Law Raises Agency Accountability

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the content of direct-to-consumer advertising; to track recalls of medical devices; and to weed out conflict-of-interest among outside advisory committees.

User fees make up about 25% of the FDA's annual budget.

"The Act may actually improve the devices that come to market," said Dr. Sigsbee. "Currently, there is a great deal of pressure from the manufacturers to get devices to market. The very survival of the company may depend on rapid approval. [This situation] sometimes lead[s] to presentations that are not complete." Regarding neurological devices, he pointed out EEG and EMG machines are crucial for some diagnoses, and depending on the practice, ultrasound machines and more sophisticated imaging equipment are also important.

"This Act gives the FDA further resources which will likely improve the oversight and, to some extent, counter the well-funded efforts by pharmaceutical and device manufacturers" to bring devices to market before they are fully ready, added Dr. Sigsbee.

The law would give the FDA almost $400 million in fiscal 2008 and in each of the next 4 years for review of medical devices and drugs, and at least $50 million for enhanced safety monitoring, according to Sen. Edward Kennedy (D-Mass.), who worked to craft a compromise with the House-passed legislation.

The agency has an "urgent need for these funds," said Sen. Kennedy in a statement. "Since 1990, the number of adverse events submitted to the FDA has increased by over 1,300%, but the agency's resources have increased only 130%."

Congress expanded the agency's authority to require drug and device makers to disclose clinical trial data to the public. The aim is for consumers to be able to search a clinical trials registry for basic information on the trial's purpose, where it's being conducted, and its outcomes goals, but also—if it is an FDA-approved product—on whether it succeeded or failed, and whether the intervention has been the subject of FDA safety inquiries or warnings, or any other public health advisories. The law also gives FDA the power to levy civil fines on manufacturers if they do not submit the data according to established deadlines.

The agency, working with the National Institutes of Health, will phase in the system, said Dr. Janet Woodcock, FDA Deputy Commissioner and Chief Medical Officer, in a briefing with reporters.

Some in Congress also had hoped to require a risk evaluation and mitigation strategy to be implemented for most newly approved drugs. Currently, only a handful of drugs are subject to these strictures, most notably isotretinoin and thalidomide.

The FDA will have leeway to decide when such programs are needed and what form they will take. Noncomplying companies can be fined up to $1 million. The agency will also have more power to order postmarketing clinical trials.

It is not clear yet whether FDA will have to issue rules to implement these new powers, FDA Deputy Commissioner for Policy Randall Lutter told reporters.

Congress renewed and expanded incentives for drug makers to study their products in children through the reauthorization of both the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act. Under the latter, the FDA can require companies to submit data on pediatric populations when they seek approval for a new dose, new route of administration, new active ingredient, or new indication. The FDA will form an internal committee to review and track these "pediatric assessments."

Under reauthorization of the Best Pharmaceuticals for Children Act, drugs that are studied in pediatric populations will continue to be granted 6 months of additional patent life, rather than the 3 months that had been sought by some legislators.

On the device side, in addition to user fees for product reviews, the law also directs Congress to appropriate $7-$8 million annually for collecting, developing, reviewing, and evaluating postmarket safety information.

The FDA also must issue rules to require each medical device to carry a unique identifier. The FDA sought comments on such a system in August 2006, but had not yet issued a rule. At the time, the American College of Cardiology said identifiers could help track adverse events. The medical device trade group AdvaMed said that use of identifiers should be voluntary, since there is no solid evidence that they will actually contribute to patient safety.

Congress also included incentives for medical device makers to test their products in children through the Pediatric Medical Device Safety and Improvement Act, which is modeled after the two pediatric drug programs.

For the first time, the FDA will collect fees from drug or device makers who voluntarily submit direct-to-consumer television ads for prebroadcast review.

Finally, the new law seeks to prevent outside advisory committee members with conflicts of interest from participating in deliberations on drugs or devices. The FDA commissioner will have the power to grant waiver in a variety of situations. ■

Advisory Group Says EMTALA Should Apply to Inpatient Transfers

BY ALICIA AULT
Associate Editor, Practice Trends

WASHINGTON — A receiving hospital with specialized capabilities, like a stroke center, has the responsibility to accept an unstable inpatient from a transferring hospital, but only if the patient had not been stabilized for the original condition requiring admittance, according to a recommendation by the Emergency Medical Treatment and Labor Act Technical Advisory Group.

The EMTALA Technical Advisory Group has met regularly over the last 30 months to advise the Secretary of the Department of Health and Human Services on improving the statute.

