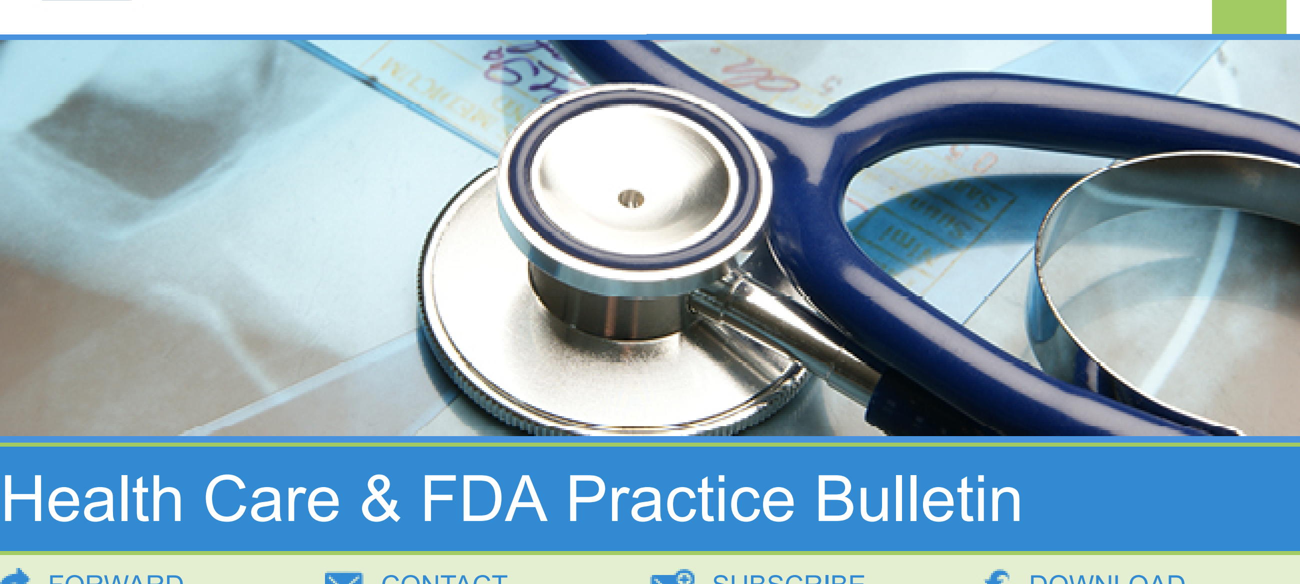
GT GreenbergTraurig



Health Care & FDA Practice Bulletin

FORWARD CONTACT SUBSCRIBE DOWNLOAD

Welcome to Greenberg Traurig's Health Care & FDA Practice Bulletin, a collection of timely articles written by our attorneys that are focused on significant developments in health and FDA law. The topics in this issue include the Affordable Care Act, health care fraud and abuse, regulatory updates, FDA news, other health care topics, and upcoming events.

In this Issue

AFFORDABLE CARE ACT

Summary of Key Provisions of the American Health Care Act (AHCA) (H.R. 1628)

By Nancy E. Taylor and Jeffrey S. Alberg

On May 4, 2017, the House of Representatives passed the American Health Care Act (AHCA) (H.R. 1628) by a vote of 217-213. The AHCA seeks to repeal and replace the Affordable Care Act (ACA). The bill now heads to the Senate where it is expected to be significantly revised.

Note: A final version of the bill, with the amendments enrolled, is found here.

The AHCA primarily focuses on changes to the individual and small group market. First, under the AHCA individuals purchasing insurance through the individual and small group market will be eligible for tax credits based on their age (rather than their income, as under the ACA). Tax credits would be higher for older individuals, but eventually phased out for individuals making more than $75,000 or families making more than $150,000.

Unlike the ACA, the AHCA does not include a mandate that all individuals have health insurance. AHCA repeals the individual mandate and replaces it with a "continuous coverage" provision. Individuals who go without insurance and seek to re-enroll in insurance coverage would face higher premiums for up to a year. Insurers would also be permitted to charge such individuals a higher premium for up to a year based on the individual's health conditions.

Patient and State Stability Fund

The bill also provides at least $115 billion for a "Patient and State Stability Fund," with an additional $8 billion provided for a similar provision. States would use these funds to build high-risk pools, which would allow the states to provide insurance to high-cost individuals, such as those with cancer and other chronic diseases.

