On-Call Requirements: Medicare Move Advised

BY NELLIE BRISTOL
Contributing Writer

BALTIMORE — Hospital emergency department on-call roster requirements should be moved from Emergency Medical Treatment and Labor Act regulations to those relating to Medicare provider agreements, a federal advisory group has recommended.

Such a move away from the regulations would ensure that plaintiffs in lawsuits could not use the requirements to file a private right of action, the recommendation's supporters said at a meeting of the Department of Health and Human Services technical advisory group on the Emergency Medical Treatment and Labor Act (EMTALA).

If on-call roster requirements remain regulated under EMTALA, "a plaintiff's lawyer could argue that the hospital has violated EMTALA—and then would have a private right of action if the plaintiff's lawyers or the plaintiff does not like the makeup of a hospital's on-call list," said Julie Mathis Nelson, J.D., of the law firm Coopersmith Gordon Schermer Owens & Nelson in Phoenix, Ariz.

The technical advisory group makes recommendations to the Department of Health and Human Services and the administrator of the Centers for Medicare and Medicaid Services on issues related to EMTALA.

Panel member Charlotte Yeh, M.D., an emergency physician and a regional administrator with the CMS, said she was concerned that moving the requirements could eliminate patients' ability to seek compensation if injured.

But panel member Brian Robinson responded that patients could still use EMTALA to seek redress. "They could argue that they were not appropriately medically screened or not appropriately stabilized, so they still have opportunities that they can argue," pointed out Robinson, president and CEO of HCA Las Vegas Market.

Gregory Demske, of the HHS Office of Inspector General, said the recommendation reflects the way the office approaches on-call roster violations now. "This change is consistent with the way we interpret the statute," he said.

EMTALA regulations declare that as a requirement for participation in the Medicare program, "hospitals must maintain a list of physicians who are on call for duty after the initial examination to provide treatment necessary to stabilize an individual with an emergency medical condition," according to CMS documents. Physician failure to respond when called could result in EMTALA violation.

CMS state operations manuals specify that each hospital has the discretion to maintain the on-call list "in a manner that best meets the needs of its patients."

The EMTALA advisory panel is exploring possible recommendations on a number of other on-call issues. Among those under consideration: whether required physician response time to a call should be stated as a specific time or a range of minutes. The panel will also review options that fall beyond the regulatory realm of EMTALA yet could ease on-call challenges.

In testimony before the EMTALA Technical Advisory Group, the American Hospital Association said many hospitals are having difficulty maintaining full-time on-call coverage.

"From the physician's perspective, they are assuming all of the liability and bearing the costs of providing services," testified Kathleen DeVine, CEO of Saint Anthony Hospital in Chicago.

Hospital groups said the increase of physician-owned specialty hospitals has exacerbated the on-call shortage by pulling specialists away from community hospitals. Specialty hospital representatives countered that their physician members often provide on-call services to hospitals in their area, including many community hospitals. ■

EMTALA Should be Applied to Specialty Hospitals, Panel Says

BY NELLIE BRISTOL
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BALTIMORE — Hospitals with specialized capabilities should be subject to the requirements of the Emergency Medical Treatment and Labor Act even if they don't have an emergency department, a federal advisory panel on the EMTALA has recommended.

The EMTALA technical advisory group recommended that the Centers for Medicare and Medicaid Services require specialty hospitals to stabilize emergency patients and accept transfers in their specialties from other hospitals.

"We were speaking to all hospitals with specialized capabilities," technical advisory group Chair David M. Siegel, M.D., J.D., said in an interview. Dr. Siegel is an emergency physician who serves as a consultant and clinical coordinator for Florida's Quality Improvement Organization.

'Specialty hospitals should not be allowed to refuse to accept transfers on the basis that they' cannot treat them because they are closed.

In a second recommendation, the EMTALA panel voted not to require hospitals with specialized capabilities to have emergency departments.

Although not specified in the recommendation, the EMTALA requirements would apply even if specialty hospitals operate only during limited hours, Dr. Siegel said. That condition was suggested by general hospital groups.

