



Testimony of Mr. Craig Yale
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on behalf of the Air Medical Operators Association
Before the Transportation and Infrastructure Committee
Aviation Subcommittee
U.S. House of Representatives
April 22, 2009

Mr. Chairman, members of the Subcommittee, my name is Craig Yale, I am the Executive Vice President of Air Methods Corporation and I am here today on behalf of the Air Medical Operators Association (AMOA). AMOA would first like to thank you all for the opportunity to offer this testimony, and on behalf of our members and their over 8,500 employees represented by the Association nation-wide, would like to thank the members of the Subcommittee for their interest in air medical transportation safety and effective oversight.

The Air Medical Operators Association is a group of companies and organizations that hold FAR Part 135 Certificates and are therefore authorized to conduct on demand air transportation. Our members are engaged in the safe operation of over 700 helicopters, nearly 92 % of those providing air medical transportation in the United States, and over 60 dedicated fixed wing air medical aircraft. Further, our members must agree to meet the safety benchmarks and standards under development by AMOA, including a commitment by each member to establish operational control systems beyond the current FAA standard, equip or operate with a system or systems to avoid terrain and obstacles recognized as effective mitigation systems by AMOA, requirements for frequent recurrent training, and the installation of flight data monitoring systems as part of an effective flight quality assurance and safety management system.

While these benchmarks are currently under development, we are very proud to point out that these initiatives represent the best practices already in place in the air medical community. In fact, we believe we are one of the most advanced industry segments in on-demand aviation. This commitment to safety technology, to training, to enhanced operational control and more robust management systems has not come in response to pending rulemaking, legislation, or recommendations. In fact, the most significant technological change in the air medical industry in the last 3 years has been the tremendous increase in the use of night vision goggles by operators, especially those operating in very low-light and rural environments. This commitment was made outside of any regulatory pressure and in the absence of an NTSB safety recommendation; rather, it was made based on a practical examination of the operating environment and the development of a rational risk mitigation strategy.

In late 2007 and throughout 2008, helicopter air medical services experienced a tragic and unacceptable number of accidents and fatalities. The tragedy of this time period is only compounded by the fact that these accidents occurred in a variety of environments and types of aircraft, leading to no clear causal factor or intervention strategy. No type of operation, size of operations, management structure, or operating area has been immune from accidents, making it impossible to point to a single safety enhancement as a universal solution. As those responsible for the safe aviation operations of air medical transport, air medical operators formed the AMOA to provide safety standards and benchmarks for the implementation and operation of a variety of risk mitigations, enhanced procedures, training methods, and new technologies that we believe, when combined with more effective management oversight and practical and effective regulation, can reduce the risk of accidents in air medical transport.

Air medical transportation has become vital to the healthcare community. Millions of Americans continue to rely on air medical transport as a critical resource, and in some cases the only option, to transport them to appropriate care in the event of a traumatic accident or serious illness. There is a misperception among the public that the nearest hospital can provide the appropriate level of

care; that is often not the case, as hospitals have become increasingly specialized and the cost of healthcare has caused the closure or significant reduction of a hospital's ability to provide care to certain types of conditions. In these situations, the sole lifeline to critically ill and injured patients is air medical transport.

Air medical operators take great pride in their commitment to providing that transportation as safely as possible; while we cannot eliminate every risk, we can provide safe and effective air medical transport as requested and appropriately determined by trained and authorized medical personnel. AMOA members have taken steps beyond regulatory compliance in areas of training, terrain and obstacle avoidance, oversight, and safety systems.

We believe that it is only through our collective effort to advance safety objectives in the following four areas that we can continue to provide the safest possible air medical transport service.

- **Terrain and Obstacle Avoidance:** Operators must provide the necessary tools to aid in the avoidance of terrain and obstacles; AMOA believes there are a small range of technologies and procedures available to accomplish that goal. It is the position of AMOA that all helicopters performing air medical transport services operate with the necessary equipment and procedures to achieve terrain and obstacle avoidance that the operator deems appropriate for their area and operation. This system can be achieved by any of the following:
 - Operating with Night Vision or Night Vision Imaging System (NVIS), with the appropriate level of initial and recurrent training.
 - Operating with some type of Helicopter Terrain Alert Warning System (HTAWS) or Terrain Awareness Warning System, with the appropriate level of initial and recurrent training.
 - Operating under Instrument Flight Rules (IFR), with the appropriate level of initial and recurrent training.

Further, it is the position of AMOA that any rule addressing terrain and obstacle avoidance must allow for the consideration of comparable options to achieve compliance.

- **Training:** Air medical services operate in a myriad of operating environments and with several different types of aircraft with different capabilities and limitations. While there are other safety objectives listed here, none of them can provide a level of risk mitigation equal to that of a frequent training program that makes use of available Flight Training Devices (FTD's), simulators or operational aircraft with instructors providing simulated scenarios, including Inadvertent Instrument Meteorological Conditions (IIMC) on at least a semi-annual recurrent basis.

It is the position of AMOA that operators provide pilots with recurrent aviation training and that training include the following scenarios:

- Inadvertent Instrument Meteorological Conditions (IIMC).

- Emergency Procedures (Engine & Component Failures).
- Night Operations.
- TAWS/HTAWS & NVIS

Further, air medical operators provide Air Medical Resource Management (AMRM) and Risk Management training to all personnel on a recurrent basis at least annually.

- **Oversight:** Effective management oversight is a critical safety component; it is not enough to provide enhanced regulations and procedures- operators must also monitor those enhancements and provide effective guidance on risk assessment and mitigation.

It is the position of AMOA that air medical operators provide effective management oversight through the development of Operational Control in compliance with Operations Specification A008 and subsequent guidance on Risk Assessment and Operational Control Centers. Further, those must include:

- Satellite Tracking or ADS-B Capability
- Approved Risk Assessment and Risk Management Procedures
- Regional or Centralized Operational Control Systems

Further, operators must initiate flight data monitoring devices and coordinate that implementation with a standardized helicopter specific Flight Operations Quality Assurance (FOQA) or similar program.