MacArthur Amendment and Coverage of Essential Health Benefits

While the AHCA leaves in place ACA requirements that insurers cover Essential Health Benefits (EHB) (such as emergency services, prescription drugs, hospitalization, pregnancy, etc.), under an amendment to the bill by Rep. Tom MacArthur (R-NJ), states would be allowed to seek a waiver to opt-out of the EHB requirements. In order to obtain the waiver, states would have to show that they would reduce premiums, increase health insurance enrollment in the state, stabilize the market for health insurance coverage, stabilize premiums for individuals with pre-existing conditions, or increase the choice of plans in the state. The amendment requires states that do not obtain a waiver to continue to require insurers to cover EHBs.

The MacArthur amendment provides for "default approval" for waivers, meaning state waiver applications would automatically be approved unless HHS specifically rejects the proposal within 60 days. The MacArthur amendment also allows insurers to charge more based on an individual's age and health status. States that opt-out of the EHB requirements would be required to set up a high-risk pool. In states opting-out, individuals who fail to maintain continuous coverage could be charged more based on their health status (likely for up to 12 months), but the state could waive this penalty. The amendment also specifically bars insurers from discriminating against those with pre-existing conditions.

Medicaid

The AHCA scales back the Medicaid expansion put in place by the ACA. The ACA expanded the program to cover adults making up to 133 percent of the federal poverty line ($15,800 for one person, or $32,319 for a family of four). Under the AHCA, the coverage expansion would stay in place until the end of 2019, but no newly eligible people could be added to Medicaid rolls after that.

The AHCA also scales back Medicaid by allowing states to seek a "block grant" rather than a per-person payment for each Medicaid recipient from the federal government. Block grants would ease limitations on states' ability to remove people from being enrolled, charge premiums, and reduce benefits for children. Regardless of whether a state seeks a block grant, they will be permitted to add a work requirement for nondisabled adults.

[back to top]

HEALTH CARE FRAUD & ABUSE

Momentum Building for Changes to Fraud and Abuse Laws

By Francis J. Serbaroli

New York Law Journal – When the Medicare and Medicaid programs were created in the 1960s, medical services were paid for almost entirely on a fee-for-service basis. For example, Medicare would pay a certain amount for a checkup in a physician's office, another amount for a physician's reading of an X-ray film, and so on (less any applicable co-pay or deductible). Most private insurers paid for medical services this way for generations, and fee-for-service would continue to be the payment method of choice for many more years to come.

Continue Reading.

[back to top]

REGULATORY UPDATES

The Interstate Medical Licensure Compact

By Francis J. Serbaroli

New York Law Journal – One of the many powers reserved to the states in our system of government is the power to license and supervise the practice of the professions, including the practice of medicine. Historically, each state has set its own requirements for physicians to obtain a license to practice medicine within its borders. These requirements usually include graduation from an accredited medical school; completion of post-graduate residency or internship training in an accredited hospital training program; passing a licensing examination; completion of continuing medical education credits; and so on. The state may also investigate whether a physician applicant for a medical license has any criminal convictions, any past or pending disciplinary actions, any mental or physical impairment, or whether the applicant has caused any harm to patients.

Continue Reading.

Telemedicine: The Link to New Value-Based Payment Models

By Sabrina R. Gallo

Law360 – The health care reimbursement landscape continues to change. Both governmental and private payers are trying to move away from traditional fee-for-service (FFS) payment models that reimburse pursuant to the number of services provided to those that reimburse based on quality or value. The Affordable Care Act established tools such as the Medicare Shared Savings Program and the Center for Medicare and Medicaid Innovation whose combined focus is utilizing alternative, value-based payment models that seek to achieve better care, smarter spending and healthier people.

Continue Reading.

Medicare Ordered to Provide Educational Outreach on Skilled Nursing Services

By Nancy E. Taylor and Jeffrey S. Alberg

On Feb. 1, 2017, the U.S. District Court for the District of Vermont adopted settlement terms proposed primarily by the Centers for Medicare & Medicaid Services (CMS) requiring the agency to implement a corrective action plan to ensure it educates health care providers, Medicare contractors, adjudicators, and other stakeholders that Medicare skilled nursing service beneficiaries do not need to show continued improvement in order to satisfy eligibility requirements—the so-called "Improvement Standard." The Medicare skilled nursing services benefit includes coverage of skilled nursing facility (SNF), home health (HH), and outpatient therapy (OPT) services for Medicare parts A and B. The case is *Jimmo v. Burwell.*

Continue Reading.

New Law Allows New York Clinics to Provide Primary Medical Care Off-Site

By Francis J. Serbaroli

The New York Legislature has enacted, and Governor Andrew M. Cuomo recently signed into law, a new provision of the Public Health Law that permits Article 281 hospital outpatient clinics (clinic) and diagnostic and treatment centers (D&TC) to provide primary care services off-site for patients who are unable to travel to the facility.

