



POLICY & PRACTICE

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FDA Warns on Beverages

A maker of one of the now-notorious, high-potency, caffeine-and-alcohol drinks said it would remove the stimulant from its product as the Food and Drug Administration warned other makers that they must do the same or face action such as seizure of their products. The FDA cautioned Charge Beverages Corp., New Century Brewing Co. LLC, Phusion Projects LLC, and United Brands Company Inc. that the caffeine represents an “unsafe food additive” that can mask sensory cues individuals normally rely on to determine their level of intoxication. The result can be risky behaviors and life-threatening situations, the agency said. Phusion Projects, which makes the drink Four Loko, announced the day before the FDA warning that it would remove caffeine and two other stimulants, taurine and guarana, from its beverages. Wake Forest University’s Dr. Mary Claire O’Brien, who has researched caffeinated alcoholic products, said that they allow drinkers to stay awake to drink more, “well beyond the amount they would otherwise be able to tolerate if they were only drinking alcohol.”

Mammography Devices Relisted

The FDA is making it easier for companies to get new digital mammography systems approved. The agency said it is reclassifying these devices, known as full

field digital mammography systems, as medium-risk (class II) devices. When first approved by the agency in 2000, digital mammography systems were categorized as high risk (class III) because of their novelty. Since then, digital mammography has been validated in scientific studies involving tens of thousands of patients, the agency said. To win approval for a class III device, companies need to prove safety and effectiveness. Class II approval involves establishing that a device is substantially equivalent to one already on the market. Today, about 70% of the mammography units in use are digital and 70% of certified U.S. mammography centers have at least one digital unit, the FDA said.

Hospital Adverse Events Common

More than 13% of Medicare beneficiaries hospitalized in late 2008 experienced at least one adverse event causing lasting harm during their stays. Among them, 1.5% experienced an event that contributed to their deaths, according to a report from the Health and Human Services Office of the Inspector General. Another 13% of hospitalized beneficiaries experienced temporary harm, such as hypoglycemia, the report found. The combination of events cost Medicare an estimated \$324 million in October 2008, the month the report covered, which means that such events

could cost \$4.4 billion a year. Physicians reviewing the data said that 44% of the adverse events, such as hospital-acquired infections, and temporary-harm events were clearly or probably preventable.

Medicare Reduces Bad Payments

Following a pledge to reduce waste, fraud, and abuse in Medicare, the Centers for Medicare and Medicaid Services said it has already reduced the error rate for claims since 2009 and is on track to cut it 50% by 2012. Improper payments don’t necessarily represent fraud and abuse, the CMS said. Instead, most such errors stem from insufficient documentation and provision of medically unnecessary services. In 2009, the fee-for-service error rate was more than 12%, or an estimated \$35.4 billion in improper claims, according to the report. In 2010, the rate has fallen to less than 11%, or an estimated \$34.3 billion. The agency said it continues to work with providers across the country to help them eliminate errors.

Industry-Physician Ties Persist

Although most physicians continue to have financial relationships with industry, the percentage has declined significantly since 2004, according to a study led by Harvard Medical School researchers in Boston. They reported in the Archives of Internal Medicine that although fewer physicians are accepting gifts such as drug samples and food, most continue to do so. About 64% take drug samples, compared with 78% in 2004, and 71% accept free food and beverages, compared

with 80% in 2004. However, the number of physicians accepting payments for consulting, speaking, or enrolling patients in clinical trials has fallen by half since 2004, according to the study. Only 18% of physicians said they accept reimbursements for meeting expenses, compared with 35% in 2004, and just 14% receive payments for professional services, compared with 28% in 2004. “These data clearly show that physician behavior, at least with respect to managing conflicts of interest, is mutable in a relatively short period,” the researchers concluded. “However, given that 83.8% of physicians have [physician-industry relationships], it is clear that industry still has substantial financial links with the nation’s physicians.”