- **Safety Systems:** All of these concepts require a collective management system that combines the attributes of these objectives into one cohesive system. Safety Management Systems (SMS), as recommended by the International Helicopter Safety Team (IHST) should be modeled after the International Civil Aviation Organization (ICAO) Safety Management Manual ([Doc 9859-AN/460](#)) and Federal Aviation Administration (FAA) Advisory Circular, [AC 120-92](#), Introduction to Safety Management Systems for Air Operators. The fully-developed SMS must represent a structured methodology for managing safety across the entire spectrum of aviation operations. The SMS attributes are interdependent and must enhance the safety of every process or activity within the collective operation or system. The SMS is dynamic and must be updated through continuous quality improvement.

This SMS must include but is not limited to the following attributes:

- Senior-Level Commitment (Advocacy, Resourcing, Values & Culture)
- Safety Structure, Hierarchy & Accountability
- Compliance-Based Requirements (Policies, Procedures, Guidelines, Checklists, etc...)
- Risk Management Methodology (Systematic Process)
- Safety Reporting (Standard & Anonymous Functionality, Proactive Hazard Identification & Reactive Occurrence/Event Disclosure)
- Root Cause Analysis/Investigation Methodology

- Safety Trend Analysis Program
- OSHA & Safety-Related Training Program
- Best Safety Practices (BSP) Sharing & Lessons-Learned
- Action-Oriented Safety Committees
- Safety Awards Program
- Audit & Surety Program

AMOA remains committed to working with industry organizations, our international partners, and governmental entities to establish and participate in voluntary programs to craft viable regulations, operations specifications, and guidance that will enhance the safety posture of the industry and allow mission availability.

To that end, AMOA is happy to present this testimony, and with it an explanation of the very complex issues and topics before the Subcommittee. Yet the subject of oversight is relatively simple: the FAA has, and should continue to maintain oversight as the sole regulator authorized to oversee aviation operations and aviation safety; state medical authorities now have and should continue to have the full authority over the medical segment of the operation. AMOA fully supports the current legal and regulatory framework and will gladly work with each of these entities to provide safe, effective, and practical regulation; however, we believe efforts to change or modify the fundamental aviation legal structure may have serious unintended consequences for aviation safety and the effectiveness and viability of air medical transport by creating a patchwork of aviation and regulatory regimes. Further, these unintended consequences could lead to limits on air medical resources especially in rural areas where they are most sorely needed, creating gaps in coverage and possibly limiting the public's accessibility to sorely needed medical care.

H.R. 1201, Bill to Increase Safety in Air Medical Services

The provisions of H.R. 1201 are rooted in the safety recommendations made by the NTSB Special Investigation Report on Emergency Medical Services Operations (Adopted Jan. 25, 2006). The recent public hearings held by the NTSB reviewed both the FAA's and the air medical industry's response to those recommendations. We believe that air medical operators have met, and in some cases exceeded, the intent of those recommendations. The following is a description of the recommendations and the actions that air medical operators have taken to address the NTSB's safety concerns. We believe these actions represent a clear commitment to the safe operation of air medical services for the benefit of flight crews, medical personnel, and the public we transport.

Observance of Part 135 Rules on all Legs of Flight

Air medical services operate under a tremendous amount of regulatory oversight. Part 135 rules are a complex set of requirements, and beyond those regulations are additional rules prescribing how a service must operate depending on the type of operation that service chooses to perform. Despite numerous inaccurate reports, statements, and articles to the contrary, air medical services operate utilizing stringent restrictions – particularly in the area of weather minimums – on all legs of a flight.

For Part 135 air medical operators, these additional requirements include FAA-issued Operations Specification A021. Recent efforts coordinated by HAI with the FAA and air medical operators to address safety issues led to significant changes to the A021 Operations Specification. These changes represent the combined efforts of the air medical operator community to increase or enhance existing requirements for industry operations.

The A021 revisions specify that if a flight, or sequence of flights, includes a Part 135 segment, then all visual flight rules (VFR) segments of the flight must be conducted within more stringent weather minimums and the minimum safe cruise altitude determined in pre-flight planning. These new weather minimums are significantly more restrictive than those prescribed in Part 135. They also are calculated to encourage deployment of Night Vision Imaging Systems. Further, A021 requires pilots to identify a minimum safe cruise altitude during pre-flight planning by identifying and documenting obstructions and terrain along the planned flight path. Helicopter Emergency Medical Services (HEMS) pilots must also determine the minimum required ceiling and visibility to conduct the flight using the revised weather minimums contained in A021.

Revised Operations Specification A021 also permits HEMS instrument flight rules (IFR) operations at landing areas without weather reporting if an approved weather reporting source is located within 15 nautical miles of the landing area or if an area forecast is available. This change corrects a long-standing issue with Part 135 operation and Part 135 IFR flight. Previously, this was allowed for only under Part 91. With this Operations Specification (OpSpec) change; air medical operators can operate IFR in nearly all situations under Part 135 rules.

Mandatory Risk Assessments (Operational Control)

As part of the changes to Operation Specification A008, risk assessments were required for Part 135 flights as part of an enhanced operational control structure; further, the certificate holder retains all responsibility for the operational control of aircraft operations, and thus the safety of each flight conducted under its Part 135 Certificate and Operation Specifications, including the actions or inactions of all direct employees and agents of the certificate holder. The certificate holder cannot transfer that responsibility to any other entity for any reason. In air medical services, this includes hospitals, medical personnel, emergency or 911 dispatching services, or any other entity. In order to ensure this oversight control, operations were required to initiate some type of operational control system. For many operators, that became Enhanced Operational Control Centers, a program that monitors and tracks flight requests, flight initiation decision making and risk management procedures, and the course of the flight itself. While some operators do this differently based on the size and displacement of their operations, the goal of maintaining oversight is essentially the same.

The completion of a risk assessment before every flight or series of flights is clearly a standard practice in the industry. When combined with the management oversight provided by enhanced operation control and the safety management of a formal Safety Management System (SMS), the benefits of these risk assessments are clear.

