v. Minnesota, 322 U.S. 292, 303 (1944), "Federal control is intensive and exclusive. Planes do not wander about in the sky like vagrant clouds. They move only by federal permission, subject to federal inspection, in the hands of federally certified personnel and under an intricate system of federal commands." ¹⁶ Abdullah, 181 F.3d at 367.

¹⁷ Schneidewind v. ANR Pipeline Co., 485 U.S. 293, 300 (1988) (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)).

¹⁸ Med-Trans Corp., 581 F. Supp.2d at 740.

¹⁹ Id.

²⁰ *Id. See also Air Evac EMS v. Kenneth S. Robinson, Comm'r of Health*, 486 F. Supp. 2d 713 (M.D. Tenn. 2007) (holding that the ADA preempted state regulation requiring, among other things, that helicopter air ambulances be equipped with avionics necessary for instrument approaches under certain weather conditions).

qualifications, these matters would fall under the purview of the FAA and therefore be preempted by federal law.²¹

As part of its authority to oversee and regulate aviation safety in the airline industry, the FAA has developed and administers an extensive system of aviation safety certification and regulation that extends to air ambulances.²² The FAA also regulates the safety aspects of medical equipment installation and storage aboard aircraft.²³ The FAA Modernization and Reform Act of 2012 (FAA 2012), Pub. L. No. 112-95, required the FAA to issue a final rule regarding helicopter air ambulance operations to address, among other things, flight request and dispatch procedures, pilot training standards, and safety enhancing technology and equipment. In February 2014, the FAA issued a Final Rule addressing these issues and implementing additional safety equipment requirements for helicopter air ambulances, minimum acceptable weather conditions, flight risk evaluation, and additional training for helicopter air ambulance operators.²⁴ FAA 2012 also required that the FAA initiate a "follow-on rulemaking" no later than 180 days after completion of the first rule.²⁵ This rulemaking was initiated on time and is currently ongoing. The requirements for this second rule are covered in

²¹ See Letter from Rosalind A. Knapp, Acting General Counsel, U.S. Dep't of Transp., to Gregory S. Walden, Counsel for Pacific Wings, L.L.C. (Apr. 23, 2007) (hereinafter "April 23, 2007 Letter from Rosalind A. Knapp"); see also 49 U.S.C. §§ 44701, 44703, 44704, 44705, 44711, 44717, & 44722.

²² Both fixed wing aircraft and helicopters can provide air ambulance services, and operators of air ambulances must obtain commercial Part 121 or Part 135 operating certificates from the FAA (together with the relevant operating specification, A021 for helicopter air ambulance operations, and A024 for fixed wing aircraft air ambulance operations). See 14 CFR Parts 119, 121 & 135.

²³ 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* April 23, 2007 Letter from Rosalind A. Knapp.

²⁴ See Helicopter Air Ambulance, Commercial Helicopter, and Part 91 Helicopter Operations; Final Rule, 79 Fed. Reg. 9932 (Feb. 21, 2014) (implementing requirements for all Part 91 helicopter operations, Part 135 rotorcraft operations, and Part 135 helicopter air ambulance operations to address safety concerns arising from an increase in air ambulance related fatalities from 2003 to 2008).

²⁵ See 49 U.S.C. § 44730(e).

sections 49 U.S.C. section 44730(e)(1)(A) & (B), and will include additional pilot training standards and requirements for safety equipment that will be worn or used by flight crewmembers and medical personnel on a flight. Under FAA 2012, helicopter air ambulance operators holding Part 135 certificates will also be required to submit annual reports to the FAA that provide information about their operations, including the number of accidents, the number of flight requests for a helicopter providing air ambulance services that were accepted or declined by the certificate holder, the number of flights and hours flown under instrument flight rules, and the number of incidents in which a helicopter was not directly dispatched and arrived to transport patients, but was not utilized for patient transport.²⁶

(2) Airline Deregulation Act (ADA) and Express Federal Preemption of Economic Issues

With aviation safety the province of the FAA, and the regulation of patient medical care the province of the states, the more complex questions of jurisdiction often concern the ADA's express preemption provision, which prohibits state economic regulation of air carriers. Congress enacted the ADA in 1978 to deregulate and boost competition in the aviation industry. Congress believed that deregulation would promote "efficiency, innovation, and low prices," as well as the "variety [and] quality . . . of air transportation services" necessary to support a robust aviation industry.²⁷ To "ensure that States did not undo deregulation with regulation of their own,"²⁸ or subject air carriers to a "baffling patchwork of rules,"²⁹ Congress included in the ADA a broad preemption clause that reads:

²⁶ See Pub. L. No. 112-95, sec. 306 (Feb. 14, 2012).