AMA Issues Social Media Policy

Physicians using social media sites such as Facebook and Twitter should carefully guard patient privacy while monitoring their own Internet presence to make sure it is accurate and appropriate, the American Medical Association said in a new policy statement. During its semi-annual policy meeting in San Diego, the AMA called for physicians to “recognize that actions online and content posted can negatively affect their reputations among patients and colleagues, and may even have consequences for their medical careers.” The AMA urges physicians to set privacy settings on Web sites at their highest levels, maintain appropriate boundaries when interacting with patients online, and consider separating personal and professional content online.

—Jane Anderson

Groups Back ACO Concept

Principles from page 1

expected to issue regulations later, perhaps by early 2011.

CMS has been looking at a risk-sharing payment methodology that would reward providers for improved quality and lower costs.

The Joint Principles for Accountable Care Organizations issued by the primary care groups outlines a number of principles that should guide that payment system. For instance, incentives should “adequately reflect the relative contributions of participating physicians,” and practices that participate in ACOs and achieve recognition as medical homes “should receive additional financial incentives,” according to the Joint Principles.

The Medicare Payment Advisory Commission (MedPAC) has backed the ACO concept and the notion of shared savings as a means to eliminate inefficiencies.

In comments submitted to CMS on Nov. 22, MedPAC Chairman Glenn Hackbarth wrote, “If structured carefully, a shared savings program for ACOs could present an opportunity to correct some of the undesirable incentives inherent in fee-for-service

payment and reward providers who are doing their part to control costs and improve quality.”

Shared savings also could “help beneficiaries receive more coordinated care and become more engaged with their care management, particularly if beneficiaries are informed when they are assigned to ACOs,” Mr. Hackbarth wrote.

The American Medical Association (AMA) also has established guiding principles for ACOs. Members approved the 13 principles at its interim House of Delegates meeting in November.

The AMA is concerned that existing antitrust and fraud rules can make it difficult for physicians to participate in ACOs. The organization called for increased flexibility in those laws, and for the FTC to provide explicit exceptions to antitrust laws for ACO participants.

ACO savings should be retained for patient care services and distributed to ACO participants, and the organizations should also be allowed to use a variety of payment models, according to the AMA principles. ■

Healthy People 2020 Launched

BY MICHELE G. SULLIVAN

Healthy People 2010 is growing up.

On Dec. 2, the Department of Health and Human Services announced the birth of Healthy People 2020, a new generation of the nation’s 10-year plan for health promotion and disease prevention.

“The launch of Healthy People 2020 comes at a critical time,” HHS Secretary Kathleen Sebelius said in a press statement. “Our challenge and opportunity is to avoid preventable disease from occurring in the first place.”

Because chronic diseases — such as diabetes, heart disease, and cancer — account for 70% of deaths and consume 75% of national health spending, Healthy People 2020 stresses incorporating lifestyle changes that have repeatedly been proved to protect against those disorders. “Many of the risk factors that contribute to the development of these diseases are preventable,” said Dr.

Howard Koh, assistant secretary for health.

“Healthy People is the nation’s road map and compass for better health, providing our society a vision for improving both the quantity and quality of life for all Americans.”

Healthy People 2020 isn’t just intended for individuals, though, Dr. Jonathan Fielding

includes a topic area for dementias that includes Alzheimer’s disease. Other new areas in the initiative are early and middle childhood and adolescent health; blood disorders and blood safety; genomics; global health; and health-related quality of life and well-being.

Like all children growing up in a technology-based society, Healthy People 2020 will incorporate the Internet and other technology media in both its message and its method. The newly designed Web site allows users to tailor information to their individual needs and look for evidence-based ways to put the program’s recommendations to work in their lives.

Developers are also issuing a challenge to encourage the tech-savvy to create easy-to-use applications for those who are working with Healthy People 2020 objectives and community health data. Winning ideas will reap financial rewards — \$4,000 in prize money is available. ■



said during a press briefing on the program’s launch. Researchers, clinicians, educators, and members of both public and private health care agencies need to band together to make the program a success, said Dr. Fielding, chairman of the Secretary’s Advisory Committee on Health Promotion and Disease Prevention Objectives for 2020.

In response to the growing elderly segment of the U.S. population, the new program