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NATIONAL TRANSPOPRTATION SAFETY BOARD

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Clarifying State and Federal Oversight of Helicopter Medical Transport
(6 pages)

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Distinguishing Federal Regulation of Aviation from State Regulation of Helicopter Air Ambulance Services as Part of States' Public Health Function

Overview

Over the past few years, the need for clarification has developed regarding the interface between state and federal oversight of helicopter medical transport services. While the oversight of aviation is clearly contained within the federal purview, oversight of public health planning and protection, emergency medical services, and the practice of medicine are clearly within the purview of the states. Helicopter medical transport bridges these two regulatory arenas.

Unfortunately, the appropriate line between state and federal oversight has been undermined by widespread use of federal preemption under the Airline Deregulation Act (ADA) to challenge state oversight of air ambulance services. As a result, the ability of states to govern the proper provision of air ambulance services as part of their established public health function has been seriously threatened. With a more than doubling of the number of medical helicopters operating in the U.S. since 2000, as well as growing public and medical concern about safety and appropriate use of helicopter medical transport services, properly defining the appropriate domain of federal and state oversight is essential. While FAA has jurisdiction over the aviation aspects of helicopter transport, states should be able to maintain certain additional requirements for the use of helicopters as air ambulances within their borders, just as they do ground ambulances, as long as such state regulation is consistent with federal helicopter aviation requirements. Accordingly, legislation should be enacted to clarify the rights of states to oversee the quality, standards, coordination, availability, and need for helicopter air ambulance services as part of their traditional role in governing health care services within their borders and distinguished from the role of the federal government in overseeing aviation.

Helicopter Air Ambulance Services Are Best Governed by States in Accordance with their Traditional Public Health Function

Regulation of the quality, standards, coordination, availability and need for health care services is a traditional state function. States regulate health planning and emergency and trauma care systems as well as the practice of medicine, including the licensure of health care practitioners, hospitals, and ground ambulances. Air ambulance services are no different from ground ambulance services except that patients are transported by air. The coordination and quality of medical care during transportation of critically ill or injured patients, whether by ground or air, should remain the purview of states.

The Institute of Medicine noted in their 2006 series on the emergency care system in the U.S. that states should "assume regulatory oversight of the medical aspects of air medical services, including communications, dispatch, and transport protocols" to better incorporate the air medical sector within the "broader emergency and trauma care system." [1] To date, however, the

[1] EMS at the Crossroads. IOM. Committee on the Future of Emergency Care in the United States Health System. National Academies Press. 2006. ISBN 0-309-66216-8

devil is in the details as to the domain of air ambulance services resulting in recurrent litigation as to the extent and domain of federal preemption.

The 2007 GAO Report on Aviation Safety [2] noted the challenges of FAA oversight of the air medical service sector, noting the complexity of relationships, the number of stakeholder entities and the limited available data regarding the number of patient transport flights. State EMS and health officials are charged with the public responsibility of establishing and maintaining a coordinated, integrated, healthcare system which includes all elements of the emergency care system from first responders to trauma centers. It is essential for State officials charged with the responsibility and accountability of the emergency care system to have the regulatory tools necessary to assure the public interest in trust of the EMS system.

Emergency patients are among the most vulnerable in healthcare. As noted in *The Rural and Wilderness EMS Agenda for the Future* State EMS and Health Authorities "Plan, integrate and regulate, at the state level aeromedical, critical care transport, and other statewide or regionwide systems of specialty care and transportation.[3] In the case of helicopter medical transport in emergency situations, patients routinely have all of the healthcare choices made under the terms of implied consent. From an aviation standpoint they are unique passengers without the choice of carriage, or carrier.

The States' Ability to Regulate Helicopter Air Ambulance Services for the Protection of Patients is Seriously Threatened

The ADA preemption provision is being utilized as a tool to dismantle numerous state regulatory structures governing air ambulance services. In North Carolina, a federal court just struck down state regulations that require air ambulance providers to serve patients 24/7, to serve all emergency patients in a region, and to be affiliated with local trauma centers. Similar challenges have taken place in numerous other states as well through litigation and opinion letters from the Department of Transportation. As one example, many states require climate control in all ambulances, including air ambulances. Certain air ambulance providers, however, have successfully challenged these state regulations for climate control in helicopters using the ADA. Many of the state regulatory structures that have been challenged were specifically designed to ensure the coordination and quality of medical care provided to patients being transported by air ambulances, and to ensure the appropriate use of scarce health care resources.

Unregulated Competition Threatens Patients and Increases Costs

As more and more state regulatory structures governing air ambulance services have been successfully challenged, many States and air ambulance providers are concerned that unregulated competition among air ambulance providers does not serve the best interest of critically ill and

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[2] *Aviation Safety: Improved Date Collection Needed for Effective Oversight of Air Ambulance Industry. February* 2007. GAO 07-353

[3] McGinnis KM, et. al. *Rural and Wilderness EMS Agenda for the Future.* National Rural Health Association, 2004. NRHA PU0904-69 Rural and Wilderness EMS Agenda for the Future. NRHA.

injured patients, especially those without the ability to pay or those in rural areas. In an unregulated air medical transport system, the desire for operating profitable services has the potential to impede patient access to air ambulance services for those in locations that are expensive to access, and for the uninsured needing emergency air medical transport.

