

Regulation Digest Weekly

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Vol. 2 No. 7

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- Time to break up the big banks
- The SEC's Dangerous Liaisons
- Regulation Not Holding Back Hiring
- H&R Block, TurboTax, and Obama's IRS lose in effort to regulate small tax preparers out of business
- Quietly Killing a Consumer Watchdog

Marketplace of Ideas

American Action Forum

- AAF Proposes Regulatory Reform That Promotes Economic Growth, *Sam Batkins*
- The Intersection of Regulation and Manufacturing, *Sam Batkins*
- 2013 Regulatory Pile On Continues: \$12 Billion in New Regulations in January, \$15.8 Billion Potentially on Tap for February, *Sam Batkins*
- 2013 Regulatory Pile On Continues, *Sam Batkins*
- The Week in Regulation: February 4-8, *Sam Batkins*

American Enterprise Institute

- Qualified Mortgage rule fails to protect borrowers or the economy, *Shadow Financial Regulatory Committee*
- Court ruling on recess appointments is an exercise of judicial overreach, *Norman Ornstein*

Center for Effective Government (Formerly OMB Watch)

- Climate Change Policies Face Challenges in Congress

Center for Progressive Reform

- Antibiotic Resistance and Agency Recalcitrance, *Lisa Heinzerling*

Competitive Enterprise Institute

- CEI's Battered Business Bureau: The Week In Regulation, *Ryan Young*

Feature Story

HHS Retrospective Review Rule Could Save \$654 Million Annually

The Department of Health and Human Services published a [proposed rule](#) that would implement some reforms to existing regulations as prescribed in President Obama's Executive orders [13563](#) and [13610](#). The orders instruct executive branch agencies to examine existing regulations for opportunities to make revisions that would reduce regulatory burdens on the public. "We are proposing to reduce regulatory burden on providers and suppliers by modifying, removing, or streamlining current regulations that we believe are excessively burdensome... This proposed rule would create savings and reduce burden in many areas. Several of the proposed changes would create measurable monetary savings for providers and suppliers, while others would create less tangible savings of time and administrative burden. We estimate one-time savings of \$22 million, and annual recurring savings of \$654 million." Among the proposals listed in the rule are a reduction in the requirements Ambulatory Surgical Centers must meet for the provision of radiological services, the reclassification of dieticians as "practitioners", the streamlining of redundant paperwork requirements, and changes to transplant center re-approval processes. [Comments](#) are due on April 8th.

In the News

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- [Regulators square off on who can sanction trader](#), *Reuters*
- [Industry presses forward on lithium battery rule](#), *The Hill*
- [SEC Settles Insider Trading Case With Houston Man](#), *Bloomberg*
- [FDIC's Norton Wants to Revise Basel III Leverage for Banks](#), *Bloomberg*

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- [Silica Rule Changes Delayed While Workers Face Health Risks](#), *NPR*
- [Exclusive: Watchdog backs off over financial adviser regulation](#), *Reuters*
- [Obama's Interior Pick Seen Promoting Expanded Energy](#), *Bloomberg*
- [Elizabeth Warren Not Ready to Back Down on U.S. Consumer Bureau](#), *Bloomberg*
- [FDA May Relax Guidelines on Early-Stage Alzheimer's Trials](#), *Bloomberg*
- [Stein Says Fed Should Consider Using Rates to Further Stability](#), *Bloomberg*
- [Obama Urged by House Democrats to Replace Fannie Mae's Regulator](#), *Bloomberg*
- [Safety regulator questions FAA's certification of Boeing 787 batteries](#), *The Hill*
- [EPA to issue climate change plan Friday](#), *The Hill*
- [FDA releases guidance for new Alzheimer's drugs](#), *The Hill*
- [Dems renew call for new FHFA head](#), *The Hill*
- [Safety official hints at longer Dreamliner delay](#), *Washington Post*
- [NTSB: Investigation shows gov't approval of Boeing 787's batteries should be reconsidered](#), *Washington Post*
- [US regulators allow Boeing to conduct 787 test flights, over unpopulated areas](#), *Washington Post*



