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Position Statement of the National Association of State Emergency Medical Services Officials on the Need for Shared State and Federal Regulation of Air Medical Services

Executive Summary

The National Association of State Emergency Medical Services Officials (NASEMSO or “the Association”) is the lead national organization for emergency medical services (EMS) and a respected voice for national EMS policy. The members of NASEMSO include state EMS directors, medical directors, trauma managers, and other officials charged with building, leading, and regulating their statewide systems of emergency medical response. The Association believes that air medical services (AMS) are fundamentally medical resources that require effective integration into the EMS system and regulation by state EMS officials.

From the early 1970’s, when civilian air medical services began in the United States, through the year 2000, there was a slow but steady growth of fixed and rotor wing air medical services. They were generally non-profit, hospital-based or governmentally-sponsored helicopter programs. The slow growth of these programs was largely because air medical services were expensive to operate and were not well reimbursed by health insurance. The slow growth allowed EMS system leaders and regulators, and AMS operators, to integrate these services into the complex emergency response systems in individual states.

In 2000, however, reimbursement for AMS dramatically changed. The Centers for Medicare and Medicaid Services (CMS) issued a new and more favorable reimbursement formula for air medical services. This allowed AMS to operate in areas where it may have been needed but previously unaffordable. The change in reimbursement was followed by extraordinary growth in the number of AMS helicopter services throughout the country. The predominant model changed to private, for-profit operators of independently based helicopters instead of non-profit hospital-based or governmental helicopters. Consolidation of these private, for-profit services into large, national or regional companies has also been noted. The growth of the for-profit, consolidator model has created medical necessity and system integration questions in many areas. It is the unprecedented growth in the numbers of aircraft in general, as well as challenges to efforts at integration, that have strained state EMS systems nationwide.

Modern emergency medical services were born as a “system” in the early 1970’s. As such, response to a 9-1-1 call for help results in a complex choreography of dispatchers, responders, and hospital personnel and resources. Changes in this system must also be carefully planned and implemented, and undertaken only after the need for such change is demonstrated by medical studies or other evaluative evidence.

Since 2000, however, the rapid injection of hundreds of new emergency medical aircraft responders into existing EMS systems has created coordination and confusion issues. New AMS operators beginning operation in a particular geographic area without effective coordination by state EMS

regulatory entities has been problematic for EMS system response when state officials are unable to set standards for accessing, dispatching, and coordinating these services. Adding to this challenge is the apparent strong desire of at least some AMS operators to avoid state integration and regulatory processes. There have been several successful court challenges by AMS operators to state emergency system planning and implementation processes.

The Airline Deregulation Act of 1978 (ADA) has been frequently cited as the major factor preempting state EMS offices from regulating fixed and rotor wing AMS as they do other emergency medical services in their jurisdictions. It is argued that the U.S. Department of Transportation (USDOT) is solely authorized to regulate these air services.

The difference, however, between aircraft operations transporting passengers that are typically regulated solely by the ADA and AMS operations are important.

First, unlike typical air carriers, AMS providers do not simply transport patients between two points, they provide sophisticated emergency medical care that must be overseen by physicians and coordinated within the EMS systems.

Second, while airline passengers can choose their mode of transport and airline, EMS patients and their families generally cannot. Patients need protection as medical consumers.

Third, unlike typical air services, AMS providers must act together with another system – the healthcare system – in order to operate. Air medical; service providers are one component of a state's health and EMS system and must routinely interact with a variety of emergency, public safety, and health care personnel and operations in order to provide services.

Air medical services are, first and foremost, medical resources that are used within EMS systems to provide patient care. State EMS agencies have the necessary experience and authority in planning, coordinating, integrating, and regulating the medical resources that are components of EMS systems to provide appropriate oversight of the medical aspects of AMS operations. However, air medical services are also air transport resources and possess certain aspects that must continue to be regulated by federal agencies.

The Association believes that clearly defined areas of federal and state responsibilities can be delineated in order to ensure effective oversight of air and medical operations of AMS services. The federal government and the states should coordinate their oversight of AMS operations in a manner that will ensure effective integration in emergency care systems and appropriate use in meeting patient needs. The federal government authority should be clarified to reserve to the states the oversight of the medical aspects of AMS operations.

