

# SYSTEMIC ILLS



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A risk profile points to latent structural issues behind the HEMS industry's safety problems.

Helicopter emergency medical services (HEMS) in the United States are plagued by a range of systemic risks — many of them embedded in the industry’s structure or oversight framework — that have led to divergent standards and interruptions in the level of health care and operational safety they provide, according to a report released by Flight Safety Foundation.

Risks associated with the absence of a well-defined national EMS structure are among the most serious of 26 specific risks identified in the *Industry Risk Profile (IRP)*, developed by Aerosafe Risk Management, which has developed similar profiles for many segments of the aviation industry. The report is available on the Internet at <[www.flightsafety.org/pdf/HEMS\\_Industry\\_Risk\\_Profile.pdf](http://www.flightsafety.org/pdf/HEMS_Industry_Risk_Profile.pdf)>.

“The current regime was not purposefully designed and has evolved over the past 20 years ... in the absence of a framework,” said the *IRP*.

The *IRP* blamed the lack of a defined structure for the development of standards that differ from state to state, as well as an increased likelihood of conflicting practices in HEMS operations nationwide.

This specific risk is associated with 17 other effects on the HEMS industry, including industry confusion about accepted practices, “no publicly visible accountability structure for the industry,” varying standards for professionals employed in the field and “lack of confidence by the stakeholders that effective health care can be effectively delivered,” the *IRP* said.

The document identified 26 sets of actions for responding to each of the 26 identified risks. Recommended responses to risks stemming from the absence of a defined structure included

convening a task force representing industry and regulatory groups to “collaboratively review the national EMS definition, framework and arrangements for their suitability and effectiveness.” After that work has been reviewed and accepted, plans should be adopted for redesigning the EMS framework “to cater for the national, state and local needs of the health care community,” the *IRP* said.

Other related recommendations were to “confirm the political position upon whether access to air medical transportation is considered an essential service” and to appoint an appropriate agency to be accountable for implementation of efforts to improve the national EMS framework. That framework should include performance-based requirements for states to use in designing and implementing a statewide EMS system consistent with a state framework, the *IRP* said. Before the national EMS framework is implemented, another recommendation calls for development of options to resolve “the question of federal versus state oversight of the medical component of HEMS operations,” the *IRP* said.

### Most Deadly Year

Issuance of the *IRP* followed an increase in HEMS accidents in recent years, concluding with 13 crashes in 2008, the most deadly year in HEMS history. These 13 crashes killed 29 people, according to data from the U.S. National Transportation Safety Board (NTSB), which conducted a four-day hearing earlier this year to identify possible safety improvements.

Two years earlier, the NTSB had issued a report analyzing 55 EMS accidents — including 41 HEMS accidents, of which 16 were fatal, and 15 airplane EMS accidents, of which five were fatal<sup>1</sup>

— and concluding that many of them could have been prevented with what the *IRP* characterized as “simple corrective actions, including oversight, flight risk evaluations, improved dispatch procedures and the incorporation of available technologies.”

The safety recommendations that accompanied the 2006 NTSB report have been discussed in various forums, including meetings of HEMS industry leaders, and some have been the subject of voluntary compliance measures by the U.S. Federal Aviation Administration (FAA) and legislation pending before Congress (see “FAA Plans HEMS Rule-Making Effort,” p. 14).

“Risk management takes place at multiple levels,” the *IRP* said.

Kimberley Turner, CEO of Aerosafe Risk Management, added, “When we started this job, we knew that industry had already been working to address the risks it faces at the operational and organizational levels. The *IRP* highlights ... key systemic risks, many of which are at the structural and oversight levels of the industry. The broader context of the *IRP* digs deep and provides a common rallying point for all of the HEMS industry to move forward.”

The *IRP*’s stated purpose is to identify “latent and systemic issues” that had not been addressed in other forums.

“It was realized that a ‘different’ approach was needed and there was great value in an industrywide risk assessment that would provide a platform for the coordination of nationwide initiatives to aggressively reduce the risk profile and the associated negative trend in safety,” the *IRP* said.