Consumer Financial Protection Bureau

- Consumer Financial Protection Bureau warns mortgage servicers about illegal protections for consumers when transferring loans

Department of Health and Human Services

- Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2012

Federal Regulations Advisor

- Monday Morning Regulatory Review – 2/11/13, *Leland Beck*

Free State Foundation

- A Recent Appeals Court Ruling on Ancillary Power Limits Could Curb Regulatory Overreach, *Seth Cooper*

Foundation for Economic Education

- Rahm's Rule of Crisis Management: A Footnote to the Theory of Regulation, *Bruce Yandle*

The George Washington University Regulatory Studies Center

- What the Unified Agenda Tells Us about Notice and Comment Rulemaking, *Sofie Miller*

Heritage Foundation

- Dodd-Frank: Dismal Findings on Rulemaking, *Diane Katz & Tom Toth*
- Tales of the Red Tape #39: Swapping Wealth Creation for Regulatory Claptrap, *Diane Katz*
- Obamacare Hassle: A 127-Million-Hour Paperwork Burden, *Alyene Senger*

The Mercatus Center

- A Process for Cleaning Up Federal Regulations: Insights from BRAC and the Dutch Administrative Burden Reduction Programme, *Joshua Hall & Michael Williams*

Penn Program on Regulation

- Can Land Use Permit Conditions Constitute a Regulatory Taking?, *Christina Reichert*
- The Regulatory Week in Review: February 8, 2013, *RegBlog Staff*
- How to Interpret a Regulation: First Principles, *Kevin M. Stack*
- Court Strikes Down IRS Program Regulating Tax Professionals, *Lauren-Kelly Devine*

[Marketing of devices that turn guns into 'legal autos' challenges reach of regulations](#), *Washington Post*

[Stein Sees Signs of Excessive Risk Taking in Some Markets](#), *Bloomberg*

[Boeing Allowed More Dreamliner Test Flights by U.S. Regulators](#), *Bloomberg*

[NTSB Head Questions Approval of Boeing Dreamliner Battery](#), *Bloomberg*

[NTSB's 787 Findings May Lead to Boeing Battery Redesign](#), *Bloomberg*

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[Federal safety agency looking at expanding Pontiac brake light recall to 550,000 vehicles](#), *Washington Post*

[As NTSB investigation of Boeing 787 Dreamliner continues, Airbus plans battery switch to sidestep woes](#), *Washington Post*

[Governance by presidential directive is on the move, no Congress required, in Obama's 2nd term](#), *Washington Post*

[Nominee for SEC chairman discloses former clients that could pose conflicts of interest](#), *Washington Post*

[FDA chief says pharmacy oversight at 'critical point'](#), *Washington Post*

[MSHA: Worker crushed under scoop at southern W.Va. mine; victim from Virginia](#), *Washington Post*

[New size limit proposed for sharks; could have big impact on fishing industry](#), *Washington Post*

[HUD finalizes discriminatory lending rules opposed by financial industry](#), *The Hill*

[Court slaps down regulations on decorative furnaces](#), *The Hill*

[EPA moves forward with climate change protection plan, asks for comments](#), *The Hill*

[Browner on Obama Regulating Greenhouse Gases](#), *BloombergTV*

[CBOE in Settlement Talks Over SEC Probe, Sets Aside \\$5 Million](#), *Bloomberg*

[Cangene's Antidote for Terrorism Toxin Works, FDA Staff Says](#), *Bloomberg*

[SEC Nominee White's Disclosure Report Shows Possible Conflicts](#), *Bloomberg*

[US Regulators Revoke Unique Exemption from Compounder in Wake of](#)

[Concerns](#), *Regulatory Focus*

[FDA Draft Guidance Outlines Risk-Based Approach to Assessing Therapeutic Proteins](#), *Regulatory Focus*