Formalized Dispatch (Enhanced Operational Control)

AMOA believes that the FAA has provided concise and practical regulatory guidance and expectations for air carriers to achieve Operational Control in that the FAA issued Notice N 8000.347, Operational Control: Revised Operations Specifications A008 and A002, which provided revised guidance and a mandatory revision for Operations Specification A008 (Operational Control), and A002 (Definitions and Abbreviations) that also included a target date for issuance of the revised Operations Specifications and a prescribed the method for implementing the amended requirements. Subsequently, the FAA issued Notice 8900.16, Special Emphasis Inspection: Operational Control, which mandated that Principal Operations Inspectors (POI) and select Principal Maintenance Inspectors (PMI) and Principal Avionics Inspectors (PAI) conduct a “Special Emphasis Inspection” of all applicable Part 119 certificate holders conducting operations under Part 135, to ensure compliance with the revised requirements.

Although the current FAA regulations do not define a standard or require an operator to maintain an Operations Control Center (OCC) to achieve operational control, the FAA issued Advisory Circular (AC) 120-96, Integration of Operations Control Centers into Helicopter Emergency Medical Services Operations, which provided recommendations to assist HEMS operators with the development, implementation and integration of an OCC and enhanced operational control procedures.

Currently, there are diverse configurations within the HEMS industry designed to accomplish the operational control requirement and OCC function. Certain air carriers utilize a centralized communication center/dispatching methodology, which may apply to their entire multi-state operation. Others utilize a localized methodology specific to the hospital and/or service. Still others utilize a regional methodology to further manage the uniqueness of the environment they operate in. These varied configurations and methodologies help support the operational control function as required by the Operations Specifications and explained in the related FAA guidance. Certain air carriers may also include an aviation subject matter expert to provide input regarding the conduct of flights as necessary or requested.

AMOA concurs with the FAA in that “HEMS operations are unique, and as such have a set of requirements that are not identical to part 121 operations. There are well-developed OCCs and enhanced operational control procedures currently in use in support of part 121 operations that could assist HEMS operators when properly adapted to the dynamic conditions that make up the environment of HEMS operations.”

AMOA recommends that the FAA, as the responsible federal agency, work in collaboration with air carriers and other stakeholders to develop viable Operations Control Centers (OCC) and enhanced operational control regulations that provide standardized guidance requirements while also allowing for optional configurations to accommodate the unique and diverse needs of the air medical transportation.

Enhancing Terrain Awareness and Obstacle Avoidance

Although not referenced in H.R. 1201, AMOA members have made significant gains in the areas of terrain and obstacle avoidance. It is the position of AMOA that each operator deems which equipment and procedures are necessary to achieve terrain and obstacle avoidance and appropriate for their area and operation.

This system can be achieved by any of the following:

- Operating with Night Vision or Enhanced Vision Systems, with the appropriate level of initial and recurrent training.
- Operating with some type of Helicopter Terrain Alert Warning System, with the appropriate level of initial and recurrent training.
- Operating under Instrument Flight Rules (IFR), with the appropriate level of initial and recurrent training.

Further, it is the position of AMOA that any rule addressing terrain and obstacle avoidance must allow for the consideration of comparable options to achieve compliance. Recent accidents have demonstrated a need for enhancements in terrain and obstacle avoidance systems, especially at night. AMOA firmly embraces this need. However, implementing this enhancement must address the risks specific to both the type of operation and the area in which they operate. Certain types of equipment, such as Night Vision Goggles, may be far more appropriate to address the risks in a rural or suburban area, whereas some operations choose to address obstacle avoidance through the implementation and maintenance of an IFR infrastructure.

The following is a further description of these specific types:

- **Night Vision Goggles:** The use of NVGs in VFR conditions will increase the ability of pilots to successfully identify and avoid terrain and obstructions in low lighting conditions at night.
- **HTAWS:** HTAWS will provide visual and aural warning of approaching terrain or obstacles which are in the HTAWS database and would constitute a hazard to continued flight on the present flight path.
- **IFR:** IFR flight would keep the aircraft above the terrain and obstructions for the en route phase and the Instrument Approach Procedure.

As discussed, a recent survey of air medical operators conducted by AMOA demonstrated significant deployment of NVGs in the air medical fleet since 2006. That same survey indicated air medical operators are committed to having 90 percent of their combined fleets equipped with night vision goggles by 2011.

AMOA encourages the implementation of H-TAWS, especially noting this NTSB recommendation, and commend the FAA, the RTCA, and the numerous participants who volunteered their time to develop minimum standards for H-TAWS in 2007. This effort culminated in the release of a Technical Standard Order for H-TAWS released in December of 2008. While H-TAWS are a safety enhancement tool, the Associations believe that NVGs and

EVS offer more effective risk mitigation, especially in take-off and landing phases, than H-TAWS, which have a limited capacity at low altitudes, slow speeds, and against low obstacles.

Installing Devices that Perform the Function Recording Flight Data

While not specifically referenced in the 2006 recommendations, flight data monitoring devices and voice recorders specifically designed for helicopter operations have developed very quickly in the last three years. As noted in the above standards under development for AMOA membership, AMOA members are committed to pursuing the implementation of these devices in aircraft and using the data collected by these devices for a multitude of different applications, including management oversight, quality assurance, training, and post-accident data gathering.

Many previous devices were too large and too heavy for installation in most helicopters; however, many new devices are smaller, lighter, easy to install and maintain. They also collect data differently, and in some cases more effectively, than some previous devices. While this is an excellent benefit to helicopter operations, the FAA still maintains specific definitions for flight data and cockpit voice recorders, leading some helicopter operators and device manufacturers to refer to these devices by different definitions in order to install the devices. This is simply a matter of the technology developing far faster than the regulatory language.

A rulemaking process to require these devices would also have to include a study on the standardization of these devices, and new regulatory language, or a re-defining of current definitions, to be effective.

Specific Modifications to H.R. 1201

AMOA supports the objectives of each of the provisions of H.R. 1201. Operators' support of these objectives is evident in their current operations and the commitments they have made as part of their membership in AMOA. While the bill is of great benefit, there are specific issues that must be addressed in order to provide both the safety benefits intended by the bill and avoiding any unintended consequences that may decrease safety or limit an operator's ability to implement these safety enhancements as effectively as possible.