²⁷ Morales v. Trans World Airlines, 504 U.S. 374, 378-379 (1992).

²⁸ *Id*.

a State, political subdivision of a State, or political authority of at least 2 States 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 that may provide air transportation under this subpart.³⁰

A company that provides air ambulance services and holds an FAA air carrier certificate constitutes an air carrier for purposes of the ADA.³¹ In interpreting the language of the ADA, courts have broadly interpreted the words "related to" in the ADA preemption provision. A state requirement may relate to the price, route, or service of an air carrier even if the impact is "indirect";³² furthermore, the ability to comply with both federal and state law does not avoid preemption. State requirements with a "significant impact" on an air carrier's prices, routes, or services are preempted.³³ Requirements that impact an air carrier's prices, routes, or services in only a "tenuous, remote, or peripheral manner," however, are not preempted.³⁴

Federal courts, as well as DOT, have opined on whether certain state regulations have an impact on an air carrier's prices, routes, or services. For example, a federal court has held that a state may not require an air ambulance operator to provide specialty care in "a defined service area," because this impermissibly relates to an air carrier's routes and would be preempted by the ADA.³⁵ In addition, DOT has opined that a state program of regulation of air ambulance operators, to the extent it included economic regulations related to airline

²⁹ Northwest, Inc. v. Ginsberg, 134 S.Ct. 1422 (2014).

^{30 49} U.S.C. § 41713(b)(1); see also 49 U.S.C. §§ 40101(a)(4), (6) & (12).

³¹ See Med-Trans Corp., 581 F. Supp. 2d at 731-732.

³² Rowe v. N.H. Motor Transport Ass'n, 552 U.S. 364 (2008) (interpreting the motor carrier deregulation statute, based on the ADA).

³³ Med-Trans Corp., 581 F. Supp. 2d at 735 (citing Rowe, 552 U.S. 364 and Morales, 504 U.S. at 378).

³⁴ 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).

³⁵ *Med-Trans Corp.*, 581 F. Supp. 2d at 738; *see also* Letter from Ronald Jackson, Assistant General Counsel for Operations, U.S. Dep't of Transp., to Lynn D. Malmstrom, President & Chief Executive Officer, California Shock Trauma Air Rescue (May 19, 2014) (hereinafter "May 19, 2014 Letter from Ronald Jackson") (citing *Med-Trans Corp.*, 581 F. Supp. 2d at 738).

certification and rates, base of operations, accounting and report systems, or bonding requirements, imposed constraints on the operators' prices, routes, and services and was preempted by the ADA.³⁶ A federal court has held and DOT has opined that state requirements for 24-hour daily air ambulance availability are preempted by the ADA,³⁷ and DOT also advised that such availability requirements are further preempted by FAA aircraft and crew operation safety regulations.³⁸ DOT further has advised that the ADA preempts state regulation of air carrier advertising because it relates to the prices charged by air carriers providing air ambulance services.³⁹

DOT also has opined that the ADA would preempt a state regulation regarding subscription or membership programs offered by air ambulances.⁴⁰ Under the program at issue, the state mandated that air ambulance services provided under a subscription program must be available to all persons, including paying subscribers and non-subscribers alike. DOT

 ³⁶ Letter from Jim J. Marquez, General Counsel, U.S. Dep't of Transp., to Chip Wagoner, Assistant Attorney General, State of Ariz. Envtl. Prot. Unit (June 16, 1986); see also Letter from James R. Dann, Deputy Assistant General Counsel, U.S. Dep't of Transp., to Donald Jansky, Assistant General Counsel, Texas Dep't of State Health Serv. (Feb. 20, 2007) (hereinafter "February 20, 2007 Letter from James R. Dann"); May 19, 2014 Letter from Ronald Jackson.
³⁷ Med-Trans Corp., 581 F. Supp. 2d at 738-739; April 23, 2007 Letter from Rosalind A. Knapp.

³⁸ April 23, 2007 Letter from Rosalind A. Knapp. In this letter, DOT noted that a 24-hour commitment among state air ambulance operators could be pursued by non-regulatory means as state or local governments could enter into contracts with the operators. Under these contracts, state and local governments would be "customers" rather than "regulators." When, however, state and local government contracts have the "force and effect of law," DOT has also opined that ADA preemption applies. May 19, 2014 Letter from Ronald Jackson. In this letter, DOT noted that when a County's contract provisions governing ambulance rates, routes and services were not the product of "ordinary bargaining" but instead appeared to be "another mechanism for enforcing County ordinances regulating air ambulance services," and were enforceable with criminal penalties, it appeared that the County's service contracts were preempted. *Id.* (citing *Am. Trucking Ass'n, Inc. v. City of Los Angeles, Cal.*, 133 S.Ct. 2096 (2013)).