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[Obama weighing executive actions on housing, gays and other issues](#), *Washington Post*

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[How Obama is wielding executive power in 2nd term](#), *Yahoo News*

[Novo Nordisk tumbles as US regulators seek more data on potential diabetes drugs](#), *Washington Post*

[Novo Nordisk Insulin Fails to Win FDA's Backing](#), *Bloomberg*

[Novo Nordisk tumbles as US regulators seek new study for potential diabetes drugs](#), *Washington Post*

[Watchdog's report raises concerns about SEC's revolving door](#), *Washington Post*

[Pro-regulation groups urge Obama to call for additional rules](#), *The Hill*

[Watchdog: Former SEC employees helping shield corporations from regulations](#), *The Hill*

[Health law rule on 'essential benefits' sent to White House for final review](#), *The Hill*

[Tougher Northeast CO2 Cap Seen Doubling Revenues by 2020](#), *Bloomberg*

[Bill to Limit Too-Big-to-Fail Risk Is Readied in U.S. House](#), *Bloomberg*

[U.S. Regulators May Want Fewer Banks, Cummings Says](#), *BloombergTV*

[FDA Approves Thalidomide Analog to Treat Multiple Myeloma](#), *Regulatory Focus*

[S.E.C.'s Revolving Door Hurts Its Effectiveness, Report Says](#), *New York Times*



Project on Government Oversight

▪ Dangerous Liaisons: Revolving Door at SEC Creates Risk of Regulatory Capture

THE GEORGE WASHINGTON UNIVERSITY

WASHINGTON, DC
REGULATORY STUDIES CENTER

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['Record-Breaking Year' for Fraud Recovery Has Roots in Regulatory Missteps](#), *Regulatory Focus*

[One Republican's plan for stopping Too Big to Fail](#), *Washington Post*

[Obama vows to flex executive muscle on multiple fronts](#), *The Hill*

[FDIC moves to clarify rules on foreign bank deposits](#), *The Hill*

[Credit unions press lawmakers for regulatory relief](#), *The Hill*

[N.Y. May Issue Fracking Permits Without Final Regulations](#), *Bloomberg*

[FDIC Advances Rule to Keep Deposit Insurance Within U.S.](#), *Bloomberg*

[Innovative Drugs May Win U.S. Approval After Early Trials](#), *Bloomberg*

[CFTC Delays Swaps Vote As Member Voices Concerns](#), *Wall Street Journal*

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[Signaling delay in regulations, NY health official says more time needed to review fracking](#), *Washington Post*

[Contentious meat labeling rule moves to White House](#), *The Hill*

[CFPB moves to help consumers, banks with regulation compliance](#), *The Hill*

[Report calls for national drug-tracking system to counter growing threat of fake medications](#), *Washington Post*

[Monster to Move Drinks to Food Labels: Beverage Digest](#), *Bloomberg*

[U.S. Audit Watchdog Funded by Company Fees Faces Sequester Cuts](#), *Bloomberg*

Rulemaking

Environmental Protection Agency

EPA Proposes Rule Mandating Increased Use of Cellulosic Ethanol in 2013

The Environmental Protection Agency published a [proposed rule](#) setting the renewable fuel standard (RFS) for cellulosic ethanol, advanced biofuels, and total renewable fuel in 2013. The rule, which applies to refineries, petroleum product wholesalers, and ethanol manufacturers, sets the minimum volume standards of cellulosic ethanol to be blended into gasoline. In November of each year, EPA sets the RFS for the following year either above or below the statutory baseline established in the Energy Policy Act of 2005. "The cellulosic biofuel industry is transitioning from research and development (R&D) and pilot-scale to commercial scale facilities, leading to increases in production capacity. Construction has begun on several facilities with multiple facilities having progressed to the start-up phase. Based on detailed information from production companies and a consideration of various potential uncertainties, we are projecting that 14 million ethanol-equivalent gallons of cellulosic biofuel will be available in 2013." Fewer than 500,000 gallons of cellulosic biofuel were produced in 2012, despite regulations requiring the production of 10.5 million gallons in 2012. [Comments](#) are due on March 25th.