"Many specialty hospitals have limited hours of operation, due in large part to their focus on outpatient services," Federation of American Hospitals' Vice President and General Counsel Jeffrey Micklos told the panel. "In the best interests of serving patients, we believe that specialty hospitals should not be allowed to refuse to accept transfers on the basis that they lack capacity to treat the individuals simply because they are closed."

While not addressing the issue of operating hours specifically, ASHA argued that there is no need to adopt any measures applying only to specialty hospitals.

"ASHA firmly believes that our members are subject to the requirements of EMTALA, as they apply to all acute care hospitals," said ASHA representative Greg Miner. "There is no reason to write new requirements directed at specialty hospitals that merely duplicate the obligation we already have under this law." Miner is the executive director of Siouxland Surgery Center in Dakota Dunes, S.D.

Both recommendations made by the advisory group were in response to questions posed by the Centers for Medicare and Medicaid Services.

The agency also asked whether specialty hospitals, "irrespective of whether they have emergency departments," are subject to the EMTALA requirement that Medicare-participating hospitals "may not refuse to accept an appropriate transfer of an individual who requires such specialized capabilities or facilities if the hospital has the capacity to treat the individual."

The recommendations were acceptable to both ASHA and general hospital representatives.

"It is clear that specialty hospitals are not shouldering their burden to provide critical community health care services, such as emergent care or caring for those least able to pay, but instead are exacerbating an existing problem," the FAH's Micklos told the panel. "However, the federation does not believe that the best way to address this deficiency is through a federal requirement that specialty hospitals maintain an emergency department."

Both the FAH and the American Hospital Association testified that the hospitals should be required to accept appropriate transfers, however.

Ethical Conflicts Surface Around FDA's Black-Box Label Rulings

BY JOYCE FRIEDEN
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MONTREAL — When members of the Food and Drug Administration's advisory panels make recommendations about placing "black box" labels on selective serotonin reuptake inhibitors, many factors influence their decision making, Philip J. Candilis, M.D., said at the annual meeting of the American Academy of Psychiatry and the Law.

First is the obvious issue of direct pharmaceutical industry influence on the panels, as seen in the cases of Bextra, Vioxx, and Celebrex, Dr. Candilis said. "Early on in the debate on anti-inflammatories, the panels had endorsed their continued use," he said. "But look at the experts who declared ties to the pharmaceutical industry." Of the 32 experts on the panel, 10 had declared some ties to the pharmaceutical industry. Each panelist had to vote "yes" or "no" to recommending each of the three medications.

"Those [10] who had consulted to the pharmaceutical industry voted 28 of their total of 30 votes in favor of these medications. Those without such conflicts cast 37 of their 66 votes in favor," he said. "So there was a substantial and statistically significant difference in how people were supported and how they voted."

But broader influences are at play as well. For instance, the FDA regulates one-quarter of the gross national product, which comes to "hundreds of billions of dollars," said Dr. Candilis, of the law and psychiatry program at the University of Massachusetts, Worcester. And to do part of that job, the agency receives millions in fees from the pharmaceutical industry, he said.

"So there's already a dependence there: 40%-50% of the [FDA's] budget comes from fees that industry pays in order for the FDA to govern the medications that they submit."

The agency also exerts pressure on its own employees, he continued. He noted that one physician testified before Congress that he'd been asked by FDA officials to alter his affidavit concerning the increased risk of suicide in children and youth taking antidepressants.

Slowly, people are becoming more aware of these conflicts and taking action to mitigate them, Dr. Candilis said. For example, Congress is now insisting that pharmaceutical companies register the results of all clinical trials, including negative results. And some professional organizations are precluding experts from peer review entirely if they have conflicts of interest.

The take-home message is this: "If we don't regulate it, Congress will, others will, people with an agenda will," he said. "We have to start doing full public disclosure of [conflicts of] interest, a transparency model, more explicit policies, less management and more recusal. We must step away from just saying, 'I'm going to tell you what I own.' " ■