The following is an explanation of the modifications that AMOA proposes to H.R. 1201:

- **Requiring a Rulemaking to Require Part 135 Rules on All Legs-** As a general matter, AMOA is not opposed to the application of key Part 135 requirements to all legs of a flight including one patient transportation segment but we urge that a FAA rulemaking process should be used to get to this requirement. Rulemaking will allow the FAA, air medical operators and other stakeholders to have input into the specifics of this requirement and ensure there are no unintended consequences. The following point is just one example of possible unintended consequences of a legislative mandate versus a participatory rulemaking process. This amendment also alleviates a concern that future enhancements to the rules, or the development of a separate set of rules for air medical services would not be impeded by this statute, thus requiring a return to Congress to get legislative relief for future safety improvements that could be accomplished better and more swiftly by FAA rulemaking.

- **Providing an Exemption for Instrument Flight Rules (IFR)**- The FAA has recognized the safety of IFR operations by providing for an exemption that allows a Part 135 Certificate Holder to conduct IFR operations to destinations without approved weather reporting at the destination. This proposed modification preserves and acknowledges that existing exemption and allows for the continued operation of the safety benefits of IFR.
- **Removing "pilots" from Flight Dispatch Procedures**- This modification would simply expand the scope of this section to include pilots, operators, and any other body that may provide some level of flight following services and allow those procedures to inform a broader audience.
- **Requiring "Devices that Perform the Function of Voice Communications and Flight Data Information"**- AMOA proposes replacing this terminology. The FAA currently has very narrow, strict definitions of CVR and FDR and those definitions are not consistent with rotorcraft design (many simply will not fit in a helicopter cockpit). This change allows for this study and rule to include the new and innovative technology currently on the market that can meet the objectives of having CVR's FDR's aboard rotorcraft. This modification also reinforces AMOA's firm commitment to flight data management and flight operational quality assurance programs as safety management tools.
- **Allowing the Study of Requiring Devices to Inform the Rulemaking**- We believe this is an excellent opportunity to ensure that the study on feasibility, once complete, will inform sound rulemaking.

Again, we strongly affirm the intent of this legislation, and offer these amendments to enhance its objectives by providing a process that assures that unintended consequences in the complex area of aircraft operational safety are not encountered.

H.R. 978, "Helicopter Medical Services Patient Safety, Protection, and Coordination Act"

AMOA believes the Helicopter Medical Service Patient Safety, Protection, and Coordination Act's (H.R. 978) shifting of authority to the states to regulate placement and authorized routing of air carriers engaged in air medical transport operations would have significant negative unintended consequences. Further, it is the position of AMOA that HR 978 provides no substantive incremental benefit to patient care or states' well-established ability to regulate medical matters, while compromising safety and enabling limitation on air medical transport access for patients and communities. We believe this compromises aviation safety, significantly harms the nation's emergency air response capacity, and limits patient access to potentially lifesaving health care.

The Courts have consistently confirmed that States already have sole and exclusive authority to control and regulate any aspect of patient care aboard an air medical aircraft. Indeed all states impose licensing requirements on air medical operators related to patient care aboard the aircraft. These licenses prescribe a number of conditions and qualifications on both medical equipment and medical personnel aboard the aircraft. AMOA fully supports and encourages the exercise of already ample state authority in this area.

Under the bill states could prescribe routes of flight, they would have authority to prohibit an aircraft from operating within the state, and they could mandate certain airframes or structural changes to airframes -- activities that are properly and safely administered by the FAA. H.R. 978 could turn the current federal aviation system into a patchwork of systems determined by state borders.

There is no countervailing justification for the resulting harm that is possible. State, not federal, protocols currently control which air medical operator is called to a scene; new federal law is not necessary provide states this authority. Air medical services do not self-dispatch; services arrive at a scene only after being specifically called and after a determination as to the need for air medical transport has been made by a trained on-scene first responder and/or a licensed physician.

In summary, H.R. 978:

- **Compromises Aviation Safety:** Allowing state authorities to create a parallel regulatory scheme for aspects of aviation now under exclusive federal authority and creating questions as to which regulatory body is controlling would be to ignore history's aviation safety lessons. Federal aviation laws and regulations are designed to ensure that a single comprehensive safety and regulatory standard exists for all aviation users throughout the entire country.
- **Significantly Undermines the Nation's Existing Air Medical Transportation Capacity:** Modern air medical transport, like the rest of the air carrier industry, is an interstate, not a local, business. Allowing each state separately to regulate the aviation aspects of this sector will produce a multiplicity of potentially conflicting state requirements that will undermine its strength and integrity, threatening its failure. This is precisely what the federal preemption provisions of the Airline Deregulation Act (ADA) were designed to avoid. The threat to air medical transport capacity will poorly serve both the nation's health care needs and its ability to respond to national and regional disasters.
- **Limits Community Access to Critical Air Medical Transport Services, Especially in Rural Areas:** Limiting the number of air medical services in a state will cause a significant decrease in access to trauma and critical health care needs, especially in rural areas in cases where state regulated systems do not determine a sufficient need based on cost for air medical services, even though a rural community or healthcare system desires it.
- **Limits Patient Care Decisions by Referring Physicians and Hospitals:** In the case of inter-facility transports, which represent more than 50% of air medical transports, physicians are currently able to make a transport determination based on their expertise and the condition of the patient, including the determination of the most appropriate receiving hospital regardless of location. This bill would limit that decision-making ability and may conflict with the Emergency Medical Treatment and Labor Act (EMTALA).

AMOA is firmly committed to increasing aviation safety for every patient by continuing our efforts for enhanced federal aviation regulations and raising the safety standard for the entire air

medical industry. Unfortunately, H.R. 978 does not enhance aviation safety; it only undermines the well-established federal aviation statutory and regulatory framework without demonstrable justification.

AMOA believes that the Department of Transportation (DOT) and FAA should retain existing sole and exclusive authority over all aviation aspects of air medical transport, with states retaining regulatory oversight and coordination of patient medical care. AMOA believes this bill's shifting of authority to the states to regulate placement and authorized routing of air carriers engaged in air medical transport operations would have significant negative unintended consequences. Further, it is the position of AMOA that H.R. 978 provides no substantive incremental benefit to patient care or states' well-established ability to regulate medical matters, while compromising safety and enabling limitation on air medical transport access for patients and communities.

