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AIR MEDICAL SERVICES: FUTURE DEVELOPMENT AS AN INTEGRATED COMPONENT OF THE EMERGENCY MEDICAL SERVICES (EMS) SYSTEM

(16 Pages)

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SPECIAL CONTRIBUTIONS

AIR MEDICAL SERVICES: FUTURE DEVELOPMENT AS AN INTEGRATED COMPONENT OF THE EMERGENCY MEDICAL SERVICES (EMS) SYSTEM

A GUIDANCE DOCUMENT BY THE AIR MEDICAL TASK FORCE OF THE NATIONAL ASSOCIATION OF STATE EMS OFFICIALS, NATIONAL ASSOCIATION OF EMS PHYSICIANS, ASSOCIATION OF AIR MEDICAL SERVICES

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INTRODUCTION AND SUMMARY

The use of air medical transport evolved from military experience, initially using fixed wing transport in the Second World War, with the widening use of helicopters initiated in the Korean conflict. Rapid trauma response systems built around helicopters were fully deployed in the Vietnam conflict. The military experience in managing trauma with rapid transport migrated to the civilian arena in the early 1970s.

As reported in a white paper by the Foundation for Air Medical Research and Education, cited and presented in Appendix 3:

> The Maryland State Police aviation program. . . in March, 1970, became 'the first civilian agency to transport a critically injured trauma patient by helicopter.' The first civilian hospital-based medical helicopter service was established in 1972 at St. Anthony's Hospital in Denver, Colorado.
>
> By 1980, some 32 helicopter emergency medical services (HEMS) programs with 39 helicopters were flying more than 17,000 patients a year. By 1990, this grew to 174 services with 231 helicopters flying nearly 160,000 patients. Ten years later, 231 helicopter services with 400 aircraft were flying over 203,000 patients each year. By 2005, 272 services operating 753 rotor-wing (helicopter) and 150 dedicated fixed wing aircraft were in operation. There are now approximately a half-million helicopter and fixed wing transports each year." This represents only approximately 3% of the ambulance transports to hospitals estimated to occur each year. However, being a relatively expensive and relatively rapidly growing emergency medical service provider segment which is being assimilated in traditional systems of ground EMS providers, it is of great interest.

Historically, air medical service (AMS) programs developed as components of hospital trauma programs and were owned and operated by these early trauma centers. Most early programs were staffed with nurse/nurse or nurse/physician teams with a physician level scope of practice rather than the evolving scope of practice for EMTs and paramedics predominantly housed in the public safety system. Many AMS providers focused their services on interfacility, high acuity transfers and often across state and even national borders. These characteristics often influenced the development of air ambulance systems to be in parallel with, or in isolation from, the development of the wider EMS system. As a result, today's AMS systems in many states are often regarded as peripheral components of

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the EMS system and lack the operational and state government regulatory integration experienced by ground EMS providers.

While earlier focus was on the unique ability of aircraft to provide rapid transport, current practice is centered on the added ability to deliver tertiary facility type critical care capabilities to an injured or ill patient whether in a community hospital, at an accident scene, or during transport. Critical injury remains a daunting challenge with recent data from the Agency for Healthcare Research and Quality (AHRQ) identifying trauma as the nation's costliest medical problem. Over the last three decades of EMS system development, the availability of helicopter EMS (HEMS) has grown to meet this challenge and has become an expectation in the delivery of contemporary trauma system care.

Largely because of changes in the healthcare system, the last decade has seen substantial growth in the number of air medical service (AMS) provider agencies and aircraft transporting patients both between hospitals and directly from emergency scenes to hospitals. Rural hospital conversion to Critical Access Hospital (CAH) status is an example of such change. This rapid growth is coupled with uncoordinated changes in the organization of services such as the appearance of multiple AMS providers within distinct hospital catchment areas and the evolution of multistate regional AMS provider organizations. The corporate organization and financing of air medical services has also undergone change. This has evolved amidst substantial variation in state and territorial regulation of the establishment and operation of air medical services and in the degree of integration of AMS within regional and state EMS systems. A 2006 report on EMS by the Institute of Medicine recommends that states assert their authority in regulating the medical aspects of AMS and improve its integration within their EMS systems.[1]

This paper was developed as a cooperative project among the National Association of State EMS Officials (NASEMSO), the National Association of EMS Physicians (NAEMSP), and the Association of Air Medical Services (AAMS). It is designed as a resource guide for state EMS system leaders, planners, and regulators to appreciate the similarities and differences between the ground and air components of the EMS system, and their development, integration, and regulation within that EMS system.

An "interrogatory format" has been used to facilitate understanding this complex issue. In this format, EMS leaders are provided with an overview of the issue and its components. They are then presented a set of "core principles," which are a key foundation for successful development, integration, and regulation within the EMS system. Also presented, in the Appendices, are resources for EMS leaders to use in this process in their states. These include a sample set of EMS regulations taken from one state and modified to reflect some of the issues discussed here, sample policies and guidelines from national expert groups in this area, and references to and content from related federal policy and material. Finally, the paper lists a set of "important questions" that are central to successful air medical development, integration, and regulation within the EMS system. They are amplified by "rationale" or discussion of the question and relevant factors to consider in answering the question. It also includes further questions that should be considered by EMS leaders in answering the "important questions" in the environment of their own EMS system and bureaucratic and political arenas.

OVERVIEW: CONTRASTING AIR AND GROUND EMERGENCY MEDICAL SERVICES

Although there are many similarities between ground and air medical transport providers, there are a number of distinct and important differences.

The ground EMS system does not appear to be growing in terms of the number of provider agencies, whereas the services offered and how they are organized are somewhat more dynamic. Ground critical care transport services, for example, appear to be filling a niche previously filled by varying care levels of ground EMS transport service and by air medical transport under certain conditions. Ground critical care transport and AMS have experienced steady growth because of a wide variety of changes in the broader organization of the health care system. Some of these include:

- Loss of full-service community hospitals in rural areas
- General contraction of the health care system with loss of emergency departments and trauma centers
- Decreasing specialist and subspecialist coverage at community hospitals (e.g., general surgery, neurosurgery, obstetrics, orthopedics)
- Increasing number of time-sensitive therapies requiring major center care (e.g., trauma, cardiac, stroke, neonatal)
- Increased specialization/concentration of Neonatal Intensive Care Unit and pediatric services
- Hospital competition for trauma and cardiac patient volume
- Regional corporate health system hub and spoke array development of hospitals and services
- Improved predictability of Medicare reimbursement due to national fee schedule
- Increasing number of "baby boomers" and rates of trauma, cardiac, and stroke

Helicopter EMS has had the most visible and publicly scrutinized growth of EMS response and transport modalities. It has grown from 293 aircraft in 1995 to 792 aircraft in 2006, with most of that growth in the last

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5 years; 2006 marked the first decline in the number of programs with two (1%) less than in 2005. However, the number of aircraft increased by 39 (5%) in the same year.

Ground EMS

Ambulance services were mostly private, untrained, for-profit enterprises in the United States until the federal government established standards and funded states and regions to develop EMS systems in the early 1970s. Currently, there are an estimated 16,000 ground EMS provider agencies in the United States which are predominantly small organizations. Exceptions are found in major urban areas and among a handful of small publicly traded corporations operating in multiple states.

Operational type or sponsorship is widely varied, including public (fire, police, and "third service"), private (for-profit and not-for-profit), hospital based, and others. Some rely solely on volunteers, others on paid staff, and yet others on a mix of the two. Most of these agencies operate primarily within discrete municipal or in some cases regional boundaries, with mutual aid to adjoining jurisdictions. Funding is derived from many sources, including Medicare, Medicaid, private insurances, local and state tax-based subsidies, subscription programs, and donations.