Introduction

The National Association of State Emergency Medical Services Officials (NASEMSO or “the Association”) is the lead national organization for emergency medical services (EMS) and a respected voice for national EMS policy. The Association is committed to the development of effective, consistent, integrated, community-based, and universally available EMS systems. Its vision is a seamless nationwide network of coordinated and accountable state, regional and local emergency care systems that employ public health principles, data and evidence as a basis for safe and effective care in day-to-day operations as well as during catastrophic events.

The members of NASEMSO include state EMS directors, medical directors, trauma managers, and other officials charged with building, leading, and regulating their statewide systems of emergency medical response. They typically lead EMS system development, and license the agencies (ambulance and non-transporting first responder) and personnel (first responders, emergency medical technicians or EMTs, and paramedics) that provide emergency patient care and transportation. They may also license ambulances and other EMS vehicles, designate trauma and other specialty care centers, and designate or certify emergency medical dispatch centers.

In 2006, following a disastrous three year period (2002 – 2005) in which 55 AMS crashes occurred (41 helicopters and 14 airplanes) killing 54 people, and seriously injuring 19 others, NASEMSO joined with the National Association of EMS Physicians (NAEMSP), and the Association of Air Medical Services (AAMS) in publishing a report on the regulation and integration of AMS in EMS systems¹.

This position paper is a synthesis of that consensus document by AMS providers and EMS leaders and regulators whose concerns remain an issue. In the past fourteen months, nine AMS crashes have killed 35 people. The Association recognizes that crash safety is truly the concern of federal regulators. However, of increasing concern to NASEMSO members is that the number of medical helicopters has more than doubled since 2000. This growth has occurred in many instances with air medical service operators resisting regulation by state EMS offices which have the needed experience and expertise in coordinating medical response. They have repeatedly, and often successfully, litigated arguing that the Airline Deregulation Act of 1978 (ADA) preempts state EMS regulation of AMS in favor of the U.S. Department of Transportation (USDOT) and its agencies.

Air medical services are not merely transport services, but are fundamentally medical resources. As such, they must be effectively integrated within emergency medical services systems and regulated by the states. The ADA was not intended to inhibit state regulation of medical care. This paper explains why Congress must address the regulatory preemption issues for AMS created by the ADA so that states may partner with the USDOT in the regulation of air medical services.

1- McGinnis KK, Judge, T et al *Air Medical Services: future development as an integrated component of the Emergency Medical Services (EMS) System: a guidance document*; Prehosp Emerg Care. 2007 Oct-Dec;11(4):353-68 Accessed in December, 2008 at: <http://www.nasemso.org/Projects/AirMedical/>

Rapid Growth in the Number of Medical Aircraft

From the early 1970's, when civilian air medical services (AMS) began in the United States, through the year 2000, there was a slow but steady growth of fixed and rotor wing air medical services. Among the reasons for this growth were the loss of full-service rural hospitals, the consolidation of specialty services (e.g. trauma, cardiac, emergency neonatal) and their organization around statewide/region-wide specialty systems of care, hospital competition, and regionalization of hospital systems.

These AMS programs were generally non-profit, hospital-based or governmentally-sponsored helicopter operations, with the occasional emergency fixed wing service in remote areas and fixed wing commercial services for non-emergency transports. That growth of these programs was slow was largely because air medical services were expensive to operate and were not well reimbursed by health insurance. As a result, these services were typically operated by large hospital systems or by governments that had other sources of funding to subsidize AMS losses. The slow growth allowed EMS system leaders and regulators, and AMS operators, to integrate these services into the complex emergency response systems in individual states.

In 2000, however, reimbursement for AMS dramatically changed. The Centers for Medicare and Medicaid Services issued a new reimbursement formula for air medical services that emerged from a "negotiated rule-making process." That reimbursement formula recognized the costs of operating AMS under the hospital-based and governmental models, employing large twin-engine helicopters, with their added indirect and other costs of the support provided by those organizations. It was, therefore, a favorable change for AMS providers.

At about this time, the extraordinary growth in the number of AMS helicopter services throughout the country began. The number of medical helicopters then more than doubled from under 400 in 2000 to 840 in 2008 (see Figure 1). Further, the predominant model has changed to private, for-profit operators of independently based helicopters instead of non-profit hospital-based or governmental helicopters. In 2006, the number of air medical service programs declined for the first time, with two (1%) less than in 2005. However, the number of aircraft increased by 39 (5%) in the same year. This trend of service consolidation and growth in aircraft numbers has continued since then.

There have been dramatic increases in the numbers of medical helicopters serving specific populations. Texas is now served by 90 medical helicopters, while Pennsylvania has 62, and Florida has 61. Oklahoma has increased from three bases and four aircraft in 2000 to 25 bases and 34 aircraft today.