⁴⁰ See Letter from D.J. Gribbin, General Counsel, U.S. Dep't of Transp., to Greg Abbott, Attorney General, State of Texas (Nov. 3, 2008) (hereinafter "November 3, 2008 Letter from D.J. Gribbin").

found that this state regulation impermissibly related to an air carrier's prices and services by regulating the terms of service and its availability.⁴¹

States are also prohibited from requiring that air ambulance operators obtain certificates of authority (also known as certificates of need (CON) or certificates of public convenience and necessity (PC&N certificates)) to operate,⁴² as operating certificates are within the DOT Office of the Secretary's jurisdiction and could be used by a state to erect economic barriers to entry into the air ambulance market.⁴³ As noted above, Congress specifically authorized the Secretary of Transportation to issue PC&N certificates.⁴⁴ The Secretary may issue a PC&N certificate to a U.S. citizen air carrier to provide air transportation if the Secretary finds the air carrier is fit, willing, and able to provide transportation and to comply with aviation

⁴¹ *Id.* After receipt of DOT's opinion letter, the Attorney General for the State of Texas issued an opinion to the Commissioner of Health Services confirming that a state subscription program involving an annual fee and a reduced charge for air ambulance services is preempted by the ADA because it relates to the prices charged by the air ambulance provider. Texas Attorney General Opinion GA-0684 (Nov. 20, 2008).

⁴² See Med-Trans Corp., 581 F. Supp. 2d at 736 (citing Rocky Mountain Holdings, LLC v. Cates, 97–4165–CV–C–9 (W.D.Mo. Sept. 3, 1997) (finding that the ADA preempts Missouri law mandating a determination that the "public convenience and necessity" requires a proposed air ambulance service); *Hiawatha Aviation*, 375 N.W.2d at 500 ("The Department of Health cannot regulate the entry into the market of Hiawatha's proposed enterprise because this is a matter of aviation services within the jurisdiction and control of the FAA."); *Baptist Hosp., Inc. v. CJ Critical Care Transp. Sys. of Fla., Inc.*, CV–07–900193, p. 2 (Cir. Ct. Montgomery Co., Ala. July 31, 2007) (finding that Alabama's "CON statute and any other statute or regulation which require [an air ambulance service] to obtain a CON prior to conducting air ambulance operations within the state are preempted under the ADA as related to the price, route, or service of an air carrier").

⁴³ April 23, 2007 Letter from Rosalind A. Knapp (finding a state's broad certification requirement for air ambulances based on the "quality, accessibility, availability and acceptability" of service, or proscription of particular hours or times of operation, to be preempted under the ADA because those requirements impermissibly relate to an air carrier's services). A federal court also found to be preempted a state Certificate of Need program requiring an air ambulance provider to obtain a "valid EMS Provider License" and have the approval of an "EMS Peer Review Committee" in place to operate as a Specialty Care Transport Program. *Med-Trans Corp.*, 581 F.Supp.2d at 737. The facts in the *Med-Trans Corp.* case disclosed that political or economic considerations, rather than medical ones, could have affected entry into the air ambulance market, and the court stated: "[t]he 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." *Id.* at 738.

⁴⁴ 49 U.S.C. § 41102.

statutes and rules.⁴⁵ Once the Secretary certificates an air ambulance operator, the competitive marketplace,⁴⁶ rather than state regulations, controls the operator's prices, routes, and services, and only the Secretary may revoke an air ambulance operator's certificate.

Finally, while the ADA preemption clause expressly applies to services performed in interstate and foreign air transportation and in connection with the transportation of mail,⁴⁷ DOT has opined that "trying to carve out intrastate service as a mechanism to avoid preemption would neither be a realistic nor productive exercise."⁴⁸ DOT has stated that "any operator with Federal air carrier authority is to be accorded the protections of the Federal preemption provision, regardless of its precise flight operations. Thus no practical niche is carved out for only its intrastate operations."⁴⁹

State Regulation of Medical Standards

⁴⁵ Id. Congress also authorized the Secretary to exempt air ambulance operators from some federal economic requirements. 49 U.S.C. § 40109. The Secretary, accordingly, requires air ambulance operators to register as air taxi operators and to provide information on, among other things, their type of service and certificate of insurance. See 14 CFR Part 298. DOT may cancel an air ambulance's registration if the operator ceases operations, the insurance coverage changes or lapses, it fails to file an amended registration when required, the air carrier certificate or operations specifications is revoked by FAA, it fails to qualify as a U.S. citizen, or DOT determines that it is otherwise in the public interest to cancel the registration. 14 CFR 298.24.