Although substantial variations within states remain, the scope of practice is clustered around the national training standards in four levels—first responder, emergency medical technician (EMT), advanced or intermediate emergency medical technicians (e.g., EMT-I), and paramedics (EMT-P). Most (46 of 50) states certify or license personnel at one or more of these levels using the competency-based testing provided by the National Registry of EMTs, a private non-profit certification agency.

Nearly all states regulate ground ambulance operations, usually defining the minimum standards for the essential components of ambulance systems. These components may include communications, medical direction, quality improvement, equipment, vehicles, personnel, and training/education. Services are often licensed/certified/approved by the state in some manner, generally through an EMS office or board. Vehicles may also be individually licensed/certified/approved, generally by the same state agency and often using vehicle inspections. Individual EMTs and other providers are often licensed/certified/approved by the same agency or by other licensing or education agencies.

A number of states have begun to define standards for ground "Specialized Care" or "critical care" ambulances as well, allowing for unique staffing and equipment for interhospital transportation of high acuity patients (e.g., Intensive Care Unit [ICU] to ICU transfer). Generally, ground critical care transport is indicated for patients requiring short distance transfer within urban areas or patients without a need to minimize out-of-hospital time.

Ground ambulances are the primary mechanism for all medical transport, both 9-1-1 requests and interhospital and interfacility transports. They are generally a stable and reliable platform for medical transport. Evolving literature has identified safety issues with ambulance transport, especially when operating in "emergency" mode (using some combination of emergency lights and siren). Lack of a consistent and universal ambulance accident-reporting system and data base hindered a nationwide analysis, however. They are virtually an "all-weather" medical transportation resource, but they are top-heavy and not designed to operate at speeds in excess of posted speed limits.

Air Medical Service

There has been little design in the evolution of the air medical system. As with the larger ground-based EMS system, individual hospitals and lead physicians, usually surgeons, championed the cause and developed resources to implement programs. However, since the first such services didn't appear until the early 1970s, they were not well integrated into the federal, state, or regional focus of early EMS system funding, development, and regulation that had begun at the same time for ground services. Thus began a parallel evolution of ground EMS and AMS, which is evident in a lack of effective AMS integration in EMS system operation and regulation in many states and regions today.

As stated above, ground EMS provider agencies often operate as a part of a local governmental authority. They may also be nongovernmental entities that are contracted, more or less formally; and subsidized, more or less generously, by a governmental authority. In either case, they are operationally accountable to the government and public in the jurisdictions in which they operate.

Few local governmental authorities operate air ambulances, even through contracts. Operational authority and accountability involve both aviation regulation provided through Federal Aviation Regulation (FAR) and medical authority and accountability are provided through provider agency, regional, and state regulation. From an aviation standpoint, it is impermissible for an entity (other than federal) to engage in air transportation unless the entity is an FAA Air Carrier Certificate holder There are 230 privately owned AMS Part 135 Certificate holders and 37 governmental AMS, Part 91 Certificate holders. A more limited role for the general public is played by the U.S. military, which provides service in AMS-underserved areas under the Military Assistance to Safety and Traffic (MAST) program, in challenging geographic regions and specialized rescue settings, and in areas housing HEMS National Guard units.

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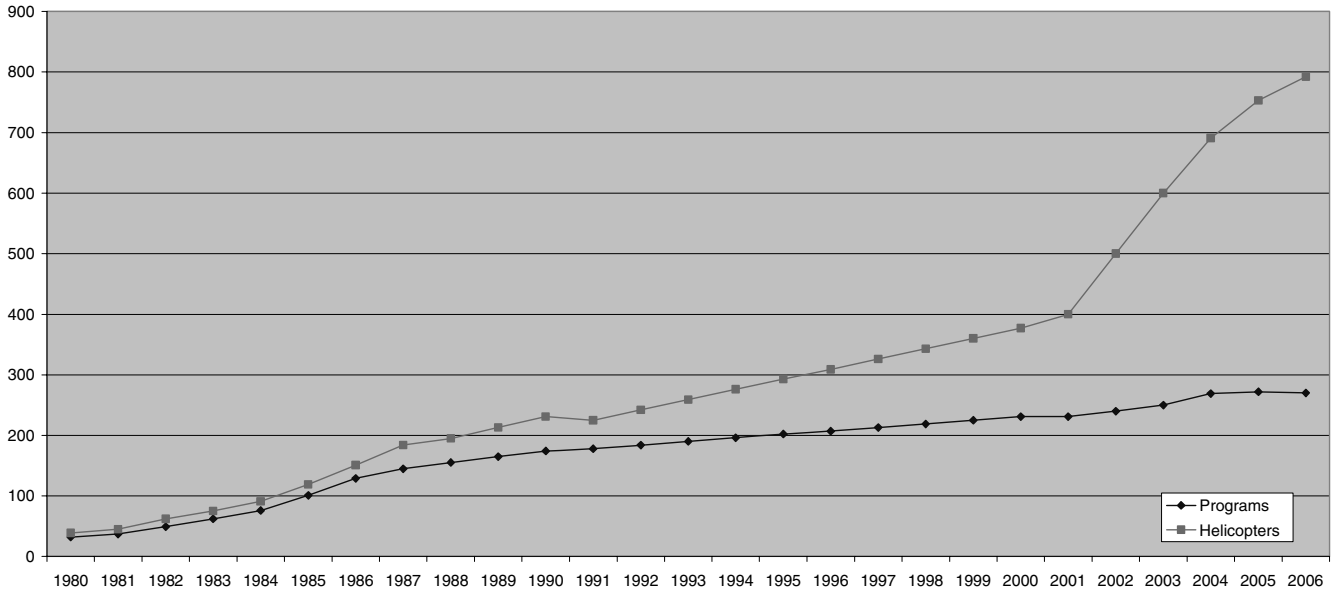

FIGURE 1. HEMS Programs and Aircraft–1980 to 2006. *Note*: 2002 and 2003 data points are interpolated from 2001 and 2004/2005 data.

The vast majority, and predominant growing sector of AMS operations, are civilian entities regulated under FAR Parts 91 and 135. There are significant differences between Part 135 and Part 91 regulations including operating minimums and duty time. Part 135 regulations are in general more stringent because they control the transport of persons for hire. To charge patients for transport, entities must carry Part 135 Certificates, and all operations with a passenger on board are governed by Part 135 regulations.

Coupled with the rapid AMS growth and capital cost constraints is a shift from the traditional model of hospital-based programs to community-based programs (both not-for-profit and for-profit) more loosely affiliated with hospitals. Some 50% of provider agencies fit this newer model.

The capabilities of AMS professional crews are generally greater than their ground EMS colleagues. Physician-level skills are the norm for the former, though most often in the U.S. are provided by nurse/paramedic teams with additional, specialized critical care certification. This care is similar to that provided in emergency/intensive/critical care units of hospitals, limited only by the space and weight constraints of the aircraft. These personnel have the opportunity to maintain their high levels of skill, relative to the opportunity afforded ground EMS professionals, because of the high percentage of their patient mix who are critically ill or injured.

There are significant operational differences between fixed wing and rotary wing air ambulances. The most widely used models of rotor wing air ambulances are limited in gross operating weight and workroom performance capability. This causes range (fuel weight) versus patient/crew carrying (useful weight) tradeoffs. Most of the HEMS aircraft currently operated in the United States are limited to visual flight rule (VFR) operations and are limited in their ability to operate in adverse weather conditions including low visibility, rain, sleet, snow, and high winds.