EPA Finalizes NESHAPs Rule & Standards of Performance for Portland Cement Manufacturing Industry

The Environmental Protection Agency published a [final rule](#) amending the National Emission Standards for Hazardous Air Pollutants (NESHAPs) for the Portland Cement Manufacturing Industry and the Standards of Performance for Portland Cement Plants. The rule, proposed in July, 2012, will alter the methodology used to measure emission of particulate matter (PM). Accordingly, the Agency estimates this change will save the Portland cement industry \$52 million in compliance costs. "This final action amends the national emission standards for hazardous air pollutants for the Portland cement industry. The EPA is also promulgating amendments with respect to issues on which it granted reconsideration on May 17, 2011. In addition, the EPA is amending the new source performance standard for particulate matter. These amendments promote flexibility, reduce costs, ease compliance and preserve health benefits."

EPA Final Rule Revises CAA Definition of Volatile Organic Compounds (VOCs)

The Environmental Protection Agency published a [final rule](#) revising the definition of volatile organic compounds (VOCs) under the Clean Air Act (CAA). "This revision adds four chemical compounds to the list of compounds excluded from the definition of VOC on the basis that each of these compounds makes a negligible contribution to tropospheric ozone formation... If an entity uses or produces any of these four HFPE compounds (these being in the family of products known by the trade name H-Galden) and is subject to the EPA regulations limiting the use of VOC in a product, limiting the VOC emissions from a facility, or otherwise controlling the use of VOC for



purposes related to attaining the ozone national ambient air quality standards (NAAQS), then the compound will not be counted as a VOC in determining whether these regulatory obligations have been met. This action may also affect whether any of these compounds is considered a VOC for state regulatory purposes, depending on whether the state relies on the EPA's definition of VOC.”

EPA Final Rule Updates National Primary Drinking Water Regulations for Total Coliform

The Environmental Protection Agency published a [final rule](#) revising the Agency's 1989 Total Coliform Rule (TCR) to introduce greater stringency and less frequent monitoring. “The Revised Total Coliform Rule (RTCR) offers a meaningful opportunity for greater public health protection beyond the 1989 TCR. Under the RTCR there is no longer a monthly maximum contaminant level (MCL) violation for multiple total coliform detections. Instead, the revisions require systems that have an indication of coliform contamination in the distribution system to assess the problem and take corrective action that may reduce cases of illnesses and deaths due to potential fecal contamination and waterborne pathogen exposure.” EPA expects to reduce the risk of public drinking water contamination from the 1989 TCR risk baseline. Because *E. Coli* is an indicator of the fecal contamination targeted by this rule, the Agency uses any reduction in *E. Coli* as a result of this rule to be a component of the rule's benefits.

Department of Health and Human Services

HHS Final Rule Mandates Disclosure of Drug Manufacturer Payments to Physicians, Teaching Hospitals

The Department of Health and Human Services published a [final rule](#) that requires certain drug manufacturers to report certain payments and transfers made to physicians and teaching hospitals to the HHS Secretary annually. This disclosure program for payments and transfers to physicians and teaching hospitals is necessary to implement section 6002 of the PPACA, and to make public information on conflicts of interest that could affect treatment decisions. “Based on the comments submitted, we anticipate that much of the total estimated burden of this final rule will fall on applicable manufacturers and applicable [group purchasing organizations]. We have estimated that the total cost of these provisions will be approximately \$269 million in the first year and \$180 million annually thereafter. We have no empirical ability to estimate the monetary benefits of this provision; however, there are nonmonetary benefits, which are difficult to quantify. Increased transparency regarding the extent and nature of relationships between physicians, teaching hospitals, and industry manufacturers will permit patients to make better informed decisions when choosing health care professionals and making treatment decisions, and deter inappropriate financial relationships which can sometimes lead to increased health care costs.”