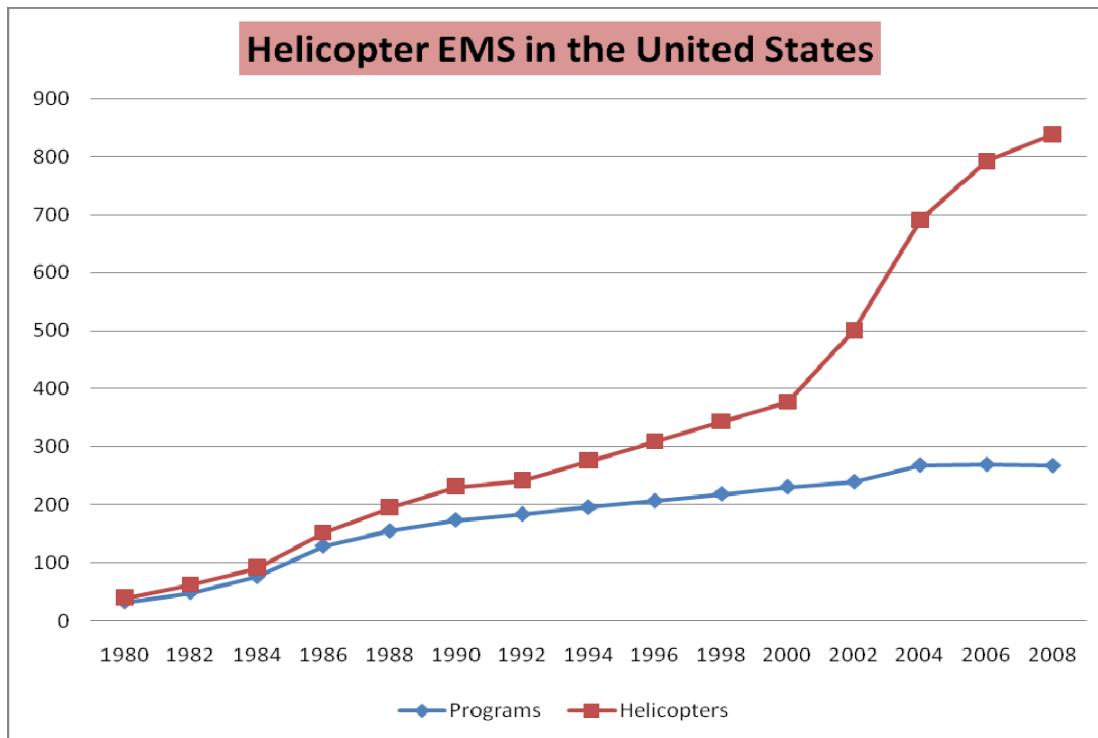


Figure 1 (Figures derived from joint consensus paper of the Association of Air Medical Services, NASEMSO, and the National Association of EMS Physicians: McGinnis KK, Judge, T et al *Air Medical Services: future development as an integrated component of the Emergency Medical Services (EMS) System: a guidance document*; Prehosp Emerg Care. 2007 Oct-Dec;11(4):353-68 Accessed in December, 2008 at: <http://www.nasemso.org/Projects/AirMedical/>. 2008 data point is from ADAMS 2008 accessed at: http://www.adamsairmed.org/pubs/AMTC08_poster.pdf in February, 2009.)

While a review of the EMS literature fails to identify any specific nationwide need for rapid aircraft growth around 2000, the goal of improved reimbursement was to allow programs to operate in areas where AMS was needed but previously unaffordable. This appears to have been effective. The trend toward for-profit operations, consolidation of programs by these operators and the rapid growth in the numbers of their aircraft raises other questions.

Regardless of cause, the growth in the number of aircraft in the past eight years has brought unprecedented challenges to state EMS systems to integrate them effectively.

Problems for Emergency Care Systems Resulting from Uncontrolled Growth

Modern emergency medical services were born as a “system” in the early 1970’s. As such, response to a 9-1-1 call for help results in a complex choreography of dispatchers, responders, and hospital personnel and resources. Figure 2 depicts that complexity. Such an interweaving of varied personnel, equipment, and facility resources requires careful coordination in order to meet the needs of the critically ill or injured patient.