The great advantage of rotary wing ambulances is their ability to land at a hospital or at the scene of an emergency without the need of an intermediary ambulance. With air speeds often surpassing 150 mph, and with straight-line travel unimpeded by road characteristics or congestion, they can bring a patient from a great distance to definitive care in a short period of time.

Their safety record has been sharply criticized in recent years, however, and use decisions should, but often do not, weigh the risk and cost of the rotary wing air ambulance against the needs of the patient for a higher level of care en route and more rapid delivery to a facility with immediate access to definitive care commensurate with their illness or injury.

Fixed wing air ambulances are limited to travel between airports and are primarily used for interhospital transfers. They are rarely used to transport victims from the scenes of emergencies because they require intermediary ground ambulances to shuttle patients between the scene, aircraft and destination facility. Their primary application is to move patients over great distances quickly, and they play an important role in emergency transfers from frontier areas. In addition to such emergency transfers, other examples of their use might include a patient in a hospital or clinic who requires care at a far distant specialty facility, or a patient who wishes to return home to be close to family.

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Fixed wing aircraft speeds can exceed 250 mph and can operate with instrument flight in more weather conditions than can HEMS without substantial added risk. Their costs are much higher than ground ambulance but less on a per mile basis than rotary wing.

Similar to ground EMS, AMS depends on a combination of revenue sources including patient billing, commercial insurance including automobile insurance, Medicare, local and state tax revenue, hospital subsidy, private and publicly traded corporate financing, and philanthropy. Unlike ground ambulance service agencies whose main cost burden is personnel, AMS providers experience disproportionately high fixed operating costs because of the capital and fixed maintenance costs of the vehicles used. As a result, air ambulance charges are on average much higher than ground ambulance charges, sometimes by as much as a factor of ten.

The rules for Medicare reimbursement sometimes conflict with state EMS and trauma system protocols and practices as well as clash with the medical judgments of referring physicians on the use of HEMS for their patients. Recent Office of Inspector General reviews of samples of two hospital-based HEMS program Medicare charges produced recommendations for Medicare to recover overpayments for inadequate demonstration of medical necessity to justify air transport, failure to document exact air miles, failure to bill other insurances when Medicare was not the primary insurance, billing Medicare for transport when a beneficiary was not transported, and failure to deliver a patient to a closest appropriate hospital. In reply, the hospitals cited their compliance with state EMS protocols, Medicare EMTALA provisions, and disagreement about the appropriateness of facilities as HEMS destinations. One recommended overpayment refund totaled nearly $ 115,000, or 12% of the HEMS program's projected annual reimbursement claims from Medicare. Should Medicare follow the OIG recommendations and attempt to recover the alleged overpayments by reducing the payments to the ground ambulance rate, the hospitals will have the opportunity to appeal, so the ultimate outcome remains unknown.

As described above, and unlike ground EMS, AMS provider transport of patients obligates them to federal regulatory oversight, focused on the aircraft, pilots, storage and attachment of equipment, and flight operations, but not on the medical providers, care, or clinical operations. On the other hand, while ground EMS has been generally tightly overseen at the state regulatory level, AMS regulation at the state level is quite variable, with some states or territories having no such regulation at all (see Appendix 2).

Also previously noted, AMS has evolved along hospital or governmental service paths paralleling, but often not integrating with, those of ground EMS provider evolution in state EMS systems. Therefore, while some state EMS offices do comprehensively regulate AMS providers, many providers (even absent EMS agency regulation) find themselves subject to myriad hospital and/or public safety statutes and regulations pertaining to their medical, public safety or nursing personnel, status as a hospital department, and placement and use of helipads.

The recently released Institute of Medicine (IOM) report on EMS amplifies upon these observations, introduces further observations about state and FAA roles in the regulation of AMS in light of the Airline Deregulation Act and makes a strong recommendation in that area:

> *"... there has been an increase in the number of air ambulances involved in crashes in recent years, and this has prompted greater scrutiny from the media and from regulators. The Federal Aviation Administration (FAA) is responsible for certifying the safety of air ambulance programs operating in the U.S. However, because of a decrease in the number of FAA inspectors, along with the rapid increase in the number of air medical providers, safety checks have not been sufficiently rigorous in recent years, according to print media reports (Meier, 2005; Davis, 2005). This comes at a time when Medicare reimbursements for air medical transport have increased and competition within the industry has grown substantially (Meier, 2005). In response to growing concerns regarding air ambulance safety, the FAA released guidelines in August 2005 instructing air ambulance firms to implement safety steps, such as using checklists to ensure that maintenance steps have been completed, and improving the decision-making regarding whether to launch in unsafe weather conditions (Davis, 2005).*
>
> *"The Airline Deregulation Act of 1978 gives the FAA, rather than the states, regulatory authority over the operations of this industry. Court cases between states and the federal government over air ambulance operations have centered largely on state efforts to control growth in air medical capacity through the certificate of need process. However, other questions regarding the federal preemption of state law have not been definitively resolved. The state of Pennsylvania recently established a protocol requiring air ambulance operations to transport patients to the nearest trauma center, rather than to the base hospital. The air medical provider contested the protocol, saying that the state was preempted by federal law. However, the FAA acknowledged in a letter to the state that it has never been its intention to regulate the medical aspects of air medical operations and the case has never been taken to court.*
>
> *"Some states currently have no regulatory framework in place to govern the medical care aspects of air ambulance providers. However, a key objective for state regulatory agencies should be to ensure coordination and improve the allocation of available assets, including air ambulances. Currently, ground EMS and 9-1-1 dispatch*

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centers sometimes call for air medical support without coordination, resulting in more than one air medical provider being dispatched to a scene. This is especially a problem in areas where there are multiple air medical services competing in the same coverage area. These providers typically market their services to EMS agencies and in instances where multiple EMS agencies are dispatched to the same event, they will sometimes each call for the air medical provider that is most known to them, resulting in multiple responses.

"Given these issues, the committee recommends that ***states assume regulatory oversight of the medical aspects of air medical services, including communications, dispatch and transport protocols.*** *The regulatory authority of the FAA should extend to the helicopters, fixed wing aircraft, pilots, and company sponsors; however, the state should regulate the medical aspects of the operation including personnel on board (nurses, paramedics, physicians), the medical equipment, and the transport protocols regarding hospitals and trauma centers. In addition, states should establish dispatch protocols for air medical response and should incorporate air medical providers into the broader emergency and trauma care system through improved communication. These are essential to more coordinated and efficient use of air capacity."*[1]

The IOM report and the trauma care literature note the importance of HEMS in the response to injuries in rural areas. It is therefore of note that the 2004 National Rural Health Association book *The Rural and Frontier EMS Agenda for the Future* makes the recommendation that EMS leaders should:

"Plan, integrate and regulate, at the state level, aeromedical, critical care transport, and other statewide or regionwide systems of specialty care and transportation."

