



National Transportation Safety Board

Washington, D.C. 20594

Safety Recommendation

Date: SEP 24 2009

In reply refer to: A-09-104 through -107

The Honorable Kathleen Sebelius
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

The National Transportation Safety Board (NTSB) is an independent federal agency charged by Congress with investigating transportation accidents, determining their probable cause, and making recommendations to prevent similar accidents from occurring. We are providing the following information to urge your organization to take action on the safety recommendations in this letter. The NTSB is vitally interested in these recommendations because they are designed to prevent accidents and save lives.

This recommendation letter addresses the helicopter emergency medical services (HEMS) industry and is derived from testimony provided at the NTSB's public hearing concerning this industry, as well as investigations of recent HEMS accidents. As a result, the NTSB is issuing four safety recommendations to the Department of Health and Human Services' Centers for Medicare & Medicaid Services (CMS). Information supporting these recommendations is discussed below. The NTSB would appreciate a response from you within 90 days addressing the actions you have taken or intend to take to implement our recommendations. Additional recommendations have been addressed to the Federal Aviation Administration (FAA), the Department of Homeland Security's Federal Interagency Committee on Emergency Medical Services (FICEMS),¹ and 40 public HEMS operators.²

Calendar year 2008 was the deadliest year on record for the HEMS industry with 12 accidents³ (8 fatal accidents) and 29 fatalities. As a result of this increase in fatal accidents involving HEMS operations, the NTSB placed the issue of HEMS safety on its *Most Wanted List*

¹ FICEMS is an advisory committee whose function is to provide guidance and coordination on EMS. No federal agency is currently responsible for EMS oversight at the national level.

² Public-use aircraft are operated by federal, state, or local government entities. Certain of their operating requirements differ from those required of non-public-use civil aircraft operators.

³ The NTSB classifies a HEMS accident as one in which the accident flight involved an aircraft dedicated to or configured for air medical operations and piloted by an EMS crew.

of *Transportation Safety Improvements* on October 28, 2008,⁴ and also conducted a 4-day public hearing to critically examine safety issues concerning this industry.⁵ Based on testimony given at this public hearing, in addition to findings from recent HEMS accidents,⁶ the NTSB believes that CMS needs to take action to evaluate the reimbursement policies for helicopter emergency medical transport and its relationship to the level of service provided by the HEMS operator.

HEMS operations provide an important service to the public by transporting seriously ill patients and donor organs to emergency care facilities, often from remote areas not served by adequate facilities. These operations, which comprise an estimated 750 helicopters, 70 commercial operators, and 60 hospital-based programs, are unique and complex, mixing highly advanced medical care with the technical challenge of safely operating helicopters 24 hours a day.⁷ Each year, approximately 400,000 patients and transplant organs are safely transported by helicopter. However, the pressure to conduct these operations safely and quickly in various environmental conditions (for example, in inclement weather, at night, and at unfamiliar landing sites for helicopter operations) increases the risk of accidents when compared to other types of patient transport methods, including ground ambulances or airplanes.

Previous NTSB Actions: Safety Study, Special Investigation, and Public Hearing

The NTSB has a long-standing interest in the safety of emergency medical services (EMS) aviation operations. In 1988, the NTSB conducted a safety study of commercial HEMS operations. That study evaluated 59 HEMS accidents and resulted in the NTSB issuing 19 safety recommendations to the FAA and to the air medical transportation industry.⁸ However, the late 1990s and early 2000s saw a rapid growth of HEMS operations and the number of accidents began to rise. Prompted by this rise, the NTSB completed a special investigation in January 2006 that analyzed 41 HEMS accidents and 14 airplane EMS accidents that had occurred during the previous 3 years, claiming 54 lives; of these fatalities, 39 occurred during HEMS operations.⁹ In this *Special Investigation Report on Emergency Medical Services Operations*,¹⁰ the NTSB identified the following recurring safety issues: less stringent requirements for EMS operations

⁴ See <http://www.nts.gov/Recs/mostwanted/aviation_improvesafety_ems_flights.html> for a discussion of these recommendations: A-06-12, A-06-13, A-06-14, A-06-15.