⁴⁶ Chapter 411 of Title 49 authorizes the Secretary to impose certain economic regulations in connection with air carrier PC&N certificates, including bonding requirements and minimum levels of passenger and third-party aircraft accident liability insurance. 49 U.S.C. § 41112. Extensive requirements for aircraft accident liability insurance. 49 U.S.C. § 41112. Extensive requirements for aircraft accident liability insurance. 49 U.S.C. § 41112. Extensive requirements for aircraft accident liability insurance are set out in 14 CFR Part 205 (and extended to air ambulance operators under 14 CFR Part 298), and DOT has found that "Congress' enactment of section 41112, resulting in the broad requirements set out by DOT in implementing regulations, leaves no room" for state regulation of aircraft accident liability insurance requirements. April 23, 2007 Letter from Rosalind A. Knapp.

⁴⁷ 49 U.S.C. § 40102(a)(5) ("'[A]ir transportation' means foreign air transportation, interstate air transportation, or the transportation of mail by aircraft.")

⁴⁸ February 20, 2007 Letter from James R. Dann.

⁴⁹ February 20, 2007 Letter from James R. Dann. This opinion is further supported by *Med-Trans Corp.*, 581 F. Supp. 2d at 729-33. In *Med-Trans*, the defendant argued that the challenged law was not preempted because it limited the "definition of 'air ambulance' to one that provides purely intrastate transport." *Id.* at 729. The court held that "defendants and amici curiae incorrectly focus on the geographic scope of the state laws being challenged rather than on the nature of the air carrier and whether the state laws relate to that carrier's prices, routes, or services." *Id.* at 731. Because Med-Trans was an air carrier, and because the state law at issue affected Med-Trans' prices, routes, and services, the court held portions of the law preempted, despite the law's intrastate distinction. *Id.* at 733.

As discussed in the sections above, preemption law protects the pro-competitive goals of the ADA and the aviation safety authority of the FAA, but allows states to regulate medical standards of care. The following paragraphs generally summarize the types of activities states may regulate to help ensure proper medical care for patients within their borders, while providing cautionary information about when FAA aviation safety issues may arise.

- 1. Medical Standards of Care and Medical Training: State regulations of medical standards of care that serve primarily a patient care objective are properly within a state's regulatory authority. States therefore may regulate the guality of emergency medical care provided to patients, including requirements related to the qualifications and training of air ambulance medical personnel, their scope of practice, and credentialing. States also may require the maintenance of medical records and data collection and reporting. A federal court has found that vehicle- or equipment-related medical training, to ensure proper patient care on board an air ambulance, would not be preempted by the FAA's safety authority.⁵⁰ Accordingly, 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. However, this same court found training or other requirements related to aviation or aircraft safety to be preempted, to the extent the requirements purport to impose aviation safety related requirements on air ambulance providers.⁵¹ DOT has similarly opined that state medical training and medically-related licensure requirements applicable to the provision of patient care by an air ambulance medical crew generally would not be preempted by federal law.⁵² DOT has cautioned, though, that the FAA has minimum safety requirements for medical personnel aboard an aircraft,⁵³ including, among other things, that the medical crew must be trained in aircraft safety, the use and storage of medical equipment installed on the aircraft, and the use of aviation terminology to avoid misunderstandings during flights.
- Medically-Related Equipment Standards: A federal court has held that the ADA does not preempt state requirements "specifying medically related equipment, sanitation, [or] supply and design requirements for air ambulances," with regard to equipment or a requirement mandating a plan to inspect, repair, and clean medical

⁵⁰ Med-Trans Corp., 581 F. Supp. 2d at 741.

⁵¹ *Id.* at 740.

⁵² See February 20, 2007 Letter from James R. Dann.

