

POLICY & PRACTICE

FDA Posts Guidance on Handouts

The Food and Drug Administration has issued updated guidance for manufacturers that distribute journal articles or other scientific publications concerning off-label uses for their FDA-approved drugs, devices, or biologics. Guidance doesn't carry the same heft as regulation, but most manufacturers heed the FDA's advice. On its Web site, the agency suggested that distributed journal articles be only from organizations using editorial boards with "demonstrated expertise

in the subject of the article," independence to review articles, and fully disclosed conflicts of interest. Authors and editors also should disclose conflicts. Acceptable articles can't be from special supplements that are funded even partially by a manufacturer. In its presentation to practitioners, an article shouldn't be highlighted, otherwise marked up, or attached to promotional materials. The FDA did not deem letters to the editor, publication abstracts, and results of phase I trials in healthy volunteers to be kosher.

Maryland Eyes Concierge Care

Maryland's insurance commissioner is considering whether to regulate models of medical practices known as "retainer," "boutique," or "concierge" practices. Ralph Tyler held an informational hearing in December in an effort to determine whether the arrangements "cross the line to trigger obligations as an authorized insurer." In concierge practices, the patient pays an annual fee in exchange for certain medical services beyond what a health insurer covers. But the agreement generally covers only preventive services. The insurance com-

mission "wants to be sure it understands these arrangements and will review the need for additional oversight or regulation," Mr. Tyler said in a statement.

R.I. Medicaid Overhaul Okayed

Rhode Island Gov. Donald Carcieri and the Centers for Medicare and Medicaid Services have reached agreement on a Medicaid reform package for the state that would emphasize home- and community-based long-term care settings over nursing home care. Primary care case management also would get a boost. The deal, which must be approved by Rhode Island lawmakers, would set a \$12 billion, 5-year spending cap on the state's program. As in other states, Medicaid costs threaten to overwhelm other spending priorities in Rhode Island, whose 2009 budget counts on millions in savings from Medicaid changes. Under the new reform plan, assessment teams would determine medical risk levels for impoverished elderly people, and only those at most risk would be guaranteed placements in nursing homes or other high-cost facilities. Others would receive care from in-home services and in lower-cost assisted living facilities. The state would enroll all Medicaid beneficiaries without other third-party coverage into a managed care plan or a primary care case management practice. Also, the state intends to expand performance-based payment incentives for Medicaid providers.

Court: Enforce Calif. HIV Law

The Los Angeles Superior Court has ordered the state to implement a 2002 law intended to extend Medi-Cal coverage to more HIV-positive Californians. The AIDS Healthcare Foundation sued to compel the Department of Health Care Services to include all HIV-positive, nondisabled individuals in Medi-Cal, California's Medicaid program. Prior to the 2002 law, only individuals with HIV who had been diagnosed with AIDS were considered eligible for Medi-Cal. The law was designed to encourage AIDS patients to move from Medi-Cal's fee-for-service program into managed care, and the state was to use savings from that change to cover HIV-positive people without AIDS. The court ruled that Medi-Cal failed to implement some measures specified by state lawmakers, such as outreach to individual AIDS patients, and made minimal efforts on others. Medi-Cal must report to the court in April about what it has done to comply with the ruling.

Markets Offer Free Antibiotics

So far this cold and flu season, five supermarket chains have said they will offer free generic antibiotics to customers. Pleasanton, Calif.-based Safeway, the Mid-Atlantic chain Giant Food, the New England-based Stop & Shop, the Florida chain Publix Super Markets, Rochester, N.Y.-based Wegmans Food Markets, and the Midwestern chain Meijer Stores all said they would supply the most commonly prescribed generic oral antibiotics to customers with valid prescriptions at no charge.

—Jane Anderson

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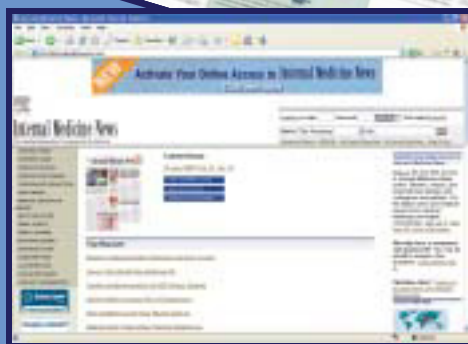
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