⁵ The NTSB's public hearing took place February 3–6, 2009. For details, see the NTSB website at <<http://www.nts.gov/events/Hearing-HEMS/default.htm>>.

⁶ Accident investigation reports are available at <http://www.nts.gov/Publictn/A_Acc1.htm>. The public may view and download docket contents at <http://www.nts.gov/info/foia_fri-dockets.htm>. Details of the recent HEMS accidents that are used to support the recommendations contained in this letter are cited later in the section of this letter titled "Recent EMS Accidents."

⁷ Estimates provided by the Association of Air Medical Services.

⁸ Most of these recommendations to the FAA were closed as a result of the June 20, 1991, issuance of Advisory Circular (AC) 135-14A, "Emergency Medical Services/Helicopter (EMS/H)," which addressed equipment, training, crew resource management, decision-making, flight-following procedures, weather minimums, and the development of safety programs for EMS helicopter flights operating under 14 *Code of Federal Regulations* (CFR) Part 135. Although the NTSB expressed concern at the time that the FAA chose to issue an AC instead of regulations, the number of EMS accidents was decreasing; thus, the recommendations were classified "Closed—Acceptable Action."

⁹ Accident rates would have been a better metric for evaluation, but HEMS operators are not required to report exposure data. Consequently, only raw counts were available.

¹⁰ *Special Investigation Report on Emergency Medical Services Operations*, NTSB/SIR-06/01 (Washington, DC: National Transportation Safety Board, 2006). The full report can be accessed at the NTSB website at <<http://www.nts.gov/publictn/2006/SIR0601.pdf>>.

conducted without patients on board; the absence of aviation flight risk evaluation programs for EMS operations; a lack of consistent, comprehensive flight dispatch procedures for EMS operations; and a lack of requirements to use technologies such as terrain awareness and warning systems (TAWS) and night vision imaging systems (NVIS) to enhance EMS flight safety. As a result, the NTSB adopted four safety recommendations specifically addressing the need to improve the safety of EMS flights. These recommendations are currently included on the NTSB's Most Wanted List.

As noted above, 2008 was the deadliest year on record, with 8 fatal accidents and 29 fatalities, up from 2 fatal accidents and 7 fatalities in 2007. During its February 2009 public hearing, the NTSB heard testimony¹¹ describing the perspectives of nearly every facet of the HEMS industry, including large and small companies, companies that conduct visual flight rules and instrument flight rules operations, hospital programs, and those who oversee HEMS operators. The hearing called upon 41 expert witnesses representing 8 helicopter EMS operators, 12 associations, 6 manufacturers, and 4 hospitals. The witnesses participated as part of 12 panels¹² that addressed particular safety issues.¹³

By taking a comprehensive look at the HEMS industry, the hearing sought to obtain a more complete understanding of why this industry has grown rapidly in recent years and explored its increasingly competitive environment. Topics examined were flight operations procedures including flight planning, weather minimums, and preflight risk assessment, as well as safety-enhancing technology such as TAWS and NVIS. Flight recorders and associated flight operations quality assurance programs were also discussed. Training, including use of flight simulators, was discussed at length, as well as corporate and government oversight of HEMS operations.

Reimbursement Practices

According to testimony provided during the NTSB's public hearing, patient transport using helicopters has increased by 88 percent over the past 10 years.¹⁴ Factors that may be associated with this increase include a continuing reorganization of the health care system with the loss of some emergency departments and trauma centers, decreasing numbers of clinical specialists and subspecialists at community hospitals, the absence of rural ground-based critical

¹¹ For a summary of the testimony, see the NTSB website at <http://www.nts.gov/events/Hearing-HEMS/HEMS_Summary.pdf>.