The *IRP* timeline calls for copies of the document to be distributed throughout the HEMS industry to enable HEMS stakeholders to develop

## FAA Plans HEMS Rule-Making Effort

The U.S. Federal Aviation Administration (FAA) plans to propose new rules, perhaps by late 2009, to impose stricter safety standards on the helicopter emergency medical services (HEMS) industry.

In a joint statement, Christa Fornarotto, acting assistant transportation secretary for aviation and international affairs, and John M. Allen, director of the FAA Flight Standards Service, told a congressional subcommittee that the agency has begun a formal rule-making project to “address many of the HEMS initiatives and best practices that have been put forth in the advisory circulars, orders and notices issued over the last several years, as well as the most recent revisions to the OPSPEC [operations specification for HEMS operations].” Plans call for the notice of proposed rule making to be published in late 2009 or early 2010.

Fornarotto and Allen told a hearing of the aviation subcommittee of the House Committee on Transportation and Infrastructure that the OPSPEC initiatives have included raising ceiling and visibility requirements for HEMS operations, requiring specific flight planning for visual flight rules (VFR) operations and providing for increased instrument flight rules (IFR) operations by allowing the use of weather-reporting sources located as far as 15 nm (28 km) from the landing location. All HEMS operators now operate according to the OPSPEC, they said.

Other FAA recommendations call for establishing operational control/dispatch systems for all operators and creating operational risk assessment programs. In addition, the FAA appointed a committee to develop standards for the use of helicopter terrain awareness and warning systems (HTAWS), and has urged creation of a stronger safety culture in the industry.

An FAA survey found that more than 80 percent of HEMS operators have adopted training programs and operational control center practices recommended by the FAA, nearly 90 percent have installed radio altimeters in their helicopters, and more than 40 percent have installed HTAWS in at least some of their aircraft, Fornarotto and Allen said. The percentage of operators using HTAWS is expected to increase with publication of an HTAWS technical standard order, they said.

“We recognize that relying on voluntary compliance alone is not enough to ensure safe flight operations,” they said, noting that the rule-making



process will mandate many of the practices that now are voluntary.

They discouraged passage of two legislative proposals dealing with safety provisions and state regulatory issues.

One bill would write into law requirements for several of the voluntary compliance measures, including conducting flights under the commuter and on-demand standards of U.S. Federal Aviation Regulations Part 135, developing consistent flight-dispatch procedures and a risk evaluation program, and requiring flight data recorders and cockpit voice recorders in EMS aircraft.

The other measure would expand the states’ authority to regulate medical aspects of HEMS operations such as the medical training of the aircraft crew and the medical equipment to

be carried in the aircraft. Supporters say it clarifies the authority of states to oversee EMS operations just as they currently oversee ground ambulances.

“The FAA does not believe that new safety legislation is needed at this time,” Fornarotto and Allen said, citing “current regulations that govern emergency medical services flights, the voluntary safety measures already being implemented by the industry, as well as the rule-making efforts underway.”

They were especially critical of the legislative effort to give the states more authority to regulate medical aspects of EMS operations.

“We are concerned that 50 separate state regimes addressing the economic regulation of air ambulances could unnecessarily complicate the industry and hinder interstate operations,” they said. “We also believe that state regulation of the economic issues could serve to limit market entry and could ultimately have a negative effect on available services.”

Robert L. Sumwalt III, a member of the U.S. National Transportation Safety Board (NTSB), praised the FAA’s plans for formal rule making, adding that, in the past, the FAA “has not taken sufficient action on [NTSB] recommendations” to overhaul HEMS operations.

Sumwalt cited the “lack of timely and appropriate action” on four recent NTSB safety recommendations that asked the FAA to require EMS operators to comply with Part 135 operations specifications — specifically for weather minimums and pilot flight and duty time limits — during flights with medical personnel in the aircraft, to implement flight risk evaluation programs, to adopt formalized dispatch and flight-following procedures and to install HTAWS in their aircraft.