Continue Reading.

[back to top]

FDA NEWS

FDA Delays Implementation of Certain Menu Labeling and Nutrition Requirements

By Karen C. Corallo

FDA has requested comments on the attached Federal Register Notice (FRN) that **delays by one year** implementation of certain menu labeling and nutrition information requirements that were set to go in effect on **May 5, 2017**. Covered establishments now have until **May 7, 2018** to comply.

Importantly, in response to stakeholder's concerns, **FDA is asking for advice in how to rewrite the rule**, weighing the burdens on industry against public health concerns. Comments must be submitted within the next **60 days**.

Continue Reading.

Off the RACC: Revisions to the Federal Labeling Regulations

By Justin J. Prochnow

Tea & Coffee Trade Journal – Big changes are underway for the labeling of food, beverage, and dietary supplement products. On July 26, 2016, significant revisions to the federal regulations pertaining to the labeling of food, beverages, and supplements, in the form of two Final Rules, became effective and, while companies have two to three years to comply with the new revisions to the regulations depending on annual sales (companies with $10 million or more in annual sales must comply by July 26, 2018 while companies with less than $10 million in annual sales have until July 26, 2019), many companies are already considering whether they should make changes now to comply with the new revisions. Whether they makes those changes now or wait until compliance is mandatory will likely depend on how those new changes impact their respective labels.

Continue Reading.

"Hot Claims" in Advertising Food, Beverage and Supplement Products

By Justin J. Prochnow

Natural Products Insider – No category of products is scrutinized more than products promoted for weight-loss. Whether it is a "magic pill" that promises weight-loss while you sleep or a special belt that will "melt the pounds away" while you sit at your desk, the FTC is likely to view such claims with a big dose of skepticism. In January of 2014, the FTC launched "Operation Failed Resolution" to stop misleading claims for products promoting easy weight loss and slimmer bodies and, as part of the launch, the FTC announced settlements against several companies, including a company selling a skin cream that would allegedly slim users' bodies and a company marketing a product to consumers in well-known and frequently-aired infomercials as a product to "sprinkle, eat, and lose weight."

Continue Reading.

Clearing the Regulatory Hurdles to Bring a Supplement Product to the Market

By Justin J. Prochnow

Tablets & Capsules – The public often wrongly perceives the dietary supplement industry as a modern-day version of the Wild West. The differences in preapproval between drugs and supplements likely causes that perception. Drugs and medical devices often require expensive and rigorous premarket approval processes, while dietary supplements require little in the way of premarket approval or notification. The perception persists due to the actions of a few bad apples and groups with axes to grind, such as drug companies with obvious motives or legislators who view the entire industry as lawless and unregulated.

Continue Reading.

Recall Communications — How To Interact Effectively With The FDA

By Justin J. Prochnow

FoodOnline – Unfortunately, food recalls aren't a matter of "if one happens," they are a matter of "when one happens." And when one happens to your company, will you be able to quickly and effectively communicate it with the FDA? This article will illustrate the recall process and offer suggestions to help you get through it. Recalls of food, beverage, and supplement products have become an all-too frequent occurrence of late. In the first three months of 2017, notices for 108 recalls were posted on the FDA's 2017 Recalls, Market Withdrawals, and Safety Alerts database. Posted recalls include products ranging from sweet peas and cheese potentially contaminated with Listeria monocytogenes to products with undeclared food allergens, such as soy and peanuts. In many situations, the company announcing the recall did not create the issue necessitating the recall, unwittingly using an ingredient from a supplier that was allegedly safe for use, only to find out after shipping out products that ingredient tested positive for a pathogen or contains a previously undeclared allergen.

Continue Reading.

[back to top]

OTHER

Revising the 2013 Reforms to the Not-For-Profit Corporation Law

By Francis J. Serbaroli

New York Law Journal – In 2013, the New York State Legislature enacted and Gov. Andrew Cuomo signed into law the Nonprofit Revitalization Act1 (NRA), the most extensive set of revisions to the Not-for-Profit Corporation Law (NPCL) in more than 40 years. We summarized those revisions in an earlier Health Law column. While the NRA provided many needed improvements to the NPCL, it also created a few problems for not-for-profit organizations. The NRA was amended twice in 2015,3 among other things to extend to Jan. 1, 2017 the effective date of the prohibition on an employee serving as the chair of the board of directors of a not-for-profit corporation; to amend the definitions of "independent director," "related party," "key employee," and other terms; and to clarify provisions related to approval of board member compensation, board quorums, board committees, and participation in board meetings where related party transactions are considered.

Continue Reading.

