OMF Proposes Rule Establishing Multi-State Plan Program for Affordable Insurance Exchanges

The Office of Personnel Management published a proposed rule implementing the Multi-State Plan Program for health insurance required by the Patient Protection and Affordable Care Act. “Section 1334 of the Affordable Care Act creates the Multi-State Plan Program (MSPP) to foster competition among plans competing in the individual and small group health insurance markets on the Affordable Insurance Exchanges (Exchanges) on the basis of price, quality, and benefit delivery. The Affordable Care Act directs the U.S. Office of Personnel Management (OPM) to contract with private health insurance issuers to offer at least two multi-State plans (MSPs) on each of the Exchanges in the 50 States and the District of Columbia. The law allows MSPP issuers to phase in coverage, but coverage must be offered on Exchanges in all States and the District of Columbia by the fourth year in which the MSPP issuer participates in the MSPP. The first open enrollment period for plans offered through Exchanges will begin on October 1, 2013, for coverage starting in January 2014.” OPM holds that this arrangement provides administrative efficiency to participating insurers, and will grant additional competition to consumers in every state. Comments are due on January 4th.
SEC seen waiting for prosecutors before pursuing SAC, Bloomberg
OSHA to get oversight of flight-attendant work conditions, Bloomberg
Basel committee said to consider delay of Bank Liquidity Rule, Bloomberg

12/1/12
Emails suggest SEC’s Schapiro delayed JOBS Act rule amid concerns about legacy, Reuters
SEC head dragged her feet on new rule at urging of lobbyist, GOP congressman says, Washington Post

12/2/12
Wall Street finds a foreign detour around U.S. derivatives rules, Reuters
D.C. debates best path to cleaner waterways, Washington Post

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Clashes over Internet regulations overshadow agenda of UN conference in Dubai, Washington Post
Geithner fight on fiscal cliff invokes Dodd-Frank resolve, Bloomberg
Bank regulations harming credit flow to business, A&O says, Bloomberg
A&O says global regulation lacks intelligence, BloombergTV
SEC charges Chinese affiliates of 5 big US accounting firms with impeding probes of companies, Washington Post
SEC charges Chinese arms of 5 accounting firms over data, Washington Post
Last-minute EPA rule change frustrates chief justice, Washington Post
Supreme Court lawyer looks for nice way to tell justices ‘I told you so’ in environmental case, Washington Post
Exchanges to ask SEC to delay audit-trail deadline, Bloomberg
Wall Street should reveal more trading-revenue data, Fitch says, Bloomberg
SEC files charges against Chinese arm of major accounting firms, Barron’s
Simpler remedies needed for banks, Wall Street Journal
U.S. court voids drug rep’s conviction, cites free speech, Reuters

12/4/12
SEC says big four audit china-affiliates blocked probe, Bloomberg
U.S. barred from prosecuting off-label sales of drugs, Bloomberg
Drugmakers nudged by FDA to find childhood cancer cures, Bloomberg
U.S. could cut power plant pollution 26%, NRDC says, Bloomberg
Banks discover money management again as trading declines, Bloomberg
High court puts spotlight on speed of rulemaking, E&E Greenwire
Fed governor Daniel Tarullo pushing for policy to rein in on bank size, Washington Post

Agencies lag on transparency, report says, Washington Post
CFTC says broker tried to manipulate wheat futures prices, Bloomberg
SEC auditor case seen jeopardizing Chinese U.S. listings, Bloomberg
SEC probe may spur more Chinese delistings, Dorsey says, Bloomberg
High-frequency traders seen profiting at small-firm expense, Bloomberg
Fed’s Tarullo says reviving Glass-Steagall may be costly, Bloomberg
Global banking under siege as nations tighten local rules, Bloomberg
Companies keeping cash overseas don’t like talking about it, Wall Street Journal
CME deliverable ‘swap futures’ see comfortable debut, WSJ MarketBeat
FDA gives more time to generic facilities to register, saying many have not, Regulatory Focus

In landmark ruling, court sees off-label marketing as protected free speech, Regulatory Focus

12/5/12
Zogenix drug may be abused at higher rate, FDA staff says, Bloomberg
FDA issues guidance meant to limit use of potentially dangerous substances in medication, Regulatory Focus
Rulemaking

Securities and Exchange Commission

SEC Publishes List of Rules Undergoing §610 Reg Flex Act Review

The Securities and Exchange Commission published a proposed rule listing nine existing SEC rules to be reviewed pursuant to the requirements of section 610 of the Regulatory Flexibility Act. The rules to be reviewed govern naming requirements for investment companies, investment company independent director disqualifications, the registration of national securities exchanges, and the registration of broker-dealers, among other subjects. “The Commission particularly solicits public comment on whether the rules listed below affect small businesses in new or different ways than when they were first adopted. The rules and forms listed are scheduled for review by staff of the Commission during the next twelve months.” Comments are due on January 3rd, 2013.