In response to the unacceptable number of accidents and tragic deaths in 2008, AMOA has joined with the Helicopter Association International (HAI) and the Association of Air Medical Services (AAMS), the national association representing all aspects of air medical transport services, in submitting to the National Transportation and Safety Board (NTSB) fourteen recommendations. These recommendations represent a cooperative effort to advance the safe operation of air medical transport services by decreasing risks through a combination of enhanced training, technology, data collection, and oversight. They represent the commitment of air medical transport services in new technologies for obstacle and terrain avoidance, in advanced training methods, in data collection and analysis, and in enhanced operational control and management oversight. We believe these initiatives are a *cooperative* and *direct* solution to the issue at hand, mindful of avoiding unintended consequences or upending existing laws and regulatory structures, and without compromising access to this valuable service.

The DOT and courts have been consistent and offered clear guidance confirming that states have complete authority over their emergency medical services (EMS) systems, including scene dispatch protocols, medical standards and training, medical equipment and its maintenance, state and local inspection for compliance with medically oriented regulations and licensure. States may not, however, limit the number of aircraft based within their jurisdiction, create "borders in the sky" through defining/restricting service areas, require certain aviation-related equipment, limit charges for air medical transport services, or in any way interfere with the licensing of pilots or the operation of the aircraft. On those occasions where states have attempted to usurp the economic authority of the DOT and the safety authority of the FAA by developing their own regulations in these areas, the DOT and the courts have intervened. AMOA believes that the federal government should retain its existing sole and exclusive authority over all aviation aspects of air medical transportation, including the authority over air carrier routes, prices and services, airspace management and aviation safety regulation and oversight.

On the other hand, H.R. 978 does not provide a substantive safety solution; rather, HR 978 would carve select protections out of the ADA and create parallel state aviation safety authority for air carriers engaged in medical transportation under the pretense these are medical and not aviation matters.

In fact, while undermining the existing, clear aviation regulatory framework, the legislation provides states with little if any incremental oversight in the regulation of medical personnel qualification and training, medical equipment and other medical matters that relate to patient care. Instead, the primary effect of H.R. 978 is to grant states authority – through certificate of need processes, required healthcare affiliations, requirements to demonstrate need and capacity for services, and other exclusionary measures – to limit access. In promoting H.R. 978, proponents have failed to demonstrate that the federal preemption of state regulation of air carrier prices, routes and services under the ADA is undermining air medical transportation safety or patient care, with no published evidence suggesting that federal laws have caused an accident or poor patient outcomes.

H.R. 978 represents a misdiagnosis of the issue at hand and is the wrong medicine for the patient. H.R. 978 provides opportunities that can only serve to limit access to patients and communities as compared to the status quo, with little substantive benefit to medical regulatory oversight for improving patient care, while creating a slippery slope for air commerce providers to be carved out of the ADA and opening up the ambiguous authority for states to *harmonize* to federal aviation rules, in place of the well-defined, strictly enforced, consistent nationwide regulations overseen by the federal government.

Exclusive Federal Airspace and Aviation Safety Authority

AMOA is concerned that H.R. 978 would have the unintended consequence of *reducing* aviation safety by its unprecedented blurring of regulatory jurisdiction between federal and state governments. Congress created the FAA and passed the ADA because it recognized that a uniform system of nationwide regulation was needed to achieve both safe and accessible air transportation without “borders in the sky.” Air medical transportation is no exception. As AAMS has stated: “It is not possible to address a perceived shortfall of the FAA’s interest in aviation safety by increasing state authority over the economics of aviation, unless the intent of the proposal is to provide some means for state regulatory authorities to usurp or assume duties currently retained by the FAA”.¹

H.R. 978 will undermine the direct and exclusive relationship the FAA currently maintains with FAA certificated air carriers by creating a parallel state aviation safety regulatory structure over certain matters, essentially creating a second bureaucracy responsible for ensuring compliance with federal regulations. Ironically, this is the very thing the ADA aimed at avoiding in its goal to maintain safety as the highest priority in air commerce, and why the preemption provision of the ADA has been successfully used to prevent states from regulating aviation safety. Supporters of HR 978 argue that medical organizations around the country have used federal preemption principles to overturn state EMS and healthcare legislation around the country and, in those cases where state EMS rules have intruded on FAA authority and they are correct. In just one example, the state of Tennessee enacted regulations requiring, among other things, that “[a]ll helicopters performing air medical missions shall be equipped with avionics and instruments necessary to enable the pilot to execute an instrument approach under instrument meteorological conditions.”² In connection with a lawsuit brought by a provider against the state

¹ AAMS Response to the “White Paper” Published and subsequently withdrawn by the National Association of State EMS Officials (NASEMSO), dated November 14, 2008.

² Tennessee Comp. R & Regs. 1200-12-1-.05(2)(c).

EMS Board, the Department of Justice (DOJ) and FAA argued that this approach “threatens the uniform system of regulation mandated by Congress in the Federal Aviation Act by placing aircraft operators under the control of at least 50 different potential state regulators, all with potentially different views of what is necessary to ensure safe operation.” The DOJ went on to say that “[t]he FAA does not seek to interfere with Tennessee’s ability to regulate the provision of emergency medical services to protect patient safety.”³ In its ruling against the EMS Board, the court rejected the notion that state regulations are permissible if they merely duplicate or supplement federal enactments but do not conflict with them. It is difficult to see how notions of “harmonization” are compatible with this and similar court rulings and ensuring safety as the highest priority in air commerce.

Finally, proponents of H.R. 978 have argued that “air ambulances are not and should not be simply air taxis”⁴ but, as related to certain rates, routes and services, air medical transport is first and foremost a medical operation (note that it is unclear how this applies to the airspace), which the states should consolidate into their regulatory purview, similar to ground ambulances. Completely missing from this simplistic analogy, apart from historical context on CON’s, is the fact that transport by a truck down the highway and transport by a helicopter in the airspace are two totally different things, with significantly differing levels of complexity, operational needs, technology, equipment and downside risk. Modern air medical transport, like the rest of the air carrier industry, is an interstate, not a local, operation, even if some aspects take place within a state. Allowing each state separately to regulate the aviation aspects of this sector will produce a multiplicity of potentially conflicting state requirements that will undermine its strength and integrity, threatening its failure. This is precisely what the federal preemption provisions of the ADA were designed to avoid. The threat to air medical transport capacity will poorly serve both the nation’s health care needs and its ability to respond to national and regional disasters.