CORE PRINCIPLES FOR THE REGULATION OF AIR MEDICAL SERVICES

Within any framework of state regulation, the following core principles should be reflected:

1. States must assume regulatory oversight of the medical aspects of air medical services that 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 personnel on board (nurses, paramedics, physicians, and others providing patient care), the medical equipment, and the transport destination protocols regarding hospitals, trauma, and other specialty centers. In addition, states should establish dispatch protocols for air medical response and should incorporate air medical providers into the broader emergency and trauma care system through improved communication.
2. Air medical resources are essential elements of contemporary EMS systems. States should ensure their effective integration into those systems and into systems of community health care where they may provide a service deemed by the state as essential in a manner more cost-effective than is otherwise available.
3. EMS systems should strive to ensure that every patient having an emergent condition that can be addressed by a nationally recognized time-critical treatment has access to quality air medical and ground critical care transport to benefit from that treatment, and that transport type is dictated by case-specific objective evaluation of distance, circumstances, and logistics of the transport.
4. Air medical and critical care medical transport represents particular expertise in the delivery of acute emergency care often with non-physicians practicing at physician scope of practice level. As such, clinical care provided by non-physicians should be overseen by physicians who practice and have expertise in emergency, critical care, and critical care transport medicine.
5. All medical transport systems should use the national consensus guidelines developed by NAEMSP and endorsed by AAMS and the Air Medical Physicians Association (AMPA) for both dispatch and post mission use review.
6. Air medical resources should operate at the level consistent with the standards developed by the Commission for the Accreditation of Medical Transport Systems.
7. Air medical transport providers should operate at the highest levels of safety practically possible, and implement and maintain comprehensive risk management and safety systems management programs.

IMPORTANT QUESTIONS

FEDERAL REGULATION AND STATE REGULATION

For AMS providers, where is the line drawn between federal regulation and state regulation?

Rationale: In general, federal law prohibits states from regulating in areas that have been explicitly preempted by federal law and those implicitly preempted because federal law thoroughly occupies the regulatory field. Under federal law, regulatory responsibilities for air transportation, including air ambulance services, are divided between the FAA, which has primary

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responsibility for safety matters and the Office of the Secretary of Transportation (USDOT), which has primary responsibility for economic matters such as pricing, licensing, and route structure.

The Federal Airline Deregulation Act of 1978 (ADA), codified in part in section 49 USC §41713, explicitly prohibits states from directly or indirectly enacting laws or regulations "related to the price, route, or service" of an air carrier that may provide air transportation. All commercial air ambulance services are provided by air carriers certificated to provide transportation under this federal law. This means that states may not regulate areas within the USDOT's economic jurisdiction.

The U.S. Supreme Court has ruled in cases where states have attempted to interpret the federal preemption too narrowly, indicating that states may neither directly nor indirectly impose laws or regulations in areas that fall within the federal preemption. For example, see the language found in *Morales v. Trans World Airlines, Inc., 504 U.S. 374, 378 (1992)*, which is included in Appendix 6.

The importance of this statute and the rather broad interpretation by the U.S. Supreme Court is significant with respect to a state's ability to regulate AMS providing interstate services. In a recent response to the State of Texas (see Appendix 6), the Federal Department of Transportation noted that these provisions may restrict or eliminate a state's ability to regulate in many areas including:

1. State regulation of aviation safety, pilots, and "weather minimums"
2. Indirect state regulation by requiring accreditation by an outside body
3. State regulation of air carrier economic matters, including rates, insurance requirements, or when and where air ambulances can fly (routes)
4. State certificate of need (CON) requirements

Furthermore, the U.S. Supreme Court has determined that states cannot directly or indirectly regulate in areas where the field has been taken by the federal government. Federal courts, with certain exceptions, have found that the FAA's statutory aviation safety authority and regulations to have implicitly preempted the field of aviation safety regulation to exclude state aviation safety regulatory action. Several documents in Appendix 6 cover this thoroughly.

The FAA does not, however, have the authority to regulate medical standards for medical personnel or medical equipment associated with commercial air ambulance operations, or the standard of medical care that must be afforded to patients transported. Accordingly, states are free to regulate in these areas, so long as these regulations do not conflict with USDOT aviation economic or FAA aviation safety regulatory prerogatives.

It is important to note that preemption questions do not always submit to a simple analysis, and there are ongoing regulatory developments and court cases regarding the preemption issue. Several states have had local regulations on aviation matters successfully challenged on federal preemption grounds. States should be aware of these federal preemption principles when considering state legislative or regulatory initiatives applicable to the commercial air ambulance services and seek appropriate counsel on the subject to ensure consistency with federal law.

In general, the challenges noted above have involved state certificate of need (CON) requirements and a state's ability to, by and large, control competition in a market by preventing expansion of existing programs or entry by new providers. States have argued that Congress never intended 49 USC §41713 to apply to air ambulance services. There have also been attempts by state legislatures to limit provider charges and, in at least one case, insurance payments.

Key to these debates is the legal definition of the terms "price, routes. and services".

Does transport price include the charge for patient care?

Can membership programs be construed as an application of "rates?"

Do "routes" impact the ability to designate appropriate destination facilities?

Does "service" include medical care? Can a state limit a provider's "services" to interfacility, trauma, cardiac, neonatal, or adult transfers?

It is likely that the intent of Congress was not to include medical care in its attempts to deregulate the airline industry; particularly since the years leading up to the 1978 ADA generally preceded the growth and commercialization of AMS. To the extent that the ADA could apply to the medical aspects of AMS, it would be an economic issue as a "service," thus falling outside of the FAA's jurisdiction. The IOM EMS report (quoted above), citing an FAA statement that "it has never been its intention to regulate the medical aspects of air medical operations," lends clarity to these questions and strongly encourages states to take up regulation in this area.

Finally, it is important to be aware that the constitutional Interstate Commerce Clause is often cited to preclude states from interfering with interstate commerce. As previously stated, many, if not most, AMS providers fall in this class of commerce. Case law has examples of exceptions made for states to regulate matters concerning the health, safety, and welfare of their citizens (*Maine v. Taylor, 477 U.S. 131,151 (1986)* ("As long as a State does not needlessly obstruct interstate trade or attempt to place itself in a position of economic isolation, it retains broad regulatory authority to protect the health and safety of its citizens . . . .")). It also has examples of where concerns for safety were

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judged to be insufficient reason to impinge on certain commercial practices (*Pacific Co. v. Arizona, 325 U.S. 761, 65 S. Ct. 1515, 89 L. Ed. 1915 (1945)*).

This last observation should not deter state EMS authorities from pursuing AMS regulations, but it highlights the importance of guidance from a state's attorney general in determining appropriate regulatory language.

What are the applicable federal regulations that govern the economic aspects of the provision of air medical services?

Rationale: As discussed above, regulation of issues "related to a price, route, or service" of an air carrier engaged in air medical services is the exclusive prerogative of the USDOT. This is the case even though many of these economic matters have been deregulated under federal law. The USDOT's regulations applicable to air carriers involved in the provision of air medical transport are located in FAR Part 298. Furthermore, an order issued by the Civil Aeronautics Board, whose functions have been subsumed by the USDOT, and still in force, generally exempts hospitals arranging air medical services as indirect air carriers from certain federal economic regulatory requirements.

Key areas covered under Part 298 include:

- Air carrier citizenship
- Liability insurance
- Limitations on use of business name

What are the applicable federal regulations that govern the aviation safety aspects of the provision of air medical services?

Rationale: In general, the operational safety of aircraft involved in the provision of air medical transport is exclusively regulated under the Federal Aviation Regulations (FAR) Parts 91 and 135. Part 91 includes "Air Traffic and General Operating Rules." Part 135 is specific to "Air Taxi and Commercial Operators."