Environmental Protection Agency

EPA Reconsiders Mercury and Air Toxics Rule and Utility NSPS

The Environmental Protection Agency published a proposed rule indicating the Agency’s intent to reconsider its February 16th final rule, National Emission Standards for Hazardous Air Pollutants from Coal- and Oil-fired Electric Utility Steam Generating Units and Standards of Performance for Fossil-Fuel-Fired Electric Utility, Industrial-Commercial-Institutional, and Small Industrial-Commercial-Institutional Steam Generating Units. “The National Emission Standards for Hazardous Air Pollutants (NESHAP) rule issued pursuant to CAA section 112 is referred to as the Mercury and Air Toxics Standards (MATS), and the New Source Performance Standards rule issued pursuant to CAA section 111 is referred to as the Utility NSPS. The Administrator received petitions for reconsideration of certain aspects of MATS and the Utility NSPS. In this notice, the EPA is announcing reconsideration of certain new source standards for MATS, the requirements applicable during periods of startup and shutdown for MATS, the startup and shutdown provisions related to the particulate matter (PM) standard in the Utility NSPS, and certain revisions to the definitional and monitoring provisions of the Utility NSPS.” Comments are due on December 31st.

Department of the Interior

BIA Rule Addresses Residential, Business, and Wind and Solar Leases on Indian Land

The Bureau of Indian Affairs published a final rule revising its existing regulations on the leasing of Indian land for non-agricultural purposes. “This rule makes the procedures for obtaining BIA approval of residential, business, and wind and solar resource lease documents (leases, amendments, assignments, subleases, and leasehold mortgages) as explicit and transparent as possible. The current regulations provide for the approval of these instruments, but do not specify the approval procedures, leading to possible inconsistencies nationwide, to the detriment of Indian landowners, lessees and lenders.” The rule additionally eliminates the requirement for BIA approval of permits of Indian land, and that “BIA must approve leases, amendments, assignments, leasehold mortgages, and subleases unless it finds a compelling reason not to do so, based on certain specified findings.”

Food and Drug Administration

FDA Final Rule Increases Ionizing Radiation Threshold for Poultry

The Food and Drug Administration published a final rule allowing for an increase in the maximum dose of ionizing radiation allowed to treat specified poultry products, and also removing a requirement to include oxygen in the packaging of these poultry products during irradiation. This rulemaking was conducted in response to a 1999 petition from the Department of Agriculture asking FDA to amend its food additive regulation pertaining to ionizing radiation in the treatment of food. A source of radiation used to treat foods is defined as a food additive by the Federal Food Drug and Cosmetic Act: “The additive is not added to food literally but is rather a source of radiation used to process or treat food such that, analogous to other food processing technologies, its use can affect the characteristics of the food… a food additive cannot be approved for a particular use unless a fair evaluation of the evidence establishes that the additive is safe under the conditions of that use. Importantly, the statute does not prescribe the safety tests to be performed but leaves that determination to the discretion and scientific expertise of FDA.” Based on FDA’s assessment, there is no evidence that increased irradiation of poultry will either pose a toxicological hazard to humans or an have an adverse impact on human nutrition.
FDA Final Rule Increases Ionizing Radiation Threshold for Raw Meat
The Food and Drug Administration published a final rule allowing for the use of a 4.5 kilogram (kGy) maximum absorbed dose of ionizing radiation to treat uncooked meat and meat byproducts to extend shelf life and reduce levels of foodborne pathogens. This rulemaking was conducted in response to a 1999 petition from the Department of Agriculture asking FDA to amend its food additive regulation pertaining to ionizing radiation in the treatment of food. FDA concluded that increasing the maximum absorbed dose of ionizing radiation to 4.5 kGy does not present a toxicological hazard to humans, nor will it adversely impact the nutritional adequacy of the overall human diet. “In summary, based on the available data and information, FDA concludes that irradiation of meat conducted in accordance with good manufacturing practices will reduce or eliminate bacterial populations with no increased microbial risk from pathogens that may survive the irradiation process.”