If Congress’ goal in the ADA was to ensure safety as the highest priority in air commerce, which air medical transport undeniably qualifies as, it is unjustifiable that any existing oversight over rates, routes and services by the federal government for air medical transport should be relegated to the states, based on comparisons to ground ambulances.

Preservation of States' Ability to Regulate Medical Care

AAMS has stated that it does not support the conclusion that federal legislation is necessary to preserve the medical care prerogatives of state officials. In a Response to the “White Paper” published and subsequently withdrawn by the National Association of State EMS Officials (NASEMSO), a paper based on previous legislation on the similar subject of expanding state authorities, AAMS stated the following:

The power and role of state officials over medical care certification, regulation, and standards associated with air ambulance operations is not now and never have been in question. States currently have the ability to regulate all medical aspects of air ambulance operations (McGinnis, Judge, & O’Connor, 2007).

³ Statement of Interest of United States of America filed Nov. 29, 2006, *Air Evac EMS v. Kenneth S. Robinson, Commissioner of Health*, Case No. 3:06-0239, U.S. District Court, M. D. of Tenn.

⁴ The “HMS Patient Safety Act (HR 978) Frequently Asked Questions” document.

AAMS does not believe there is need for new, far-reaching federal legislation to clarify that States have the right to regulate medical care. Federal Courts and the United States Department of Transportation (DOT) have repeatedly done so by stating that the Federal preemption established by the ADA does not limit a State's ability to control medical care. Most recently, in the North Carolina case decided on September 26, 2008, the Federal District Court Judge held that limiting competition through a CON process was indeed preempted by Federal Law. However, the Judge clarified that this would not impact a State's ability to oversee and regulate medical care: *"As detailed above, those portions of the challenged laws and regulations that relate primarily to patient care are not preempted, and the state's interest in overseeing the medical aspects of air ambulance service is thus not unduly compromised."*⁵

The document entitled "Overview of The Helicopter Medical Services Patient Safety, Protection and Coordination Act (HR 978)" asserts that "in the past few years, the appropriate boundary between state and federal oversight of HMS has been undermined" and that "there is lack of clarity between these two spheres [aviation and medical] and this threatens patient safety and the quality of patient care and impedes the proper coordination of services." This is simply not the case. The DOT and numerous courts have clearly delineated, particularly in recent years, the areas in which states control medical care and the areas in which the federal government controls aviation operations, as presented in: "Federal Preemption of State Regulation over Air Ambulances," *Air Medical Journal*, 2008 (Exhibit A).

In summary, AMOA agrees with AAMS' analysis, supported by numerous DOT and court decisions, that states currently have clearly-defined authority and means to regulate medical care and supports the continued exercise of this authority. The assertion that the HMS Patient Safety Act will "ensure a level playing field where all helicopter medical service providers must meet quality standards and participate in a coordinated air medical transport system that promotes the best interests of the patients"⁶ is without merit. States already have this authority.

Full Access for Patients and Communities

If, as has been demonstrated above, the states already have the authority over medical care and the federal government has the regulatory authority over aviation operations, the remaining question becomes: How does this bill affect safety and patient care in ways that cannot already be accomplished within the existing regulatory framework? The simple answer is the bill creates the opportunity for states to regulate access, which can only be more limiting than the status quo, through CON's and/or other similar exclusionary measures currently preempted under the ADA's regulation of rates, routes and services, and which has been the central issue in many of the state challenges to the ADA.

There is no factual or anecdotal evidence that CON processes increase the availability of air ambulance services to a community. In fact, CON's are designed to limit, rather than expand,

⁵ IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NORTH CAROLINA, WESTERN DIVISION NO.5:07-CV-222-FL, September 26, 2008.

⁶ The "HMS Patient Safety Act (HR 978) Frequently Asked Questions" document.

competition. This often results in decreasing access. Most state healthcare CON laws can be traced back to a 1974 federal requirement tied to funding, which was repealed in 1987. CON's were designed to control cost in a time when hospitals and many other healthcare providers were reimbursed based on cost. The CON process was never very effective at controlling costs, and now that hospitals are no longer paid based upon their costs the value of CON's in any aspect of healthcare is questionable. Unfortunately, the CON process, in the very few states retaining it, can become a political tool used by incumbents to keep competition at bay by creating barriers to entry.

In 2003, the Federal Trade Commission (FTC) and the Department of Justice Antitrust Division conducted 27 days of hearings on competition and policy concerns in the healthcare industry, interviewing nearly 250 panelists. A written statement prepared for a Joint Session of The Health and Human Services Committee of the State Senate and The CON Special Committee of the State House of Representatives of the General Assembly of the State of Georgia, on February 23, 2007 by Mark J. Botti, Chief, Litigation I Section, U.S. Department of Justice, Antitrust Division states:

“The Antitrust Division’s experience and expertise has taught us that Certificate of Need laws pose a substantial threat to the proper performance of healthcare markets. Indeed, by their very nature, CON laws create barriers to entry and expansion and thus are anathema to free markets. They undercut consumer choice, weaken markets’ ability to contain healthcare costs, and stifle innovation. We have examined historical and current arguments for CON laws. They do not provide an economic justification for depriving consumers of the benefits of free markets. To the extent non-economic goals are pursued, the use of CON laws to help pursue them imposes substantial costs. Those goals can be better achieved through other mechanisms.” He went on to add: *“CON laws appear to raise a particularly substantial barrier to entry and expansion of competitors because they create an opportunity for existing competitors to exploit procedural opportunities to thwart or delay new competition.”*

With respect to the use of CON's in the air medical transport industry, AAMS has noted the following:⁷

History has shown that those few States who implement CON-type regulatory schemes designed to regulate the number of air ambulance providers stifled competition, resulting in fewer, not more air ambulances, and this, in turn, results in less, not more availability to the public, thus decreasing access to life-saving services. In a twenty year period between 1986 and 2006 there were eight instances where States attempted to limit the number of air ambulance providers in their jurisdiction based on a CON-type regulation. In each of these cases (Minnesota 1986, Arizona 1987, Nebraska 1989, Missouri

⁷ AAMS Response to the “White Paper” published and subsequently withdrawn by the National Association of State EMS Officials (NASEMSO), dated November 14, 2008.