The applicable aviation safety requirements in the FAR are too voluminous to include in this paper. The major areas covered under these regulations include:

- 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
- Flight Crew Licensing
- Flight Crew Member Limitations and Crew Rest Requirements
- Crew Member Testing Requirements
- Training Requirements
- Aircraft Performance Operating Limitations
- Equipment, Instrument and Certificate Requirements
- Special Flight Operations
- Maintenance, Preventive Maintenance and Alterations
- Operating Noise Limits

For additional history and background information regarding the FAA's role in regulating air transport, see Appendix 6. Documents in the appendix include:

- The Federal Aviation Administration and Flight Standards: History and Organization
- General Direction, Guidance, and Procedures—Public Aircraft
- Public Aircraft Operations
- Flight Standards Handbook Bulletin for Air Transportation
- 2006 FAA Request on "Helicopter Shopping"
- Airline Deregulation Act and Other Relevant Court Documents

States should also be familiar with the regulatory requirements and other pertinent laws as they relate to public versus private aircraft and public versus civil missions. The documents in Appendix 6 are intended to assist in this discussion.

How does a state approach crafting air medical regulations and what should be included?

Rationale: It is beyond the scope of this paper to consider the implementation details of state administrative requirements for rule making except to encourage EMS officials to invite the participation of those to be regulated from the outset of drafting such regulations.

In the course of developing this document, the Air Medical Task Force conducted a review of state statutes and regulations pertaining to AMS. A summary of the findings was prepared and distributed to state EMS offices for review and correction. Appendix 2 contains the results. States for which regulatory language could be found are listed. Those states that reviewed and approved their listings are noted. Those listings that were not approved may contain inaccuracies. These result, in large part, from AMS regulatory content being scattered throughout any given state's statutes and regulations (e.g., agency licensing, vehicle licensing, and personnel licensing sections), which may not have been available at the time of the review.

A number of states have chosen to adopt the Commission on the Accreditation of Medical Transport Services (CAMTS) Standards in total or by reference, and several states require CAMTS accreditation as a condition for licensure. States requiring CAMTS accreditation may be challenged on three fronts:

- Assertions that these comprehensive standards go beyond the minimum necessary to ensure the safety and well-being of patients, crew, and the public and therefore may constitute an "unfunded mandate" (sensitivity to this issue varies from state to state and

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over time, and may be less of an issue with regard to a privately operated business than an operation operated by local government)
- Assertions that successful accreditation may require a service to meet specific safety requirements that exceed FAA standards and are thus federally preempted
- Assertions that the requirement of outside accreditation as a condition of licensure may circumvent the state's own administrative procedures act which sets out rule making, due process. and appeal rights (an historical bellwether would be whether the state EMS agency has incorporated other nationally recognized standards into its licensure requirements such as National Registry of EMTs' certification or federal KKK standards for ambulances).

That said, states, such as Maryland, that cite CAMTS as a standards requirement in some fashion for licensing are confident in their position, given their experience with hospital accreditation requirements and the bases for challenge such as these. The extent to which "unfunded mandates" are a sensitive issue outside of requirements placed on local governmental jurisdictions varies greatly from state to state. Many states cite other national standards such as KKK ground vehicle specifications and National Registry of EMT certification standards as conditions for certification/licensure. State attorney general's offices should be consulted in these matters.

There are specific air medical issues that are not covered by FAA regulations and, because of the unique nature of HEMS, typically are not found in the general requirements of ground ambulance operations. Most, if not all of these HEMS-specific issues are addressed in the CAMTS standards. Other sources for information used by states in crafting regulatory standards include publications by Helicopter Association International, the Airborne Law Enforcement Association (ALEA), and the National EMS Pilots Association (NEMSPA).

The State Medevac Committee for the Commonwealth of Virginia recently studied and referenced CAMTS, NEMSPA, and ALEA standards for this in adopting a state regulation.

What are essential components for state regulation?

Again, the standards cited above should be sources. Some basic considerations for inclusion are:

- Identification of provider agency (corporate entity and headquarters, FAA certificate holders, location of base of operations to serve state)
- Insurance held (the USDOT requires air carrier liability insurance for air carriers engaged in air medical operations)
- Clarity in advertising (can the advertised service be provided?)
- Medical oversight (source, qualifications)
- Clinical care standards (scope of practice, proposed crew makeup, and number of practitioners to sustain service)
- Access and use protocols
- "Ambulance" equipment and compartment
- Emergency scene operations versus interhospital transfer only (be aware that attempts to impose limitations on these might be perceived as federally preempted because it deals with "routes")
- Interoperable communications equipment and integration
- Responsibility to provide for ground safety training for EMS/public safety personnel
- Integration with state trauma and other specialty care programs
- Integration with other AMS providers in a system
- Destination protocols
- Quality assurance program and oversight
- Subscription or membership programs (although these may be federally preempted or not allowed by state insurance laws if perceived as a form of insurance in the state)
- Basic aircraft attributes for emergency medical purposes and vehicle license for permanent aircraft (be aware that aircraft safety and certification requirements are the prerogative of the FAA, and regulation of related issues may be perceived as federally preempted)
- Waiver to allow unlicensed operation in non-routine emergency situations.

Should public/government operators be required to meet the same licensing standards as private providers?

Unless their operation is governed by another state EMS office with similar standards, all AMS providers within a state should be treated identically.

Do states have the ability to limit the number of AMS operating in a given state?

State Certificate of Need (CON) regulations used to do this have been successfully challenged under the Airline Deregulation Act of 1978. In states with CON-type provisions for ground services, it is not uncommon for one party or another in an application process to appeal a decision. Rather than limiting AMS providers, state EMS offices may consider asking applicants to explain how the proposed service would integrate with current access systems for scene responses so that ground responders and public safety dispatchers have no confusion. They should also explain how their service is to be advertised to hospital-based users so that there is no confusion about choosing among available services.

One essential issue in state oversight of AMS is ensuring the actual identity of the air medical provider.

While the vast majority of ambulance service is accessed through the publicly overseen 9-1-1 system, patients, families, or hospital case managers needing to

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arrange urgent transfer or patient repatriation through long distance ground or air transportation often must rely on other information sources to access service providers.

Common information sources include local phone directories or provider websites on the Internet. A major challenge to service requestors is the lack of oversight of information posted and provided through these sources. Although many of the services providing information through these sources are reputable, high-quality, medically led organizations, the veracity of self-provided information is not easily ascertained. It is often not clear if a service provider located through these information sources is licensed by a state regulatory agency, has adequate physician oversight, or in some cases even employs clinical or aviation staff.

This is essentially a "buyers beware" market in which the purchaser of ambulance service often does not have adequate information as to quality, safety, or who the true identity of the ambulance service provider is.

In fact, there are many "Air Ambulance" services who advertise on websites and in the Yellow Pages of every major city, who neither own nor operate aircraft nor do they employ medical teams. In many cases, there is a location listed with a toll-free access number that is at best a shell "office" rather than a staffed physical location. These "Air Ambulance" services are, in reality, brokers. Brokers are paid to arrange transports and are motivated to make these arrangements at the least cost rather than highest quality of medical care. The lack of medical or regulatory oversight, either through the Federal Aviation Administration or a state EMS or health agency, is problematic and could have the potential to result in untoward incidents.

Where do state quality improvement activities for AMS fit?

In some states these may be a part of the regulatory process, and in others they may fall outside of that process but within state, regional, or local medical direction systems. There should be some mechanism available at a system level that offers a forum for quality improvement reviews free from legal discovery or other impediments to open and frank discussion.

LICENSING ISSUES FOR MULTIPLE STATE OPERATIONS

How should AMS provider agencies be licensed when operating in many states?

Rationale: Virtually all AMS provider agencies operate regionally or nationally. Seven multistate AMS program Part 135 Certificate holders own or operate nearly 80% of the total helicopter fleet. These include Air Methods/Air Methods LifeNet, CJ Systems, Petroleum Helicopters Incorporated Air Medical, Air Evac EMS Lifeteam, Omniflight, Metro Aviation, and eraMed.