FDA Proposes Revoking Identity Standards for Jelly, Jams, & Preserves
The Food and Drug Administration published a proposed rule revoking the standards of identity for artificially sweetened jelly, preserves, and jams. The standards of identity, established in 1959, allow the use of sugar, saccharin, sodium saccharin, and calcium saccharin to sweeten jelly, preserves and jams. Sweeteners produced in the intervening 50 years are prevented by the identity standards from being added to these products in most circumstances. Additionally, fruit spreads containing non-nutritive sweeteners must be labeled with the phrase “artificially sweetened,” and may not have other labeling indicating nutritive content. This rulemaking, in response to a 1997 petition from the International Jelly and Preserve Association, would revoked the standards of identity and allow jelly, jams and preserves to include sweeteners other than sugar, saccharin, sodium saccharin, and calcium saccharin. “Revoking the standards would provide consistency and uniformity among such products because all fruit spreads sweetened with non-nutritive sweeteners would be subject to the same requirements. This proposed rule also is consistent with FDA’s proposed general principles for modernizing food standards… Considering the information in this document, we are proposing to revoke the standards of identity for artificially sweetened jelly, preserves, and jams in §§ 150.141 and 150.161, respectively. We request comments on our tentative conclusion that these two standards of identity are obsolete and unnecessary, and that revoking them would promote honesty and fair dealing in the interest of consumers.” Comments are due on March 4th, 2013.

Department of Transportation
FAA Proposes Minimum Altitudes for Use of Autopilot
The Federal Aviation Administration published a proposed rule establishing harmonized minimum altitudes for the permitted use of autopilots. “The FAA proposes to amend and harmonize minimum altitudes for use of autopilots for transport category airplanes in order to streamline and simplify these operational rules. The proposed rule would enable the operational use of advanced autopilot and navigation systems by incorporating the capabilities of new and future autopilots, flight guidance systems, and Global Navigation Satellite System (GNSS) guidance systems while protecting the continued use of legacy systems. This would allow the FAA to enable the benefits of Next Generation Air Transportation System (NextGen) technologies and procedures (Optimized Profile Descents, Performance Based Navigation (PBN)) to enhance aviation safety in the National Airspace System (NAS). The rule would accomplish this through a performance-based approach, using the certified capabilities of autopilot systems as established by the Airplane Flight Manual (AFM). The proposal would also give the FAA Administrator the authorization to require an altitude higher than the AFM if the Administrator believes it to be in the interest of public safety.” Comments are due on February 4th, 2013.

Agencies

Food and Drug Administration
FDA Seeks Industry Representatives for Device Good Manufacturing Practice Advisory Committee
The Food and Drug Administration is seeking nonvoting industry representatives to serve on the Device Good Manufacturing Practice Advisory Committee (DGMPAC). Members of the DGMPAC “[r]eview proposed regulations issuance regarding good manufacturing practices governing the methods used in, and the facilities and controls used for manufacture, packaging, storage, installation, and servicing of devices, and make recommendations regarding the feasibility and reasonableness of those proposed regulations. The committee also reviews and makes recommendations on proposed guidelines developed to assist the medical device industry in
meeting the good manufacturing practice requirements, and provides advice with regard to any petition submitted by a manufacturer for an exemption or variance from good manufacturing practice regulations.” Interested industry applicants must send a letter stating membership interest to FDA by January 3rd, 2013.

**Department of Energy**

**DOE Announces $130 Million in Funds for Energy Research Projects**

The Department of Energy announced the provision of $130 million in federal funding for 66 separate research projects selected by DOE’s Advanced Research Projects Agency – Energy (ARPA-E) through the OPEN 2012 program. “The OPEN 2012 projects will focus on a wide array of technologies, including advanced fuels, advanced vehicle design and materials, building efficiency, carbon capture, grid modernization, renewable power, and energy storage. The projects were selected through a merit-based process from thousands of concept papers and hundreds of full applications. The projects are based in 24 states, with approximately 47% of the projects led by universities, 29% by small businesses, 15% by large businesses, 7.5% by national labs, and 1.5% by non-profits. Today’s announcement brings ARPA-E’s total portfolio of projects to about 285 projects for a total of approximately $770 million in awards.” Information on each of the individual projects can be found here.