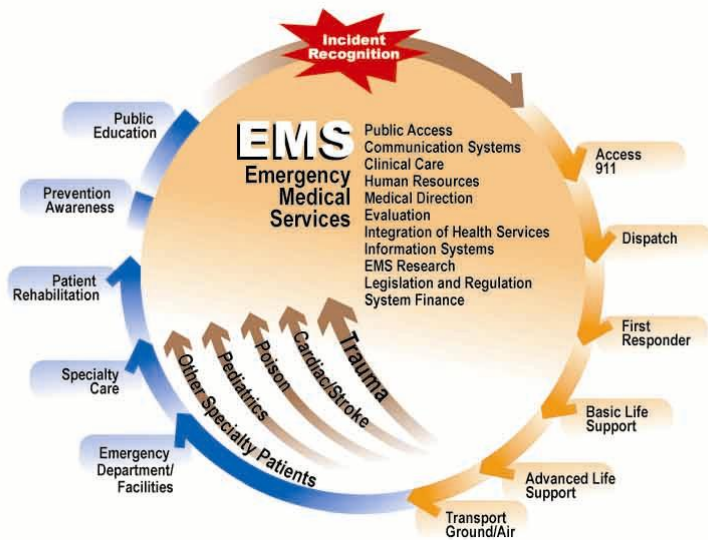


Figure 2 Source: USDOT; National Highway Traffic Safety Administration; Office of EMS

Changes in this system must also be carefully planned and implemented, and undertaken only after the need for such change is demonstrated by medical studies or science evidence. To implement any change typically requires new protocols and procedures, the training of hundreds or thousands of personnel, and the establishment of ways to monitor the effect of the change on EMS response, patient care, and patient outcome.

As the EMS systems in regions and states matured past basic structural issues, and as AMS providers became more prevalent, the frequency and complexity of their interaction increased. Regional systems of trauma care were proven effective if certain rules and protocols about accessing AMS immediately, the location and availability of AMS, interacting with AMS on the scene of the injury, and selection of hospital destination were followed. Other time-dependent conditions such as stroke and heart attack require similar rules and protocols for emergency decision-making.

These rules and protocols have become the basis of regionalized or statewide systems approved and enforced by state EMS officials. Their credibility is supported not only by the medical literature, but by their inclusion in formal state-level planning processes, and by the federal government’s own rulings in situations impacted by the Emergency Medical Treatment and Active Labor Act (EMTALA).

It is of the utmost importance to patient welfare that unequivocal rules and protocols exist to guide the following decisions:

- What AMS providers may hold themselves out to serve the public in the state?
- What are the requirements for licensure to operate as an AMS provider in the state?
- For which patients and circumstances is emergency AMS is to be summoned?
- Who is authorized to summon emergency AMS?
- What emergency AMS is to be requested by distance, location, type/level of care provided, and availability?
- Who is to be called, and how, to summon emergency AMS and how does this fit with the 9-1-1 public safety answering point (PSAP) system?
- Under what conditions may a second emergency AMS provider be sought if a first contact is unavailable?

- How will emergency AMS and ground EMS at the scene interact and make decisions about patient care and transfer?
- To what hospital will the patient be flown?

Since 2000, the rapid injection of hundreds of new emergency medical aircraft responders into existing EMS systems, often without benefit of some of these rules or protocols, has created coordination and confusion issues. In some areas, there are more aircraft than necessary to carry those relatively few patients who need to be transported by air. There is often pressure to fly more and more patients who do not require this method of transport, unnecessarily increasing health costs for all and exposing greater numbers of patients to avoidable risks.

New AMS operators or aircraft beginning operation without effective coordination by state EMS regulatory entities has been problematic for EMS system response. When state officials are unable to set standards for accessing, dispatching, and coordinating these services response confusion may result. As just one example, NASEMSO members have reported instances when multiple air medical services respond unnecessarily to one car crash in an uncoordinated fashion and when they have not been asked to respond by a public safety dispatch agency. This is similar to 1970's era "call-jumping" by ground ambulance services, which EMS systems effectively put to an end long ago.

The sudden expansion of air medical assets has been a formidable challenge for state EMS systems and to state EMS offices throughout the U.S. Adding to this challenge is the apparent strong desire of at least some AMS operators to avoid state integration and regulatory processes involved, in favor of rapidly ramping-up new operations to provide more helicopter flights. As a result, there have been several successful court challenges by AMS operators to state emergency system planning and implementation processes.