Patient needs for specialty care at the scene and at specialty centers, patient needs for return from specialty care to home or home hospitals, system needs for mutual aid resources (e.g., for Hurricane Katrina, 31 agencies from 14 states deployed over 50 rotor and fixed wing aircraft), and business models of AMS provider agencies and health care systems all drive the need for AMS operations that are not confined to geographically distinct operating areas.

As noted earlier, this is further complicated in the fixed wing arena by brokers of services who may advertise services within a state but not actually own any aircraft or employ medical personnel. These services predominantly provide both emergency and non-emergency repatriation (return of patients to home or home hospital) nationally and internationally. An Internet or phone book search will usually identify multiple organizations, tied only to an 800 number, advertising AMS within a state.

Because states have universally accepted the responsibility for regulating health care practices and settings, it is natural that EMS is universally, to a greater or lesser degree, state regulated. All states must regulate the medical aspects of air medical services which advertise service and/or operate in their states as a part of this responsibility. Services that are based outside of the state but advertise and operate in the state are no exception because the public may have no way of knowing where they are based.

The manner in which states approach this regulation and detail its content may depend on the AMS resources available. Are there enough native AMS resources to serve all areas in the state at the current or anticipated level of regulation of those providers? Do any outside AMS providers play an important role in the overall EMS system in any part of the state? Do outside AMS providers play a role in disaster preparedness plans?

A place to start may be with the manner in which the state treats bordering state ground ambulance activity in the state:

- Does the state allow non-native ground EMS to transport from outside of the state to points inside the state without license? This is probably the case because most state EMS regulators are primarily concerned with calls for EMS originating within their borders and the EMS providers which respond to those.
- Does the state provide for outside ground EMS responding by request of instate providers in multiple casualty and mutual aid circumstances? This is probably the case, with variation around the threshold of occasional "mutual aid" becoming routine "operation." This is an important consideration in AMS, particularly HEMS, because most missions to a scene or hospital or airport in the state might be stretched to be interpreted as "mutual aid" at the request of instate providers.

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Ground EMS providers based outside of the state that routinely operate in the state are probably required to be licensed by the state. At this point, comparison with the ground EMS regulations probably becomes less instructive unless the state has alternatives to the licensing process for ambulances licensed out of state. Are there provisions for such operators (e.g., reciprocity-agreement/interstate compact/interstate MOA based shortcuts to licensure)? If so, could similar agreements apply to AMS or be developed for AMS given the AMS regulations used by one of the involved states absent regulations in the state routinely receiving the outside AMS resources? A compact established between the Idaho and Utah EMS offices is an example (Appendix 1).

A weakness in the concept of regional interstate compacts is the difficulty with which a distinct region is defined, particularly when fixed wing operators are considered. Do we wait for the domino effect of expanding compacts to include yet more services and adjoining states until the nation is covered? Or do national associations enter a process to consider a universal model minimum set of regulatory provisions acceptable for universal state adoption?

The former will be a protracted process of negotiation as states create their own regulations and as compact areas begin to bump into one another. This may be inevitable, but it would be more efficient to jump-start the process by exploring the latter. Key national associations led by the authors should explore this. They might begin with a strawman such as a comprehensive regulations sample that they develop from existing laws or the standards found in CAMTS accreditation.

Short of a regional or national solution, states can individually implement provisions to grant reciprocal licenses through case by case review of other states' regulations. This injects the kind of subjectivity that frustrated efforts at interstate personnel licensing reciprocity for years and slows license applications where one state has not yet evaluated the other state's air medical regulations. It is a starting point for some states however. It is recommended that this process be facilitated by the automatic granting of licensure to CAMTS-accredited AMS operators for the duration of their accreditation. This is known as "deemed status" recognition.

Should licenses be issued to aircraft and/or AMS personnel, as well as agencies, in cross-border situations?

The heart of this question is addressed in the State Regulation section above. States are encouraged to consider whether the state in which the applicant is licensed has regulatory provisions for oversight of the AMS operator's aircraft and personnel. If so, then that state EMS office, in its role of protecting the public, has deemed those provisions to be adequate. Because the state to which an application for reciprocal licensure is being made experienced a rule-making process that resulted in different requirements, do those requirements protect the public in a substantially better way?

Considerations of whether a state should require actual provider licensing, rather than deemed status under a compact or other reciprocal provision, may include a number of factors. These may include the number of responses per year into the state by a provider agency and similarity of regulations between the two states. As an example, the State of Maryland delineates a process and reporting requirement for limited activity in the state by an out of state provider but requires licensure of any provider agency that transports more than 25 patients per year in the state.

In all cases, states should develop a waiver or otherwise immediately accessible plan to facilitate services doing a low number of transports and providing disaster response. These considerations should include service and personnel licensing/certification and practice credentialing.

INTEGRATION OF AMS IN THE STATE EMS SYSTEM

To what extent should air ambulances be integrated into the existing local, regional and state EMS systems?

Rationale: Because states have universally accepted the responsibility for regulating health care practices and settings, it is natural that EMS is universally, to a greater or lesser degree, state regulated. A number of states have expanded this role to leadership and coordination of the overall EMS system. Those states that simply regulate EMS must regulate the medical aspects of air medical services that advertise service and/or operate in their states. These states are encouraged to be creative in extending their licensing authority to assist in facilitating the smooth integration of AMS, especially where AMS crosses local, regional, and state EMS boundaries. Those state EMS offices with the authority to lead and coordinate the EMS system are encouraged to include AMS to other statewide subsystem components such as trauma care, emergency pediatric care and ground critical care transport, which they may already address.

Incorporated within this question are the following issues:

- Dispatch
  - AMS use criteria
  - Coordination with 9-1-1 system
  - Authorized requestors
- Communications and coordination with scene units and hospital staffs
- Destination decisions

Local, regional, and/or state levels as appropriate to the structure of the statewide system(s), must incorporate appropriate physician medical control and quality

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assurance/improvement mechanisms to allow the system to continually refine its processes, including review of the appropriateness of AMS dispatch and use, coordination with local system personnel, and destination decisions. Outcomes must be relentlessly reviewed for opportunities for improvement. State regulations should require these components in local, regional, and statewide EMS systems. What resources exist within the state that might take on this responsibility in an objective fashion?

Dispatch—AMS Use Criteria

It is essential that AMS, especially HEMS, be carefully integrated into the EMS system beginning with considerations of medical oversight and practice. While most AMS missions are hospital-to-hospital, high acuity transport, 30–50% of its activity (varying with locale) is direct scene response. In many rural and frontier areas, both HEMS and fixed wing providers are literally first response and primary transport agencies.

Air ambulances provide an opportunity for the rapid transport of patients with emergent conditions requiring time-dependent definitive care. They also incur significant costs and risks that must be balanced against the benefits in each situation.

Clear guidelines for the use of air versus ground resources in each jurisdiction must be developed, with a focus on improving patient outcomes as the overarching criterion. A place to start would be reviewing a state's, or a locale's, trauma center activation/local hospital bypass protocols for adaptation to HEMS activation protocols. Access protocols for scene response should be consistent throughout the state. In addition, 2005 and 2006 AAMS position statements generally call on AMS providers to follow CAMTS standards, use the NAEMSP Guidelines for Air Medical Dispatch for prospective dispatch and retrospective review (Appendix 3), develop and maintain a health care compliance plan, and develop and maintain a safety management system (see also FAA AC 120-92, June 2006).