The NTSB is drafting additional recommendations involving HEMS oversight, equipment and training, he said.

Rep. James L. Oberstar, the Minnesota Democrat who chairs the Transportation and Infrastructure Committee, said that the FAA's voluntary guidance to HEMS operators and the stricter requirements for weather and visibility operating requirements are "steps in the right direction" but that additional action is required.

"While some progress has been made by the FAA regarding HEMS safety issues, FAA must commit to long-term action to ensure that patients and flight

medical crew aboard HEMS flights reach their destinations safely," Oberstar said.

Matthew Zuccaro, president of the Helicopter Association International, whose members include 93 U.S. air medical service operators, told the subcommittee that the FAA's rule-making process is "unacceptable in terms of the length of time it takes to effect a rule change." Congress should direct the FAA to revise those procedures to "expedite implementation of beneficial safety initiatives, when appropriate," he said.

Sandy Kinkade, president of the Association of Air Medical Services, encouraged allocation of more federal funds and research for expanding the low-altitude aviation infrastructure, including "private-use hospital helipads, regional airports and other routinely utilized locations"; expanding low-altitude, off-airport weather reporting; and expanding "FAA ... capabilities surrounding the certification and approval of NVGs [night vision goggles] or similar enhanced-vision systems."

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a response by July 15. One authorized representative from each stakeholder group will be invited to a risk reduction planning conference in August, when strategies will be approved and combined into an overall risk reduction action plan to be presented to the industry.

After that, designated representatives will provide status reports every six months on progress in implementing risk reduction plans, and at some yet-to-be-determined point, the plans will be updated.

"As the context of the industry changes, appropriate triggers for a full update or overhaul of the HEMS *IRP* will be determined," the *IRP* said. "These triggers may include significant progress in completion of the risk reduction measures, emergence of significant new risks ... or the accident profile of the industry is not visibly decreased.

"The industry [is] to continue on the six-monthly cycles for the formal management of risk until an acceptable risk profile is achieved."

### 'Very High' Risks

Of the 26 distinct risks identified in the report, eight were classified as "very high" — including three that were placed at the uppermost level in that category — and the remaining 18 were classified as "high."

Those at the uppermost level, in addition to the risks associated with the absence of a well-defined national EMS structure, were:

- "The risk that the current medical reimbursement model (primary payer model) is no longer adequate to provide the appropriate level of financial coverage for either the current operating costs of the service or the impending upgrade of capability required through the addition of technology"; and,
- "The risks associated with the complexity, non-alignment and lack of clarity around the roles and scope of federal, state and county agencies involved in oversight of the HEMS industry."

### Medical Reimbursement

The *IRP* identified 13 effects on the HEMS industry of the medical reimbursement risk, including inconsistencies from one state to another in the primary payer model and pricing pressure on HEMS operators. Pricing pressures may mean that some safety-related training practices, including simulator training, will be considered expendable luxuries.

In addition, reimbursement from Medicare,<sup>2</sup> without additional commercial insurance reimbursements, "will not allow HEMS transport programs to meet operational expenses and maintain financial viability," the report said. Also among the risks are that more advanced helicopters with safer equipment — such as twin-engine aircraft equipped for instrument flight rules (IFR) flight, helicopter terrain awareness





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## Complexities of Oversight

The *IRP* said that the complexities surrounding the roles of agencies involved in HEMS oversight can lead to inconsistency with criteria and protocols that determine how HEMS assets will be used and to challenges for the industry in identifying requirements.

Other effects of the risk on the industry include the fact that

and warning systems (HTAWS), and night vision goggles (NVGs) — and better-trained flight crews may not be affordable.

The formula for Medicare reimbursement “fosters the proliferation of new programs that operate in rural areas and that incur the lowest operational overhead,” the *IRP* said. “The higher reimbursement from Medicare for transports from rural areas, which pays only for ‘loaded miles,’ inadvertently penalizes transport programs operating in urban and suburban areas.” (“Loaded miles” refer to the distance flown when a patient is aboard the helicopter.)