Air Medical Services Cannot be Regulated as Simple Air Carriers

The Airline Deregulation Act of 1978 (ADA) has been frequently cited as the major factor preempting state EMS offices from regulating fixed and rotor wing AMS as they do other emergency medical services in their jurisdictions. It is argued that the U.S. Department of Transportation (USDOT) is solely authorized to regulate these air services, and that, under the ADA, states are precluded from regulations that would affect "rates, routes, and services" of AMS programs.

When the ADA was passed, however, civilian air medical services had existed for only a few years, and state EMS agencies were only beginning to regulate EMS. How air medical services fit into EMS systems and might be regulated by them had not been well developed and was not considered when the ADA was enacted. Further, provisions for AMS regulation beyond the same general air safety and other requirements placed on any air carrier and flight crew were not considered. Finally, the types and levels of medical care that are now provided by AMS services did not even exist when the ADA was enacted.

The differences between aircraft operations transporting passengers that are typically regulated solely by the ADA and AMS operations are important.

First, unlike typical air carriers, AMS providers do not simply transport patients between two points. While one of the benefits of AMS is certainly speed of transport, equally or more important

is the high level medical care that can be provided at the scene and while the patient is en route during transport. This is sophisticated medical care that must be overseen by physicians and coordinated as part of the overall medical response to the patient.

Second, while airline passengers can choose their mode of transport and airline, EMS patients and their families generally do not have this same choice with AMS providers. Patients need protection as medical consumers of services about which they, under emergency circumstances, do not have the ability to make informed decisions.

Third, unlike typical air services, AMS providers must act together with another system – the healthcare system – in order to operate. AMS providers are one component of a state’s health and EMS system and must routinely interact with a variety of emergency, public safety, and health care personnel and operations in order to provide services. These include 9-1-1 dispatchers, first responders and paramedics, police and fire who respond to an incident, as well as the hospitals, physicians and nurses who participate in that system. For an EMS system to be successful there must be a high degree of coordination among all components and state oversight is required to assure that this coordination is effective. Consequently, AMS providers should be subject to the same coordination requirements as are all other components of the EMS and health care systems.

State EMS Agencies Should Team With Federal Agencies to Provide Effective Oversight of AMS Providers

First and foremost, air medical services are medical resources that are used within EMS systems to provide patient care. State EMS agencies have the necessary experience and authority in planning, coordinating, integrating, and regulating the medical resources that are components of EMS systems to provide appropriate oversight of the medical aspects of AMS operations. Recently, Federal Aviation Administration officials have been quoted as stating that Congress had not intended the ADA to apply to the medical operations of AMS². Indeed, in 2006, the national Institute of Medicine called upon state EMS agencies to regulate the medical aspects of AMS².

NASEMSO asserts generally that states must be given responsibility for regulatory oversight of the medical aspects of fixed and rotor wing air medical services which advertise service and/or operate in their states. This oversight includes communications, dispatch and transport protocols. States should regulate the medical aspects of the operation including medical personnel on board (nurses, paramedics, physicians, and others providing patient care), the medical equipment, and the transport destination protocols regarding hospitals, and trauma and other specialty centers. In addition, states should have exclusive right to establish dispatch protocols for air medical response and should incorporate air medical providers into the broader emergency and trauma care system through improved communication.

Specifically, NASEMSO asserts that the following components of AMS (in addition to the clarifications in the federal section below) should be the regulatory purview of state EMS agencies and parts of their system coordination or licensing/certifying responsibilities, as they currently are for ground ambulance services:

- Determining the need for new AMS programs and aircraft.
- Coordinating the distribution of aircraft to ensure good statewide access. This should include the authorized leadership role in system response planning and implementation, and

2 – Institute of Medicine, National Academy of Sciences; *Emergency Medical Services at the Crossroads*; 2007; 162. Accessed in February, 2009 at: http://books.nap.edu/openbook.php?record_id=11629&page=162.

approving aircraft basing and jurisdiction. It should also include authority to assure dispatch procedures required to achieve the closest, appropriate response.