¹² The 12 sessions included Current EMS Models and Reimbursement Structures; State Oversight and Competition; Patient Transport Request Process; Flight Dispatch Procedures; Safety Equipment and Flight Recorders; Flight Operations Procedures and Training; Corporate Oversight; Safety Management Systems; and FAA Oversight.

¹³ Additionally, several organizations designated as parties to the public hearing had an opportunity to question the witnesses directly. The parties, who were designated for their technical expertise in their respective fields, were the FAA; Association of Air Medical Services; Helicopter Association International; National EMS Pilots Association; Professional Helicopter Pilots Association; Air Methods (representing a relatively large operator); and CareFlite (representing a relatively small operator).

¹⁴ See exhibit 3A at <<http://www.nts.gov/Dockets/Aviation/DCA09SH001/411077.pdf>>.

care transport, and Medicare reimbursement practices for HEMS transport resulting from the establishment of a national fee schedule.¹⁵

Testimony indicated that, historically, HEMS services were provided under contract from a sponsoring hospital or a public agency such as a police department, most of which are non-profit.¹⁶ Such HEMS services were usually integrated into the local EMS transport system. Most newer HEMS services, however, are supplied by HEMS providers unaffiliated with a hospital or public transport. In these types of operations, the EMS helicopter, medical crew, pilots, and supporting infrastructure are provided by an aircraft operator. Ordinarily, a physician on the operator's staff serves as the medical director for patient transport services. Transport requests are typically initiated by physicians or 911-type services.

Testimony indicated that the recent growth of HEMS providers appears to have been primarily market driven. That is, HEMS providers have been added in geographic regions where the potential patient populations are adequate and reimbursement rates are favorable for ensuring that the HEMS provider has the level of income required to stay in business. Often no integrated local or regional plan exists to provide guidance on where HEMS providers are needed or how they should be integrated into other forms of emergency response and patient transport. Consequently, multiple HEMS providers may provide coverage in some geographic regions, while other regions may not have adequate patient populations to support any HEMS providers. The free market approach to HEMS transportation therefore encourages competition in certain geographical areas due to a higher concentration of HEMS providers.

The costs associated with establishing a HEMS service are high. These costs include, at a minimum, acquiring a helicopter and modifying it for medical transport, employing pilots to fly the helicopter, employing clinical crewmembers to take care of the patients, providing continuing training for the pilots and crew, employing mechanics to maintain the helicopter, and funding the large variety of associated support costs. These costs can easily reach into millions of dollars per year. Additional safety-related equipment and training would raise costs even more.

Most HEMS providers receive no reimbursement from health insurance companies, Medicare, or state Medicaid programs unless a patient is transported. As a result, these HEMS providers must transport patients to generate revenue.¹⁷ Medicare reimbursement practices for HEMS transport provide a flat rate along with a per-mile rate. These rates are stratified by urban and rural environments.¹⁸ Consequently, those operators that have the lowest operating costs, or that transport the most patients, stand to make the most money. Thus, the NTSB is concerned

¹⁵ See exhibit 5-G at <<http://www.nts.gov/Dockets/Aviation/DCA09SH001/409994.pdf>>.

¹⁶ Hospital-sponsored HEMS services are known as "hospital-based" or "traditional" HEMS services. HEMS services provided by governmental entities are typically called "public-use" HEMS services. HEMS services provided by stand-alone organizations with no hospital affiliation are typically called "community-based" services. Community-based services can be for-profit or not-for-profit.

¹⁷ In contrast, some public-use HEMS services do not charge for patient transport. For example, the State of Maryland's HEMS service is funded by a surcharge of \$11 for each vehicle registered in the state. Some community-based HEMS providers also offer "subscription" programs where participants pay a yearly fee and are provided free HEMS transportation if transported by that HEMS provider. This is essentially a form of supplemental HEMS transport insurance.