Generally speaking, access should be determined by patient clinical conditions, the need for advanced life support, or critical care interventions not available from ground providers, the need for rapid transport to the most appropriate hospital or when travel conditions prevent timely transport to closest appropriate hospital (may not be "closest" hospital; see the 2006 AMPA Position Paper on "Appropriate Destination" in Appendix 3).

The NAEMSP has offered guidelines for consideration in the development of such systems (see NAEMSP Air Medical Dispatch document in Appendix 3):

- In some EMS regions, the air medical crew is the only rapidly available asset that can bring a high level of training to critically ill/injured patients. In these systems, there may be a lower threshold for air medical dispatch.
- Systems in which there is widespread advanced life support (ALS) coverage, but such coverage is sparse, may see an area left "uncovered" for extended periods if its sole ALS unit is occupied providing an extended transport. Air medical dispatch may be the best means to provide patient care and simultaneously avoid deprivation of a geographic region of timely ALS emergency response.
- Disaster and mass casualty incidents offer important opportunities for air medical participation. These roles, too complex for detailed discussion here, are outlined elsewhere.

The NAEMSP has established a table of "Questions That Can Assist in Determining Appropriate Transport Mode" (see NAEMSP Air Medical Dispatch document in Appendix 3):

- Does the patient's clinical condition require minimization of time spent out of the hospital environment during the transport?
- Does the patient require specific or time-sensitive evaluation or treatment that is not available at the referring facility?
- Is the patient located in an area that is inaccessible to ground transport?
- What are the current and predicted weather situations along the transport route?
- Is the weight of the patient (plus the weight of required equipment and transport personnel) within allowable ranges for air transport?
- For interhospital transports, is there a helipad and/or airport near the referring hospital?
- Does the patient require critical care life support (e.g., monitoring personnel, specific medications, and/or equipment) during transport, which is not available with ground transport options?
- Would use of local ground transport leave the local area without adequate emergency medical services coverage?
- If local ground transport is not an option, can the needs of the patient (and the system) be met by an available regional ground critical care transport service (i.e., specialized surface transport systems operated by hospitals and/or air medical programs)?

Should air medical resources be used for direct-scene *medical* patients (e.g., time-critical heart attack and stroke care), particularly in rural/frontier areas?

Considering the risks and costs, and the geographic attributes of the state, are there non-time-dependent situations in which air ambulance transport and/or delivered medical services may be appropriate?

Are there operational reasons other than clinical necessity that should prompt the use of air medical resources?

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There are examples of systems in which all three of these questions answer in the affirmative. Considerations to address them are found not only in the rapidly evolving literature on time-dependent treatments such as medical and surgical interventions for heart attacks but in local conditions affecting the EMS system. For example, is it appropriate to call a helicopter to transport a patient with a broken hip when ground transport will leave the local rural area without EMS services (on the other hand, what if the agency has a relatively low annual call volume and probably won't get another call that day)? Or if the local hospital is unable to provide the local BLS ambulance with a nurse for pain medication administration en route? What did the system do before AMS was available in these circumstances?

Some systems employ physician medical directors to authorize HEMS or fixed wing launch. Other systems have standing orders, particularly for HEMS activation and launch. They may mix these with autolaunch criteria (see Appendix 3). What are the resources available in the system available for activation/launch decisions? What is the level of trust within the system to support such decisions given these resources?

Dispatch—Coordination with 9-1-1 System

The IOM report on EMS stated: "Currently, ground EMS and 9-1-1 dispatch centers sometimes call for air medical support without coordination, resulting in more than one air medical provider being dispatched to a scene. This is especially a problem in areas where there are multiple air medical services competing in the same coverage area. These providers typically market their services to EMS agencies and in instances where multiple EMS agencies are dispatched to the same event, they will sometimes each call for the air medical provider that is most known to them, resulting in multiple responses."

In the 1970s, a similar EMS system response problem, called "call-jumping," began to be recognized. Whether as a result of open competition, lack of single, uniform dispatch systems, or other reasons, multiple ambulances were known to arrive at a single scene. This has been virtually eliminated through the evolution of EMS systems, their dispatch components, and their regulatory provisions.

It is of interest that one modern form of this problem, resembling the most troublesome form of 1970s call-jumping, results from AMS providers responding to calls based on radio traffic they hear rather than having been specifically requested to respond. This is often justified by these providers as better serving patients by responding faster to those potentially injured. This practice can be confused, sometimes not unintentionally, with nationally recognized practices such as "early activation" and "autolaunch." The difference is that the former is based on the decision of an individual provider resulting from their interpretation of radio traffic, whereas the latter practices are based on the decision of an independent dispatch system resulting from regional/statewide guidelines or protocols that dictate establishing minimum facts about the call prior to launching. For a discussion of this issue, please see the AAMS position statement on early activation and autolaunch in Appendix 4.

Some marketing practices of AMS providers contribute to the problems cited by the IOM report, above. Examples include instructing non-EMS first responders to call a specific AMS for patients that do not meet the state's criteria for AMS use, instructing ground responders to request a specific service through a direct phone number without coordinating the AMS response through the public safety answering point (PSAP) or incident commander, and the practice of paying fire departments for landing zone assistance.

Whether the causes of the modern-day AMS problem in any particular area are competition and/or a lack of system coordination and regulation, they must be mitigated. It is the state EMS agency's responsibility to ensure this through a combination of system leadership and coordination, and licensure and regulation.

How does the state prevent *ground* EMS provider "call-jumping"? Where multiple AMS providers are available for scene calls, can similar provisions be implemented?

States should develop protocols for EMS providers that define the criteria and procedures for requesting AMS response as well as "early activation" or "autolaunch" practices if used.. Where feasible, protocols should direct EMS providers to request AMS through the local or regional PSAP or other designated medical communications center. Protocols should also address criteria for the selection and dispatch of the closest most appropriate AMS responder.

Another reason for insisting on this type of arrangement is to prevent "helicopter shopping." This occurs when an AMS provider refuses a flight because of poor weather conditions or other safety reasons, and a second AMS provider is then called and not told that the first provider has declined the flight. There may be circumstances in which the second program can safely manage the flight but it must be notified at the time of request that another program has already declined it and why it was declined. A 2006 letter from the FAA requesting state EMS offices' assistance further outlines this issue and is included in Appendix 7 (*2006 FAA Request on 'Helicopter Shopping*).

Idaho and Maryland operate centralized statewide EMS communications centers that effectively manage the issues discussed in this section. States, regional, and local EMS systems may also benefit by us online systems to track the availability of AMS as well as other emergency resources.

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Dispatch—Authorized Requestors

Who is authorized to request an AMS launch?

AMS resources are expensive. In some systems and under certain conditions their operation may add risk to a patient encounter, and their value will potentially be lost to others while on a particular mission. State planners, therefore, should include regulatory or other measures to ensure that those in a position to commit these resources are appropriately prepared to do so. The state should require that AMS providers operating in the state collectively participate in the offering a uniform training program for ground EMS and hospital staffs, other public safety personnel, and PSAP and other dispatch personnel involved in AMS activation on the approved system and requirements for that activation.

Response delay in rural settings is a concern when ground EMS must arrive on a scene and make a determination before air assets are launched. The Centers for Medicare and Medicaid Services (CMS) allow reimbursement for air medical missions activated by first responders with appropriate training (Medicare Act of 2004, Section 415). At least one researcher asserts that systems allowing first responder activation appear effective. No states allowing first responder activation, including other public safety personnel, have reported problems with inappropriate use. See Falcone article cited in Appendix 3 for a discussion of these issues. The exception to this exists where marketing by individual AMS providers is targeted at first responders not regulated by the EMS system and encourages AMS access without involvement of a dispatch system approved by the state EMS agency (see previous section).