The Duties of Governing Board Members

By Francis J. Serbaroli

New York Law Journal – Historically, the health care sector in New York has been largely the domain of not-for-profit (NFP) organizations. Most hospitals, about half of the nursing homes, many home health agencies and clinics, and even a number of major health insurers and managed care plans are NFP corporations. While membership on the board of trustees or board of directors of these NFP organizations has always carried important responsibilities, the challenges facing these governing boards in today's environment are almost unprecedented. In addition to adjusting to the ongoing implementation of the Affordable Care Act, there is heightened federal and state regulatory scrutiny, more and more Medicare and Medicaid payment audits and liabilities, increased competition, more consolidations among hospitals and other providers, and many other cross currents that these organizations have to navigate.

Continue Reading.

Not-for-profit Hospitals and Health Care Providers Facing Retirement Plan Class Actions

By Jeffrey D. Mamorsky, Terry L. Moore, and Francis J. Serbaroli

There has been much media coverage of the recent class action lawsuits filed against some of the most prestigious universities in the United States by university employees. These class action lawsuits allege that the universities breached their fiduciary obligations in running their defined contribution 403(b) retirement plans by allowing the plans to pay excessive investment, record-keeping and administrative fees, thereby resulting in reduced retirement savings for their employees. The roster of current defendants includes Yale, MIT, Vanderbilt, Duke, Cornell, Johns Hopkins, and the University of Pennsylvania, among others, and more class actions of this type against other universities are expected. These suits are similar to the fiduciary-duty breach hidden fee litigation that has bedeviled corporate 401(k) plan sponsors for years. The suits also claim that some university retirement plans offer too many investment options (Duke University allegedly offered more than 400; John Hopkins, 440; and Vanderbilt, 340), have multiple recordkeepers (John Hopkins allegedly has five recordkeepers; Duke and Vanderbilt, four) and the universities failed to put record-keeping and other services for their retirement plans out for competitive bidding on a periodic basis.

Continue Reading.

[back to top]

EVENTS

15th Annual Rocky Mountain Intellectual Property & Technology Institute

Westmimster, CO | Westminster Westin Hotel | June 1-2, 2017

The 15th Annual Rocky Mountain Intellectual Property & Technology Institute is scheduled for June 1-2 at the Westin Westminster Hotel in Westminster, CO.

Attendees will hear from practice and thought leaders nationwide, the chief judge of PTAB and the chief judge of TTAB, the PTO regional director, SPEs, and the commissioner of trademarks. Attendees will learn about six things to do that may limit IP liability; developments in licensing; the new Defend Trade Secrets Act; open source; privacy and data security; and what's next from leaders in the technology.

Greenberg Traurig's Ian Ballon (Silicon Valley/Los Angeles) will give the "2017 Copyright Update," reviewing how copyright law has changed in the past year. GT's Anthony Robinson (Denver) will give a talk entitled, "Food for Thought: Marketing Food, Beverages, and Supplements Under a Microscope," which will cover how to navigate the regulations enforced by state and federal agencies, the competitive challenges of the NAD and Lanham Act claims, and how to avoid the courtroom. Greenberg Traurig is an event sponsor.

2017 Physicians Legal Issues Conference

Chicago, IL | InterContinental Chicago Magnificent Mile | June 8-9, 2017

On June 8-9 at the InterContinental Chicago Magnificent Mile, the ABA Health Law Section, the Chicago Medical Society, and the American Association of Physician Leaders will join together to present the 2017 Physicians Legal Issues Conference.

Per the conference website, physicians continue to face challenging odds in a rapidly evolving

healthcare market - whether remaining independent, adapting to "employment" by an integrated system, or addressing consolidated payer markets with little or no negotiating power. When confronted with aggressive hospital systems, lower reimbursement, and daily practice challenges, physicians are learning to adapt and thrive in very innovative ways. This program offers physicians, attorneys and their administrative partners an opportunity to learn how these issues are being addressed by physicians and how they can succeed at maintaining viable medical practices that offer quality services at their core. As a combined educational program with the American Bar Association Health Law Section, the Chicago Medical Society, and the American Association of Physician Leaders, physicians and their legal counsel will have access to national speakers and will be educated on key issues affecting employer and hospital relationships, business and industry responses to payer consolidation and market control, and every day "survival" techniques in hospital and private practice settings.

Sean McKenna of Greenberg Traurig's Health Care & FDA Practice will be speaking at this event. His panel will discuss "Healthcare Compliance & Enforcement Investigations: Leading Practices for Outside and In-House Counsel to Work Efficiently and Collaboratively." Greenberg Traurig is a sponsor of the event.

[back to top]