The suggested three-part risk treatment strategy calls for the development of a plan to evaluate and, if necessary, to re-develop, the medical reimbursement model to ensure that related risks have been minimized; the implementation of a medical reimbursement or revenue model to cover operating costs as well as investment in “future capability improvements”; and the recognition that competition among HEMS operators should occur on a regional or state level rather than on a “task-by-task basis” in which those in need of HEMS service call several competing operators — a situation that sometimes results in one operator accepting a flight after others have declined because of instrument meteorological conditions (IMC) weather or other factors.

“no single regulatory body has responsibility for [overseeing] the EMS system as a whole,” that “conflicting regulatory priorities may place operators in a position where they make decisions that are not optimal for either the aviation or medical areas” of the industry and that regulators may make independent decisions in one of those areas that would be less than optimal in the other area, the *IRP* said.

The eight points in the risk treatment strategy include analyzing all U.S. bodies that have “some level of accountability or responsibility” for HEMS regulation and producing a centralized stakeholder database; establishing a group to develop an integrated oversight model; and developing options to clarify areas that are within both federal and state oversight.

## Operating Environment

Among the other risks, the *IRP* said, is that the operating environment, infrastructure and standard industry practices for both inter-facility flights and “scene flights” (conducted to and from accident sites and other off-airport and off-helipad locations) is “not sufficiently designed at the HEMS system level, leading to the increased variance and application of flight profiles, safety standards and safety risk exposure to patient, aircraft ... and the public.”

**“Conflicting regulatory priorities may place operators in a position where they make decisions that are not optimal for either the aviation or medical areas.”**

Resulting issues for inter-facility transfer flights involve flights that are conducted under visual flight rules (VFR) when IFR operations might be possible, increased potential for controlled flight into terrain or loss of control because of inadvertent encounters with IMC and potential for traffic conflicts near busy hospital helipads.

Issues for scene flights involve the heavy reliance on VFR procedures, even when weather conditions are marginal. As a result, flights often are conducted at low altitudes, with less margin for error; night flights may involve reduced visibility and increased risks for VFR operations; and flights may include inadvertent entry into IMC.

The risk treatment strategy called for implementing task briefing and debriefing processes industrywide, implementing a low-altitude IFR route structure as part of the National Airspace System and adopting “necessary infrastructure to allow the IFR inter-facility flights to be conducted in a more controlled ‘standard flight profile’ similar to that of a routine aviation operation that flies from known point to known point.”

In addition, the strategy recommended that HEMS aircraft be equipped to enable pilots to safely return to visual flight conditions in case of an inadvertent IMC encounter, and that they be equipped with technology such as NVGs, HTAWS and ADS-B (automatic dependent surveillance–broadcast) to assist pilots during VFR flights at low altitudes.

### Blurred Responsibilities

The *IRP* also challenged the blurred lines of responsibility that have arisen between flight personnel and medical personnel, especially

with the increased involvement of medical crewmembers in NVG operations, passenger briefings, aircraft loading and unloading, and operational risk management.

This results in confusion “for both pilots and medical crew about specific roles in promoting aviation safety and how to apply and use the education they have each received in air medical resource management,” the document said.

The recommended risk treatment strategy called for “regulatory clarification of the status of on-board medical personnel,” followed by action to ensure that the requirements are enforced. ➤

### Note

1. NTSB. *Special Investigation Report: Emergency Medical Services (EMS) Operations*, SIR-06/01. Jan. 25, 2006.
2. Medicare is U.S. government health insurance for people age 65 or older, and for younger people with specific disabilities.

### Further Reading From FSF Publications

Werfelman, Linda. “Closing the Loop.” *AeroSafety World* Volume 4 (March 2009): 14–18.

Werfelman, Linda. “Critical Care.” *AeroSafety World* Volume 3 (September 2008): 12–17.



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