

FDA Streamlines Terms for Drug Application Responses

BY MIRIAM E. TUCKER
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The Food and Drug Administration will no longer issue “approvable” or “not approvable” letters when a drug application is not approved, but will instead issue a “complete response” letter at the end of the review period, the agency has announced.

The change, effective on Aug. 11 for all drug applications, applies regardless of when the applications were submitted.

“These new regulations will help the FDA adopt a more consistent and neutral way of conveying information to a company when we cannot approve a drug application in its present form,” Dr. Janet Woodcock, director of the agency’s Center for Drug Evaluation and Research, said in a written statement.

Currently, when assessing new drug and generic drug applications, the FDA can respond to a sponsor in one of three types of letters: (1) an “approval” letter, meaning the drug has met agency standards for safety and efficacy and can be marketed for sale in the United States; (2) an “approvable” letter, which generally indicates that the drug can probably be approved at a later date provided that the applicant provides certain additional information or makes specified changes (such as to the labeling); or (3) a “not approvable” letter, meaning the application has

deficiencies generally requiring the submission of substantial additional data before approval.

A “complete response” letter, which will replace options 2 and 3, will be issued to inform the company that the review period for a drug is complete and that the application is not yet ready for approval, the statement said.

The move brings the drug licensing application process in line with that of biologics, for which ‘complete response’ letters have been used since 1998.

The letter will describe specific deficiencies and, when possible, will outline recommended actions the applicant might take to prepare the application for approval.

The way in which the FDA communicates its decisions to approve an application—option 1—will not change.

The move brings the process for communication about drug licensing applications in line with that of biologics, for which “complete response” letters have been used since 1998. The revision should not affect the overall time it takes the FDA to review new or generic drug applications or biologic license applications, the agency said.

Other changes included in the new FDA rule involve modifications to the schedule for reviewing amendments to licensing applications, classification of responses to a complete response letter, (i.e., resubmissions), timelines for submitting a response to a complete response letter and administrative actions for a failure to respond, and definition of an efficacy supplement. ■

Congress Passes Doctor Pay Increase, Medicare Reform

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Washington’s summertime wrangling paid off for physicians as Congress successfully overrode President Bush’s veto of legislation to stop a 10.6% cut to Medicare physician payments.

The legislation (H.R. 6331), which passed the House and Senate by veto-proof margins in July, extends the 0.5% Medicare pay increase in place for the first half of 2008 through the end of the year and gives physicians a 1.1% raise for next year.

H.R. 6331 also encourages physicians to use electronic prescribing by providing incentives to those who e-prescribe and imposing penalties on those who do not.

The bill, which also authorizes increased bonus payments under the Physician Quality Reporting Initiative and delays implementation of the Competitive Acquisition Program for durable medical equipment until 2009, relies on controversial cuts to the Medicare Advantage

program to fund the pay update. Officials at America’s Health Insurance Plans, which represents the health insurance industry, estimated that the bill will cut nearly \$14 billion from the Medicare Advantage plans over the next 5 years.

The American Academy of Family Physicians praised the passage of the legislation and called on Congress to end the yearly cycle of 11th-hour congressional negotiations over physician payments.

“Congress must make good use of the time afforded them by H.R. 6331,” Dr. James King, AAFP president, said in a statement. “They must pass Medicare reform that discards the destabilizing and flawed sustainable growth formula and in its place implements the Medicare Economic Index as the basis for physician payment calculations.”

The Sustainable Growth Rate formula links physician payments to the gross domestic product and critics say it does not take into account the actual costs of medical practice. ■

POLICY & PRACTICE

Newborn Hearing Screening Urged

All newborn infants should be screened for congenital hearing loss that is present at birth, the U.S. Preventive Services Task Force has recommended. The task force gave screening a B recommendation, meaning that, “there is moderate certainty that the net benefit is moderate to substantial.” Congenital hearing loss occurs in approximately 1-3 infants/1,000; infants at high risk include those who have spent more than 2 days in a neonatal ICU, those diagnosed with certain syndromes, and those with a family history of childhood hearing loss, according to the task force. However, half of infants with hearing loss have no identifiable risk factors. Children whose hearing is impaired at birth, during infancy, or in early childhood can have problems with verbal and nonverbal communication and social skills, increased behavioral problems, and lower academic achievement, compared with children who have normal hearing, according to the task force. “Screening at birth allows for hearing loss to be detected early and is associated with better outcomes for infants who test positive,” said Dr. Ned Calonge, task force chairman.