⁵³ See id.; see also FAA Advisory Circulars 135-14A and 135-15A.

equipment on board.⁵⁴ DOT also has provided guidance on the permissibility of state medical equipment requirements related to air ambulance providers, writing that state medical requirements for such items as patient oxygen masks, litters, and patient assessment devices on board air ambulance aircraft are permissible so long as FAA requirements pertaining to safe installation and carriage aboard an aircraft are met.⁵⁵ Similarly, DOT has opined that state requirements for medical services provided inside an air ambulance, including minimum requirements for medical equipment, are not preempted as long as applicable FAA safety standards are met.⁵⁶ Thus, if a state requires particular medical equipment on board air ambulances and this equipment in turn necessitates a certain level of electrical power, there is no preemption as long as applicable FAA safety standards for installation or operation of the equipment have been found permissible, states may not prescribe aircraft equipment standards for air ambulances; these are preempted by the FAA's safety authority.⁵⁷

- 3. <u>Patient Care Environment:</u> DOT has stated that a proposed state rule mandating cabin climate control in air ambulances would not be preempted by the ADA if it serves primarily a patient care objective and if its installation conforms to FAA safety standards.⁵⁸ Other state requirements similarly related to the provision of patient care would not be preempted if they serve primarily a patient care objective and meet FAA requirements pertaining to safe installation and carriage aboard an aircraft.⁵⁹
- 4. <u>Medical Transport Plans and EMS Communications</u>: A federal court has found that state equipment requirements mandating that air ambulances synchronize voice radio communications with local EMS resources are not preempted if the equipment is necessary for proper patient care.⁶⁰ Further, this same court held that the ADA does not preempt a state requirement for written plans on transporting patients aboard an air ambulance to appropriate facilities.⁶¹ States may establish medically-related protocols to determine the mode of transportation for patients with emergency medical conditions in accordance with triage criteria and the appropriate medical institution to receive the patient, such as a trauma or STEMI center. States

⁵⁴ Med-Trans Corp., 581 F. Supp. 2d at 739-40.

⁵⁵ See April 23, 2007 Letter from Rosalind A. Knapp.

⁵⁶ See February 20, 2007 Letter from James R. Dann.

⁵⁷ Air Evac EMS, Inc. v. Robinson, 486 F. Supp. 2d 713, 722 (M.D. Tenn. 2007) (discussing a particular variety of altimeter mandated).

⁵⁸ Letter from Robert S. Rivkin, General Counsel, U.S. Dep't of Transp., to Lucille F. Bond, Assistant General Counsel, State of Tenn. (Nov. 12, 2010).

⁵⁹ See Med-Trans Corp., 581 F. Supp. 2d at 740-741 (recognizing that, while FAA preemption in the area of aviation safety is absolute, a state may adopt medically-related regulations that are necessary for patient care and do not "stray into the field of aviation safety").

⁶⁰ Med-Trans Corp., 581 F. Supp. 2d at 739-740.

⁶¹ *Id*.

may also develop medically-related EMS dispatch protocols to help assess and coordinate transportation needs for EMS patients. However, the FAA maintains authority for safety-related aviation requirements, including aircraft equipment requirements and the conditions under which an aircraft may be dispatched (as opposed to EMS medical dispatch requirements).⁶² The pilot in command of any aircraft is "directly responsible for, and is the final authority as to, the operation of that aircraft."⁶³ Accordingly, while EMS 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 as to the flight, is the flight crew's responsibility under FAA regulations and cannot be regulated by a state. For state EMS system planners, this means that an EMS agency, medical institution, or first responder could request helicopter air ambulance services, but the decision whether to fly the aircraft must remain with the pilot in command.

5. License and Accreditation Based on Medical Care Standards: DOT has opined that licensing requirements that exclusively address medical care or related medical care standards (as opposed to aviation economic matters or aviation safety) would not be preempted by the ADA that and could be imposed either directly with specific state requirements or indirectly through accreditation requirements.⁶⁴ DOT also has opined that state requirements for accreditation by an outside body would not be preempted by the ADA to the extent that accreditation requirements pertained exclusively to medical care.⁶⁵ Similarly, DOT has 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.⁶⁶

⁶² See 49 U.S.C. § 44701; see, e.g., 14 CFR 135.141-135.185, 135.201-135.229, 135.261-135.273 (Part 135 Rules regarding Aircraft and Equipment, VFR/IFR Operating Limitations and Weather Requirements, and Crewmember Flight Time and Duty Period Limitations and Rest Requirements); see generally 14 CFR 121.591-121.667 (Part 121 Dispatching and Flight Release Rules).

⁶³ 14 CFR 91.3.

⁶⁴ See April 23, 2007 Letter from Rosalind A. Knapp; February 20, 2007 Letter from James R. Dann.

⁶⁵ See February 20, 2007 Letter from James R. Dann.

⁶⁶ See November 3, 2008 Letter from D.J. Gribbin.

Conclusion

State regulators may contact DOT seeking guidance on whether a proposed regulation would violate the ADA or address aviation safety. In addition, although DOT is the lead federal agency for interpreting the ADA, state attorneys general may provide helpful guidance upon the request of a state official (and, in turn, may consult with DOT).