Activation protocols should reflect that there may be initial uncertainty as to patient's clinical condition. This is especially true in rural areas with extended first response times. Properly trained 9-1-1 dispatchers should be allowed to launch or place an aircraft on stand-by. Formal systems of emergency medical dispatch and/or those that include special AMS training for dispatchers should consider autolaunch protocols for rural areas (see AAMS 2006 position statement in Appendix 3). These must include the ability of ground EMS providers to cancel aircraft en route and a system of use review which continuously weighs the risks, benefits, and costs of the autolaunch protocol.

Coordination with Scene Units and Hospital Staffs

Communication capabilities and protocols should be in place to allow two-way communication between AMS dispatch/flight following, PSAP/public safety dispatch for any scene, ground EMS and public safety units, and any hospital. Such communication should be easily initiated by any of these system participants.

In addition to the AMS activation training discussed above, all ground EMS and hospital staff with responsibilities that include patient delivery/reception operations with helicopters, especially while rotors are turning, should receive appropriate ground safety training provided by the same group of AMS providers.

Protocols for scene and hospital HEMS interaction should be statewide.

Destination Decisions

How should destination decisions be determined?

While destination decisions for many types of EMS transport are either those of the patient or their family, transports to facilities for time-dependent interventions generally cannot be left to someone who does not have adequate knowledge of the care capabilities of potential destination hospitals. Ideal systems have predesignated destinations for time-critical needs from any point within their jurisdiction, using plans based on a careful assessment of available clinical and transport resources.

States that have not done so should develop requirements for plans that accomplish this goal and that incorporate the previously mentioned physician oversight and quality improvement mechanisms.

Some federal requirements already exist, such as the Emergency Medical Treatment and Active Labor Act (EMTALA), which requires that all patients coming onto the property of any Medicare-approved facility receive a Medical Screening Exam (MSE) for life-threatening conditions by a qualified caregiver before any questions are asked regarding payment. The specific standard and additional material may be found in Appendix 7.

In some cases it may be desirable for ground EMS to transport a patient to a hospital helipad simply for a safe place to deliver the patient to a helicopter. Use of hospital helipads as rendezvous points without MSE performance is specifically allowed, in the context of a preestablished trauma care system.

Additional guidance from the CMS 2004 *State Operations Manual Appendix V - Interpretive Guidelines Responsibilities of Medicare Participating Hospitals In Emergency Cases* (Part II "Interpretive Guidelines" §489.24[a[) clarifies the responsibilities of Medicare participating hospitals with regard to the use of the hospital helipad as a transit point for an EMS service intercept with a medical helicopter:

> *"The following two circumstances will not trigger EMTALA:*
>
> *"The use of a hospital's helipad by local ambulance services or other hospitals for the transport of individuals to tertiary hospitals located throughout the State does not trigger an EMTALA obligation for the hospital that has the helipad on its property when the helipad*

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is being used for the purpose of transit as long as the sending hospital conducted the MSE prior to transporting the individual to the helipad for medical helicopter transport to a designated recipient hospital. The sending hospital is responsible for conducting the MSE prior to transfer to determine if an EMC exists and implementing stabilizing treatment or conducting an appropriate transfer. Therefore, if the helipad serves simply as a point of transit for individuals who have received a MSE performed prior to transfer to the helipad, the hospital with the helipad is not obligated to perform another MSE prior to the individual's continued travel to the recipient hospital. If, however, while at the helipad, the individual's condition deteriorates, the hospital at which the helipad is located must provide another MSE and stabilizing treatment within its capacity if requested by medical personnel accompanying the individual.

"If as part of the EMS protocol, EMS activates helicopter evacuation of an individual with a potential EMC, the hospital that has the helipad does not have an EMTALA obligation if they are not the recipient hospital, ***unless a request*** *is made by EMS personnel, the individual or a legally responsible person acting on the individual's behalf for the examination or treatment of an EMC."*

Appendix 3 contains an AMPA position statement on determination of appropriate destinations. This should be reflected in statewide protocols. Appendix 1 includes a Pennsylvania AMS destination protocol which covers a broad range of considerations.

Do hospital-owned helicopters have to deliver a patient to that hospital's ED for the purpose of MSE because the patient in the helicopter is considered "on the hospital property"?

This question is not yet clear in EMTALA legal review. In general, CMS Guidelines dictate that a hospital-owned ambulance is considered an extension of the hospital and operational policies must meet EMTALA requirements. The EMTALA Manual does list an exception for hospital diversion "pursuant to community-wide EMS protocols." The transport of a patient pursuant to state or regional trauma protocols to the closest appropriate hospital rather than the hospital which owns an aircraft has not been legally reviewed.

OTHER QUESTIONS

States that have developed air medical regulations have dealt with certain common questions. Most of these have been addressed above or are addressed in materials cited above. The following are some that deserve special attention.

Should there be a minimal level of staffing/scope of practice for air medical transport?

Speed of transport and access to remote scenes was the first primary reason for the evolution of AMS. Today, it remains an important feature of this transport mode. Equally important, however, is its ability to bring to the scene or to the remote medical facility a higher level of medical intervention than would otherwise be available there or en route to a specialty facility. Standards of organizations, such as CAMTS and ALEA, call for advanced life support and, preferably, critical care transport capabilities provided by two medical staff on board. This depends on the environment and mission of the particular service.

Should there be separate aircraft and staffing requirements for more specialized transport?

Certain types of patients, such as children, neonates, and cardiac patients requiring intraortic balloon pumps, require special equipment that may require altering cabin configurations. Changes to cabin configuration require not only medical provider input but adherence to FAA regulations. Therefore, programs serving certain specialty facilities with a significant volume of transports should have dedicated aircraft with specialty configurations. State EMS planners should contact systems with experience in these settings through AAMS or AMPA before navigating the waters of rule making in these areas.

Are single engine aircraft acceptable for HEMS use?

This is a major debate without a clear answer. Some states have opted to require a dual engine minimum as is the standard in Canada and Europe. However, because the FAA does not distinguish HEMS use in their certification of single engine aircraft, these state restrictions may be federally preempted. Furthermore, evaluation of HEMS crash data to date provides no clear evidence of a dual engine safety advantage. Over water, mountainous terrain, extreme weather, and other working environment considerations may persuade regulators in one direction or another.

What other aircraft considerations have states encountered in establishing AMS regulations?

In addition to the engine question, are those of number of pilots, and required presence of autopilot and IFR (Instrument Flight Rules) capability. State requirements governing flight crew complement and aircraft equipment having aviation safety implications are generally federally preempted. The Canadian government requires dual engine, dual pilot, and IFR. Canadian HEMS have never experienced a crash.

Most U.S. HEMS programs are single pilot and VFR (visual flight rules). In addition, most do not have autopilot capabilities or terrain avoidance warning systems (TAWS) The National Transportation Safety Board has called for new technology in this arena, but the FAA has not yet agreed that this technology should be required for HEMS. The FAA has recently changed its requirements with regard to HEMS Operations Specifications and weather/visibility (see Appendix 6:

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HBAT 06-01), which may be instructive for state EMS planners.

APPENDICES

In a unique effort to provide the reader with complete resource documents at their fingertips, Appendices 1–7 can be accessed by going to the NASEMSO website http://www.nasemso.org/NewsAndPublications/News/Reports.asp. Once there, please select "Prehospital and Emergency Care Air Medical Article Appendices". This web page contains extensive reference materials on air medical services, which may be directly downloaded by the reader.