1997, Kentucky 1998, New York 2000, Tennessee 2002, Hawaii 2006) the State reversed their position either as a result of a court order, or at the direction of their State's Attorney General, thus allowing more air ambulances to operate within their jurisdiction. In each of these instances, there was, and continues to be, a net increase in the number of air ambulances providing services in those states, and therefore a net increase availability of the service to the public.

Currently only six (6) States continue to attempt to regulate the number of air ambulance providers through a CON process (Connecticut, Maine, Massachusetts, Michigan, North Carolina, and Vermont). According to data from the Atlas and Database of Air Medical Services (ADAMS), (The Center for Transportation Injury Research, 2008, NHTSA, 2005), those states that regulate the number of helicopters via a CON process have fewer helicopters relative to their population than do states that allow free market competition to dictate the number and location of helicopter air ambulances. While this fact alone may not tell the entire story as population density and the distances between major hospitals should also be considered, it is consistent with the experience of the past twenty years, in that the CON process tends to limit rather than expand the number of air ambulances. The national average is 1 helicopter per 346,000 people. By comparison, those few States that attempt to limit the number of helicopter air ambulances average far less than half that ratio:

- Connecticut -- 1 helicopter for every 1,702,783
- Maine -- 1 helicopter for every 637,462
- Michigan -- 1 helicopter for every 903,495
- Massachusetts -- 1 helicopter for every 1,587,274
- North Carolina -- 1 helicopter for every 536,621
- Vermont -- 0 helicopters for a population of 608,827 (served by an aircraft in NH)

As the healthcare industry undergoes its own changes, the demand for air medical services, particularly for millions of rural Americans who are unable to access specialty care in a timely fashion without the aid of air medical services, has become even greater, including for the following well-documented reasons:

- Loss of full-service community hospitals in rural areas, as well as local, community-based ambulance services;
- Decreasing specialist and subspecialist coverage at community hospitals (e.g., generally surgery, neuro-surgery, obstetrics, orthopedics);
- Decline of specialist and sub-specialist physicians willing to take unassigned patients (most of whom are uninsured or under-insured) at community hospitals;
- Declining capabilities of rural EMS services which are heavily volunteer dependent;
- General contraction of the health care system with the loss of emergency departments and Level I and II trauma centers;

- Increasing number of time-sensitive therapies requiring major center care for the treatment of time dependent diseases, especially cardiac, stroke and trauma patients;
- Regional corporate health system hub and spoke array development of hospitals and services; and
- Increasing number of “baby boomers” and rates of trauma, cardiac and stroke.

It is incumbent upon the healthcare system and medical authorities to allow medical providers to meet that increasing demand as part of our nation’s healthcare infrastructure with the highest levels of safety and quality patient care to ensure the public trust, acknowledging that different types of providers serve different types of communities, even within a state, and one size does not fit all.

In summary AMOA fully supports, promotes and encourages the wide ranging ability and authority of state EMS and other medical officials to regulate the medical aspects of air medical transport and continue to license air medical transport services under this authority. Limiting the use of air medical transport service is not a safety solution; simply flying less theoretically may lead to fewer accidents, but that will not increase aviation safety in air medical transport services. Furthermore, facilitating means for limiting the use of air medical transport services is in direct opposition to improving patient care. We do not believe that providing states with the ability to reduce or restrict access of air medical resources to communities have the patients’ best interests in mind. This was demonstrated in an earlier, similar rendition of this bill in North Carolina, one of six states with an air medical CON, where patients flown by out of state operators were prevented from picking up a North Carolina patient and flying that patient to a North Carolina hospital, thereby requiring transport to an out of state hospital, by virtue of the state’s certificate of need regulation. This regulation was overturned.

The assertion that “the ADA has been used been used to overturn long standing state EMS and public health regulations to enable unfettered entry into geographic areas where air medical programs already exist and to eliminate the need to comply with quality air medical transport standards”⁸ flies in the face of the facts and circumstances of the North Carolina, Tennessee and other legitimate operator challenges to state EMS regulations. We believe H.R. 978, and the ability it would provide a state to limit the number of aircraft operating within a state is not only in conflict with the intent of the ADA, but we believe it represents bad public policy. H.R. 978 would create the potential for a patchwork of 50 different state regulatory structures governing the aviation economic aspects of air medical transportation, parallel state aviation safety regulatory structures, undermining the capacity of the nation’s air medical transportation resources, unnecessarily restricting the number of aircraft available to respond to medical emergencies and putting a significant number of current and future aviation and medical professionals’ jobs at risk.

⁸ The “HMS Patient Safety Act (HR 978) Frequently Asked Questions” document.

Other Air Medical Issues Important to Aviation Safety

Government Operators Compliance with Part 135 for Air Medical Transport

All operators engaged in the air medical transportation of the public, including government operators, should be required to comply with the same aviation safety standards. As the NTSB has noted, the public, in most circumstances, has no choice in determining which operator provides an air medical transport because flight requests are made by healthcare or state or local government personnel. The public has the right to expect, regardless of the operator's identity or operating model, the same aviation safety standards to apply.

Current federal law supports this conclusion. In 1994, Congress changed the law to significantly narrow the class of aircraft considered "public aircraft" to those which federal aviation safety requirements do *not* apply. This was done to protect the passengers on aircraft operated by government agencies by minimizing the discrepancy in applicable aviation safety standards. Under the law, public aircraft are limited to those engaged in a "government function." The examples of government functions specified in the law do not include air medical transportation or any other activity involving the routine transportation of the public. Further, the status of an aircraft operation as public or civil under the law does not depend exclusively on whether the operator is reimbursed for the transportation; if an aircraft is not engaged in a government function, then it is not a public aircraft and the factor of reimbursement is irrelevant.

The law means, in brief, that government operated aircraft *not* engaged in the narrow class of operations considered a "government function" are civil aircraft and must comply with all the federal aviation regulation applicable to civil aircraft, including Parts 91 and 61. If the government agency is being reimbursed for the transportation it provides, it must, as a general matter, have a Part 135 operating certificate.