Some Tween Web Use Risky

More than one in five “tweens” (children aged 8-12 years) post personal information online, including pictures, their hometown, and their age, according to a survey on Internet safety by cable company Cox Communications and the National Center for Missing and Exploited Children. In addition, 27% of tweens aged 11-12 years admit to posting a fake age online, 28% of tweens have been contacted over the Internet by someone they don’t know, and 11% have responded and chatted with an unknown person online, the survey found. Still, the poll found that most parents are discussing Internet safety with their children: 73% of the 1,015 tweens contacted said their parents had talked to them “a lot” about online safety. Children whose parents have discussed online safety are more likely to perceive posting personal information as unsafe, and also to tell their parents if they are contacted by a stranger, the survey found.

SCHIP Reporting Bill Introduced

Rep. Charles W. Boustany Jr. (R-La.) has introduced legislation that would require states to report how many children enrolled in the State Children’s Health Insurance Plan actually receive a primary care visit each year. In addition, the legislation would encourage states to survey patients to determine if enrolled children are getting needed care in a timely manner. “Congress has a duty to ensure SCHIP coverage actually delivers timely care to enrolled children,” said Rep. Boustany, a cardiovascular surgeon, in a statement. “Studies show children with Medicaid or SCHIP receive fewer recommended checkups and fewer visits with primary

care providers than [do] those with private coverage.” The bill also would require states to report their plans to target enrollment outreach to needy children who don’t already have private coverage.

Child Skin Infections Rise

Children aged 4 years and younger were hospitalized with skin infections more than 34,000 times in 2006, a 150% increase from 2000, according to data from the Agency for Healthcare Research and Quality. The AHRQ analysis of hospitalization trends in children shows skin infections ranked as the 8th most common reason for child hospitalizations in 2006, up from 17th in 2000. Reasons for the increase were unclear but may be linked in part to increasing resistance to antibiotics, according to AHRQ. Meanwhile, respiratory diseases remained the top reason for child hospitalization, while other leading admissions of children in 2006 included gastritis; intestinal infections and other digestive disorders; meningitis, epilepsy, and other nervous system disorders; adolescent pregnancy; diabetes, nutritional deficiencies, and other metabolic or endocrine disorders; and depression, bipolar disease, and other mental disorders, according to AHRQ.

Patients Rate Own MDs Higher

Parents believe that their children’s pediatricians always or almost always listen carefully to them and explain things in a way that is easy to understand, but they don’t rate physicians and nurses in the same practice quite as highly, according to the second patient experience survey conducted by Massachusetts Health Quality Partners. The nonprofit coalition of physicians, patients, insurers, and hospitals asked 51,000 patients at 400 practices about their satisfaction on such issues as getting timely appointments, how well doctors know their patients, and how efficiently doctors coordinate care. More than 95% of parents responding said their child’s doctor always or almost always listened to them and explained issues carefully, giving clear instructions about what to do about symptoms. But only about 85% of parents rated other doctors and nurses in the same practice as highly.

Most Drink Fluoridated Water

Nearly 70% of U.S. residents who get water from community water systems now receive fluoridated water, according to a study published in the July 11 issue of *Morbidity and Mortality Weekly Report*. The CDC found that the proportion of the U.S. population receiving fluoridated water, about 184 million people, increased from about 62% in 1992 to 69% in 2006. The percentage of people served by community water systems with optimal levels of fluoridated water ranged from less than 9% in Hawaii to 100% in the District of Columbia, the report said.

—Jane Anderson