¹⁸ The Medicare representative at the hearing indicated that the fee schedule for HEMS provides a per-trip rate of \$3,308 (urban) and \$4,962 (rural). Mileage rates are \$21.53 (urban) and \$32.30 (rural) per mile.

that the current reimbursement strategy used by CMS serves as a disincentive for some HEMS operators to make capital investments or other improvements that would increase the level of transport safety provided and thereby reduce risk.

Testimony provided by a medical director affiliated with a large, six-hospital, urban-based HEMS program highlighted the issues associated with reimbursement practices by Medicare and other health insurance programs. This medical director manages a HEMS program that serves six medical centers in an urban center in the northeastern United States. They, as an organization, have decided to operate their HEMS aircraft in a manner that far exceeds the minimum safety requirements set by the FAA, which is responsible for aviation safety oversight and regulation. This decision has cost this HEMS program approximately \$25 million over the last 20 years above that obtained from patient transport reimbursement. The six hospitals work jointly to make up the shortfall in revenue. Similarly, another witness, who operates a HEMS program in the southern United States in an urban area, indicated that his organization also chose to operate its EMS helicopters in a manner that exceeds the minimum FAA safety requirements for additional equipment and training costs. This program's difficulty is that a local HEMS competitor chooses to operate its EMS helicopters to the absolute minimums required by the FAA, which results in considerable competitive pressure since the competitor can fly fewer patients and still generate profits since their operating costs are considerably less.

Much of the increased cost associated with operating at safety levels above that required by the FAA is associated with installing additional equipment on board the helicopter, such as autopilots or TAWS, and providing training for the pilots. For example, EMS helicopters are not required to be approved to fly in reduced visibility (often called instrument meteorological conditions or IMC). To do so requires additional equipment as well as advanced pilot training, both of which are expensive. Adding this capability to EMS helicopters reduces the risk of the most likely scenario associated with HEMS fatal crashes, encounters with reduced visibility operations at night. Numerous HEMS operators have added the equipment necessary to ensure their capability to fly in reduced visibility, as well as the requisite training, even though there is no regulatory requirement or financial incentive to do so.

Because the FAA is responsible for setting minimum standards for flight safety, the NTSB has, concurrent with this letter, issued recommendations to the FAA to improve the safety of HEMS operations, including installation of the safety equipment described above. The NTSB expects the FAA to enact changes in the safety requirements for HEMS operators in response to these recommendations. However, the NTSB is concerned that the current CMS reimbursement structure may be inadequate to cover the additional costs associated with new safety requirements.

HEMS transport is an important part of the nation's health care system, and the numerous powerful forces that influence how HEMS operators provide these services include regulatory requirements set by the FAA and reimbursement practices determined by CMS, state Medicaid systems, and private insurers. The NTSB recognizes that HEMS transport must be economically viable but also believes that the primary goal of HEMS transport must be the safe and medically appropriate transport of patients.

To that end, the NTSB believes that a CMS reimbursement structure requiring compliance with safety standards that incorporate HEMS safety recommendations issued by the NTSB since 2006 would encourage HEMS operators to increase their level of flight safety to best industry practices rather than minimum legal requirements. These standards should include compliance with 14 CFR Part 135 for all flights with medical personnel on board, scenario-based pilot training, implementation of a preflight risk evaluation program, formalized flight and dispatch procedures, and safety management systems. Additionally, these standards should call for installation of FAA-approved TAWS, NVIS, flight data recording systems for monitoring, and autopilots if a second pilot is not present. CMS should also implement effective audit methods to ensure compliance with these requirements. Therefore, the NTSB recommends that CMS evaluate its existing HEMS reimbursement rate structure to determine if reimbursement rates should differ according to the level of HEMS transport safety provided. Further, the NTSB recommends that if the findings from the evaluation conducted in response to Safety Recommendation A-09-104 reveal that higher levels of reimbursement are required to increase the level of safety, CMS establish a new reimbursement rate structure that considers the level of HEMS transport safety that is required.