- Approving the hours of service of AMS providers for the purpose of effective integration.
- Requiring medical responsibility and oversight for AMS, including:
 - Establishing policies and procedures to guide determinations of the medical necessity for flights and for the method(s) of flight dispatch, launch, multi-aircraft coordination, and communications with all EMS system participants involved;
 - Establishing protocols for the determination of appropriate destinations for patient transport;
 - Establishing the protocols for use by medical flight crews;
 - Establishing and enforcing clinical care standards (scope of practice, proposed crew make-up, and number of practitioners to sustain service).
- Determining the methods for licensure/certification of medical flight crews, the medical adequacy of aircraft and their processes and requirements for their EMS licensure/certification (includes requirements for patient medical care support such as air conditioning and quality of air sources, and adequacy of compartment for medical operations);
- Determining arrangements for reciprocal EMS licensure/certification of air medical services among states and territories and the use of interstate agreements or other tools to assure appropriate patient care when state borders are crossed.
- Identification of provider agency (corporate entity and headquarters, FAA certificate holders, identity of medical providers);
- Establishing requirements for insurance held (beyond the USDOT requirement of air carrier liability insurance for air carriers engaged in air medical operations) to address medical liability;
- Assuring clarity in advertising (identity of type/level/availability of medical care and providers);
- Establishing and enforcing dispatch, access and use protocols (including identification of authorized callers).
- Assuring interoperable communications equipment and integration.
- Assuring provision of ground safety training for EMS/public safety personnel.
- Assuring integration with state trauma and other specialty care programs.
- Assuring integration with other AMS providers in a system.
- Assuring quality assurance program involvement and oversight.
- Establishing waiver to allow unlicensed operation and alternative staffing requirements and qualifications in non-routine emergency situations.
- Use of “deemed status” in licensing/certification decisions for personnel and agencies, including the application of standards from nationally recognized standard setting bodies.

At the same time, however, AMS are also air transport resources and possess certain aspects that must continue to be regulated by federal agencies. These aspects include air transport safety and air system integration and operation.

It should continue to be a federal responsibility to regulate:

- Air carrier citizenship
- Air Transport Related Liability insurance

- Limitations on use of Business Name
- Pilot in Command Authority
- Aircraft and Equipment
- Aircraft Airworthiness
- Flight Operations Specifications
- Certificate Requirements (Part 135)
- Doing Business As (DBA) Requirements
- Operating Limitations and Weather Minimums
- Non-Medical Flight Crew Licensing
- Non-Medical Flight Crew Member Limitations and Crew Rest Requirements
- Non-Medical Crew Member Testing Requirements
- Non-Medical Training Requirements
- Aircraft Performance Operating Limitations
- Non-Medical Equipment, Instrument and Certificate Requirements
- Special Flight Operations
- Maintenance, Preventive Maintenance and Alterations
- Operating Noise Limits

The general provision of federal responsibility, however, for “rates, routes and services”, is inappropriate and must be further parsed. As specific examples:

- “Rates” includes the charge for patient care and is reimbursed by third-party insurance providers including Medicare. State EMS agencies (directly or by delegation to local jurisdictions) and Medicare and other third party payers (and not other federal agencies), should regulate AMS “rates” as they do for ground ambulance services.
- Membership programs or subscription services must also be construed as an application of “rates” only if the regulatory responsibility is changed per the previous paragraph. Free market competition through subscription programs, uncontrolled except by the USDOT would be disruptive to the effective dispatch and coordination of AMS response to emergencies. Such dispatch must be without regard to membership or subscription status in an emergency.
- “Routes” must never be construed to impact the ability of states to designate appropriate destination facilities or EMS providers to use best judgment in determining how to transport a patient to them. Destination choice is a medical decision and cannot be a free market instrument of competition. The term “routes” implies “routine”, which is not a concept that applies in emergency medical circumstances.
- The term “services” must be defined to include the medical care provided by AMS. As such, a state EMS system and agency should be able to coordinate, limit and integrate an AMS provider’s “services” to emergency response, interfacility, trauma, cardiac, neonatal, or other transfers as it deems medically appropriate.

Finally, it is important that the constitutional Interstate Commerce Clause not be interpreted to limit state EMS regulation of fixed or rotor wing AMS. State EMS agencies should be responsible for assuring the type and level of patient care of any such provider.

Conclusion

An unprecedented growth in the number of emergency medical aircraft has occurred in the past eight years. Changes in reimbursement for AMS have allowed services to grow in areas where they had been needed but were previously unaffordable. Questions remain about the increasing predominance of for-profit AMS operations, their consolidation of AMS programs, and their contribution to the growth of aircraft numbers. Uncontrolled insertion of new aircraft and AMS providers in an EMS system has been disruptive to states attempting to provide effective EMS system response and patient care. The federal government and the states should coordinate their oversight of AMS operations in a manner that will ensure effective AMS use in state EMS and health care systems and appropriate use in meeting patient care needs. The federal government authority should be clarified to reserve to the states the oversight of the medical aspects of AMS operations.

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