FAA actions to implement the law in this area have not been assertive and consistent, as was pointed out during the NTSB hearing. In 1995, the FAA issued an advisory circular in an attempt to explain the public aircraft law in which the agency, on its own initiative, included "medical evacuation" as a "government function" under certain, but illogical and unclearly defined, circumstances. This advisory circular created confusion among operators and the public. For example, certain government operators were using surplus military aircraft not eligible for airworthiness certificates in typical air medical operations, calling these public rather than civil aircraft operations, which was clearly not consistent with the intent of the law.

In 2003, the FAA took action after several years of deliberation to correct this problem by amending Order 8700.1 to clarify the definition of public aircraft for FAA inspectors and confirm their safety oversight responsibilities for the majority of air medical operations by government operators. The amendment was intended to clarify the ambiguity created by the advisory circular and brought into line FAA practice with the intent and scope of the public aircraft law. In a nutshell, Order 8700.1 *assumes* that medical evacuation, *as a routine matter*, is not a government function, unless one or more specified, non-routine factors are present to change that assumption. Therefore, government operators engaged in typical air medical operations are engaged in civil aircraft operations, subject to the applicable federal aviation

safety regulations. This amendment to the order was followed by a Flight Standards training program for its inspector workforce.

Some government operators engaged in air medical transportation, on their initiative, have sought and received Part 135 operating certificates. Other government agencies engaged in air medical transportation of the public on a routine basis do not have Part 135 certificates for this transportation, although it appears that at least certain operators understand these operations to be civil aircraft operations requiring airworthiness and airmen certificates and governed, among other things, by the requirements of Part 91.

Since the FAA order was amended in 2003, FAA pronouncements on this subject have once again been inconsistent, and the extent of FAA oversight to ensure the regulatory compliance of government operators engaged in air medical transportation remains unclear. During the past several years of focus on HEMS safety, it appears the FAA has taken no actions to require or even advise government operators engaged in air medical transport without a Part 135 operating certificate to implement the enhanced aviation safety measures applicable to commercial air ambulance operators.

The discrepancy in aviation safety standards governing the air medical transportation of the public has no public policy or legal justification. We believe the FAA should:

- Confirm aircraft used by government operators in the air medical transportation of the public are engaged in a civil aircraft operation, unless non-routine factors are present, and the government operator is thereby required to comply with applicable federal aviation safety regulations to civil aircraft.
- Take whatever additional action is necessary to require government operators engaged in air medical transportation, regardless of whether compensation is received for the transport, to comply with the same weather minimums, flight planning requirements, equipment requirements, pilot training, communications, and any other standards specifically made applicable to all other operators engaged in air medical transportation.

The NTSB should reconcile its accident reporting classification for government operators engaged in the air medical transportation of the public on a routine basis with federal law treating these operations as civil aircraft operations. These operations, among other things, should be classified as “Part 91” or “Part 135” (if the government operator holds a Part 135 certificate), and not “public” or “public use” for purposes of documenting the applicable regulations governing the accident.

Instrument Flight Rules Operations and Improved Infrastructure

Given the differences in operating environments, we support the use of different approaches to raise the level of safety at HEMS operations. Depending upon the operating environment and mission, NVGs, HTAWS and IFR all offer enhanced safety for HEMS operations. The greater the percentage of inter-facility transports, the more opportunity there is to operate in the IFR environment. While the technology is currently available to extend the protections of the IFR systems to certain aspects of a HEMS operation in certain geographic locations, the IFR system

is not currently able to fully support low altitude operations. One AMOA member is currently working with the FAA and avionics and aircraft manufacturers on a three-year project to design and test a “low level” IFR en route network as well as “precision” WAAS GPS approaches; these joint initiatives are an industry first, are in their infancy, and require continued support.

The enhancement of the low-altitude infrastructure must include the placing of approved automated weather reporting systems at hospitals. This is of immense value to the communities in which these hospitals are located and the patients they serve. We see this as an extension of the funding provided for more than 75 years to rural airports by the DOT/FAA. One of the key justifications for such funding is to be able to airlift patients from rural locations to larger hospitals that are nearly always located in larger communities.

There should also be further assessment of developing an IFR supported system for high potential rendezvous points bringing the protection of the IFR system to scene generated transports. Supporting the development of an IFR infrastructure for more aspects of HEMS operations would be an important addition to safety. From the national healthcare perspective, higher levels of care have consolidated and it is more cost effective for our society to move the patients to the care needed from areas where the care is not available. As a regulatory agency, the FAA sets minimum standards. Those standards should be enhanced in an appropriate manner that takes into account the different operating environments of HEMS operators.

Conclusion

AMOA remains committed to the principal that advancing safety through both voluntary standardization efforts and regulatory oversight will result in a decrease in air medical accidents. Further, we believe that through effective cooperation with state officials, exercising their current authorities over the medical segment of the operation of air medical transport, we can continue to provide this service in a safe manner when deemed appropriate by medical personnel. The current rulemaking process allows for this cooperative effort to take place. Air medical operators working together, and in conjunction with federal authorities for the development of practical and effective aviation safety rules will ensure the safest possible transportation; these operators working in conjunction with the medical community and state medical officials will result in similar levels of oversight in the medical arena. While we cannot promise that there will never be another accident of a medical or transportation nature in an air medical helicopter, we can collectively promise to work together to ensure that those accidents are prevented to the fullest extent of our abilities as providers and regulators.

There are many myths about air medical services circulating in the media and in conversations concerning the efficacy and necessity of this service. As we believe we have illustrated through this testimony, air medical transport services are a vital component of the emergency medical system and are a highly regulated and appropriately overseen segment of both the aviation and medical communities. Air medical services, either for-profit or non-profit, submit to the same licensure and oversight process at both the federal and state level, both respond to requests for transport only when deemed appropriate by referring medical personnel and do so without the knowledge of or guarantee of payment. Finally, despite allegations that air medical helicopters are poorly equipped and under-regulated, these aircraft are in fact some of the most

technologically advanced aircraft, under the most scrutiny from management and regulatory agencies, providing helicopter transportation in the United States today.

In closing, we ask that you continue your vigilance on behalf of the public we transport, and help us support this vital service.

Sincerely,



Craig Yale
Executive Vice President,
Air Methods Corporation
On Behalf of the Air Medical Operators Association (AMOA)



Howard Ragsdale
President, AMOA



Christopher Eastlee
Managing Director, AMOA