Dr. Ralph Sacco, professor and chairman of the department of neurology at the University of Miami, commented on the recommendations. "It does make sense that acute neurological issues are treated in hospitals that are prepared to deal with acute neurological issues." However, he added "one way we try to avert [a transfer] from ever happening is by designating stroke centers in advance and by designating [emergency medical service workers] to only take stroke patients there in the first place."

Dr. Sacco was not a member of the advisory group.

If the Centers for Medicare and Medicaid Services—which is charged with writing the rules for and enforcing EMTALA—follows the recommendation, it's likely the EMTALA interpretive guidelines would be altered, or a new regulation would be issued, said panel chairman Dr. David Siegel, an emergency physician and senior vice president at Meridian Health, in Neptune, N.J.

The recommended change came after heated debate over whether EMTALA should apply to any inpatient transfers to hospitals with specialized services, such as a stroke center or a catheterization lab. The four CMS officials on the panel all voted for the recommendation.

But other panelists had reservations. The change would "open up a whole new universe of potential issues," said advisory group member Dr. John A. Kusske, chairman of the department of neurologic surgeons at University of California, Irvine, Medical Center. Dr. Kusske was concerned that if EMTALA was applied to these transfers, it might make it harder to find specialists to take on-call duty.

Dr. Sacco added, "We hope people don't abuse the system, by saying, 'this patient is unstable, let's invoke this urgent rule and move them somewhere else.'"

Dr. Sacco previoulsy served as director of the Stroke and Critical Care Division at Columbia University, New York.

"The other thing that's happening that could improve the ability to stabilize cases elsewhere is telemedicine," he added.

Dr. Charlotte S. Yeh, a panelist from the CMS, said the agency has lacked clarity on whether EMTALA applies to these circumstances, and thus has not actively enforced any complaints.

The clarification will help CMS shape its enforcement policy, said Dr. Yeh, who also is an emergency physician.

The advisory group also made a number of recommendations aimed at strengthening hospitals' ability to find and retain on-call physicians.

And it unanimously supported the recommendation that liability protection be provided to hospitals and physicians who provide EMTALA care.

The full accounting of the technical advisory group's final recommendations will be included in its final report to the HHS secretary, which should be published in the fall, Dr. Siegel said.

"Unfortunately, there are issues beyond the statute, such as reimbursement and liability, that must be addressed to ultimately solve the problem." ■

Hospitalists Reduce Length of Stay in Stroke and Pneumonia

BY TIMOTHY F. KIRN
Sacramento Bureau

Hospitalists discharge patients an average of almost 1 day earlier than do nonhospitalist physicians. The difference is greater for patients with conditions like stroke that require close monitoring, according to a study.

The likelihood of readmission or mortality is not greater in those discharged earlier, reported Dr. William Southern and colleagues at Montefiore Medical Center, Albert Einstein College of Medicine, New York.

Dr. Southern's study looked at data from all 9,037 patients seen at the center's teaching hospital, Weiler Hospital, from 2002 to 2004. The study compared the lengths of stay and outcomes of patients cared for by a hospitalist faculty-member team versus patients cared for by faculty who were not hospitalists and who spent no more than 2 months per year on inpatient service (Arch. Intern. Med. 2007;167:1869-74).

Their analysis showed patients seen by hospitalists stayed an average of 5.0 days, versus 5.9 days for those seen by nonhospitalists.

The biggest reductions in stay for the hospitalists were stroke patients (a mean of 8.6 days vs. 12.5 days), sepsis (8.6 days vs. 12.3 days), pneumonia (6.9 days vs. 8.4 days), heart failure (4.6 days vs. 5.8 days), and asthma/chronic obstructive pulmonary disease (3.5 days vs. 4.5 days).

Dr. Southern said these patients could likely benefit most from close monitoring.

Only arrhythmia patients had a longer stay in the care of a hospitalist (4.3 days vs. 4.0 days).

The complexity of discharge planning also appeared to be a factor, Dr. Southern said.

The study indicated that for patients going home, hospitalist care reduced the mean length of hospital stay by less than half a day. For those going to home health care, the reduction was about a day, and for those going to a skilled nursing facility, it was about 2 days.

These reductions can probably be attributed to hospitalist physicians having greater familiarity in working with ancillary staff, such as social workers or discharge planners, Dr. Southern said.

One shortcoming of the study was that only 5 hospitalist groups were included, versus 54 nonhospitalist groups. It would be easier for an outlier among the hospitalist groups to influence mean length of stay.

And although the study found no significant differences in 30-day mortality and in-hospital mortality, it was not large enough to detect small possible differences, he said. ■