Many states and providers are also concerned that unregulated helicopter air ambulance service promotes a proliferation of medically unnecessary and unsafe air transport. Air ambulance services should only be used when it is safe to do so, when the services are medically necessary and when transportation by air is preferable to transportation by ground. Competition and reimbursement should not inadvertently or improperly incentivize patient transport. Allowing such creates the conditions for unnecessary transports and flying in unsafe conditions. Indeed, Federal EMTALA[4] rules require a physician to certify that "the benefits outweigh the risks" of transfer and to "ensure that the transfer of an unstabilized individual is effected through qualified personnel and **transportation equipment**." It is clear there is a shared oversight and regulatory responsibility at the Federal and state levels. Strong evidence suggests that the result in totally unregulated state environments is that patients are flown by air when much less expensive ground ambulance service would be more appropriate.

Air ambulance services are distinguishable from traditional "air carriers" in that they are transporting patients requiring advanced and lifesaving medical care, not passengers or goods. The purpose of the ADA was to promote competition in the movement of air passengers and goods by "air carriers". The ADA was focused on enabling competition among air carriers in the commercial aviation realm. The embryonic air ambulance market was not within the contemplation of the law's drafters. The ADA was enacted prior to the development of trauma systems and air ambulance networks. Air ambulances are not transporting business travelers, vacationing families or goods, where "choice" of air carriers is based on traditional market forces such as price, route and service. Rather, air ambulances are transporting critically ill and injured patients who need timely and coordinated transport to life saving trauma centers.

Notions of competition presuppose the opportunity for the buyer of the service to exercise meaningful consumer choice. But consumers of medical emergency services are not able to do so -- they are critically ill or injured patients, often victims of traumatic injury such as automobile accidents, who need to be transported to the nearest appropriate trauma center as designated by the State's health plan.. The responding aircraft is ordinarily ordered by emergency responders (who are usually not financially responsible for the service) on behalf of the patient who is likely unconscious, disoriented or otherwise incapacitated. "Competition" is not a meaningful concept in this situation. Most air ambulance services are reimbursed on the basis of established fee schedules and not on the basis of market mechanisms anyway.

State Regulation of Air Ambulance Services Fills Gaps in Helicopter Medical Transport Regulation and Does Not Impede FAA Regulation of Aviation Safety

The Federal Aviation Administration (FAA) has and should retain comprehensive regulatory control governing aviation safety related to such matters as airworthiness, crew training, and

[4] Department of Health and Human Services. State Operations Manual. Appendix V. Interpretive Guidelines: Responsibilities of Medicare Participating Hospitals in Emergency Cases. May 2004.

flight operations. However, FAA, by its own admission, is not in the business of regulating the patient care or service coordination aspects of air ambulance operations. The FAA issued an Advisory Circular in 1991 recommending a variety of "best practices" (related to issues such as communication, equipment and training) for air ambulance helicopters, however, the document does not have the force of law.

While FAA has jurisdiction over the aviation aspect of helicopter transport, the ADA should not be utilized to prohibit states from regulating the provision of helicopters as air ambulances as long as state regulation is consistent with federal helicopter aviation requirements. States are in the best position to determine the proper balance of market and regulatory mechanisms for helicopter air ambulance services within their borders to ensure coordination, integration with emergency and trauma systems, and protect against unnecessary overuse. Just as states regulate and set licensing standards for hospitals and ground ambulances, states should be able to require proper training and qualifications of medical personnel, as well as the essential equipment and aircraft standards necessary while transporting critically ill and injured patients to ensure they receive the highest possible quality of care aboard the air ambulance transporting them.

But because States' legal authority to oversee air ambulance services has been called into question and the FAA has limited its involvement, a gap has developed in the regulatory scheme regarding access, availability and quality of helicopter air ambulance services. States should not be required to regulate in those areas, but nor should they be preempted from regulating coordination and quality of care for their residents as long as their regulations do not conflict with Federal aviation safety laws.

Legislative Proposal to Clarify State and Federal Oversight of Helicopter Medical Transport Services

In an effort to clarify the appropriate domains of state and federal oversight a coalition of air ambulance providers from across the country has proposed legislation to delineate the appropriate oversight balance. Working from the principles outlined in consensus Association of Air Medical Services, National Association of State EMS Directors, and National Association of EMS Physicians *Air Medical Systems: Future Development* white paper[5] the coalition has proposed legislation to set the appropriate extent and the limits of state oversight. Delineating this balance will lead to a more integrated emergency care system and eliminate the continued contentious litigation as to the extent of the federal preemption.

The proposed legislation **would** recognize the ability of a state to regulate, to the extent each may choose to do so, the number of helicopter air ambulance providers operating in a given state or service area within a State, the destinations of patient transport, minimum coverage and coordination standards, and the quality of medical care provided by such air ambulances. The proposed legislation **would not** require states to regulate air ambulance services in any way, would not impede Federal law with respect to aviation safety, would not affect interstate transport except as provided by mutual aid agreements, would not grant new regulatory authority

[5] McGinnis KM, Judge TJ, et.al. *Air Medical Systems: Future Development as an Integrated Component of EMS Systems*. Prehospital Emergency Care. 11:4; 353-368 October 2007.

directly to political subdivisions, would not affect fixed wing services, and would not alter current law with regard to existing limits on state regulatory authority over air carrier services related to rates, taxes or user fees.

The proposed legislation enables an organized approach to state regulatory oversight of helicopter medical transport services. It will also improve the coordination of oversight shared by the FAA and State EMS and health authorities. Enactment of this important legislation is essential to honoring the trust of patients, their families, and the public who expect the availability of timely, safe and coordinated helicopter medical transport services where and when they need them.