This approach is not without precedent. The Department of Defense (DOD) has requirements for any commercial air carrier providing transportation services for DOD personnel.¹⁹ These requirements, developed by the DOD, exceed the minimum safety requirements specified by the FAA and include, but are not limited to, minimum equipment requirements, pilot performance standards, operating procedures, training, maintenance, flight reviews, and routine audits. The DOD conducts routine audits of approved air carrier providers to ensure they continue to meet these minimum safety standards.

Since CMS provides a significant portion of reimbursement for the HEMS industry, the NTSB believes that a safety standard established and enforced by CMS would provide a powerful incentive for HEMS operators to enhance the safety of their operations. Therefore, the NTSB recommends that CMS develop minimum safety accreditation standards for HEMS operators that augment the operating standards of 14 CFR Part 135 by including, for all flights with medical personnel on board, (a) scenario-based pilot training, (b) implementation of preflight risk evaluation programs, (c) formalized flight and dispatch procedures, (d) safety management systems, and (e) the installation of FAA-approved TAWS, NVIS, flight data recording systems for monitoring, and autopilots if a second pilot is not used. Further, the NTSB recommends that, once the accreditation standard requested in Safety Recommendation A-09-106 is developed, the CMS establish a policy that provides Medicare reimbursement for HEMS transportation only to those HEMS operators that meet those standards.

Therefore, the National Transportation Safety Board recommends that the Centers for Medicare & Medicaid:

Evaluate your existing helicopter emergency medical services (HEMS) reimbursement rate structure to determine if reimbursement rates should differ according to the level of HEMS transport safety provided. (A-09-104)

¹⁹ *DOD Commercial Air Transportation Quality and Safety Review Program*, DoDI 4500.53, October 20, 2008, <<http://www.dtic.mil/whs/directives/corres/pdf/450053p.pdf>>.

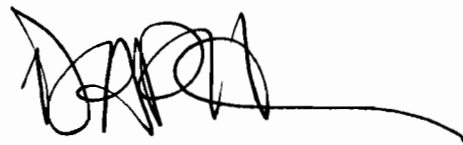
If the findings from the evaluation conducted in response to Safety Recommendation A-09-104 reveal that higher levels of reimbursement are required to increase the level of safety, establish a new reimbursement rate structure that considers the level of helicopter emergency medical services transport safety that is required. (A-09-105)

Develop minimum safety accreditation standards for helicopter emergency medical services (HEMS) operators that augment the operating standards of 14 *Code of Federal Regulations* Part 135 by including, for all flights with medical personnel on board, (a) scenario-based pilot training, (b) implementation of preflight risk evaluation programs, (c) formalized flight and dispatch procedures, (d) safety management systems, and (e) the installation of Federal Aviation Administration-approved terrain awareness warning systems, night vision imaging systems, flight data recording systems for monitoring, and autopilots if a second pilot is not used. (A-09-106)

Once the accreditation standard requested in Safety Recommendation A-09-106 is developed, establish a policy that provides Medicare reimbursement for helicopter emergency medical services (HEMS) transportation only to those HEMS operators that meet those standards. (A-09-107)

In response to the recommendations in this letter, please refer to Safety Recommendations A-09-104 through -107. If you would like to submit your response electronically rather than in hard copy, you may send it to the following e-mail address: correspondence@ntsb.gov. If your response includes attachments that exceed 5 megabytes, please e-mail us asking for instructions on how to use our secure mailbox. To avoid confusion, please use only one method of submission (that is, do not submit both an electronic copy and a hard copy of the same response letter).

Chairman HERSMAN, Vice Chairman HART, and Member SUMWALT concurred in these recommendations.

A handwritten signature in black ink, appearing to read 'D. Hersman', with a long horizontal line extending to the right.

By: Deborah A.P. Hersman
Chairman