Department of Commerce

NOAA Withdraws Proposed Rule Requiring Shrimp Trawlers to Install Turtle Excluder Devices

The National Oceanic and Atmospheric Administration is [withdrawing](#) its May, 2012 [proposed rule](#) requiring certain boats that trawl for shrimp to be equipped with Turtle Excluder Devices (TEDs). NOAA intended for the implementation of this proposed rule to prevent incidental bycatch of sea turtles in southeastern shrimp fisheries (all sea turtles in US waters are listed as either endangered or threatened under the Endangered Species Act). The withdrawn regulation would have required all trawlers to be equipped with TEDs, including skimmer trawls, pusher-head trawls, and vessels using wing nets that instead currently abide by tow-time restrictions. After further looking into the matter, NOAA found that “the potential benefits of a TED requirement in the Gulf of Mexico skimmer trawl fisheries are significantly less than previously estimated in the [Draft Environmental Impact Statement]. Therefore, given the potentially significant economic ramifications a TED requirement would have on fishermen participating in the inshore skimmer trawl fisheries combined with highly uncertain ecological benefits to sea turtle populations compared to the status quo based on the new observer data, we concluded a final rule to require all skimmer trawls, pusher-head trawls, and wing nets (butterfly trawls) in the Gulf of Mexico to use TEDs in their nets is not warranted at this time, and are withdrawing our proposed rule.”

Department of Agriculture

FNS Proposes Rule Establishing Stricter Nutrition Standards for Food Sold on School Campuses

The Food and Nutrition Service published a [proposed rule](#) that would amend the National School Lunch Program and School Breakfast Program by setting nutrition standards for foods sold in public schools. These nutrition standards apply to foods sold on school campuses at any time during the school day that are not part of existing school meal programs. The proposed rule would require that any food sold in the school must either meet a requirement for nutritional daily value or be a fruit, vegetable, dairy product, a protein food, a “whole-grain rich”



grain product (50% or more whole grains by weight or have whole grains as the first ingredient), or a combination food that contains at least ¼ cup of fruit or vegetable. Additionally, the proposed rule sets calorie requirements for beverages, including those sold in school vending machines. Under these standards, allowable beverages to be sold in schools are diet sodas, water, milk, 100% juice, and drinks with fewer than 50 calories per 8 oz. serving. The Agency also proposes calorie and fat requirements for foods sold in schools. [Comments](#) are due on April 9th.

Department of Energy

DOE Proposes Rule to Set Energy Efficiency Standards for Residential Boilers

The Department of Energy published a [proposed rule](#) announcing a public meeting and the availability of a [framework document](#) to amend the energy conservation standards for residential boilers. DOE will hold a meeting on Wednesday, March 13th from 9:00am – 2:00pm to discuss the framework document and the need for an amendment to the existing energy conservation standards for residential boilers. The existing standard, promulgated in 2007, was rendered obsolete by the 2007 passage of the Energy Independence and Security Act (EISA), which further specified efficiency standards for residential boilers. “After the public meeting and the close of the comment period on the Framework Document, DOE will collect data, conduct the analyses as discussed in the Framework Document and at the public meeting, and review the public comments it receives. DOE considers public participation to be a very important part of the process for determining whether to amend energy conservation standards and, if so, in setting those amended standards. DOE actively encourages the participation and interaction of the public during the comment period at each stage of the rulemaking process. Beginning with the Framework Document, and during each subsequent public meeting and comment period, interactions with and among members of the public provide a balanced discussion of the issues to assist DOE in the standards rulemaking process.” [Comments](#) are due on March 28th.

Department of Homeland Security

DHS Extends Comment Period for Proposed Rule to Curb Sexual Abuse in DHS Confinement Facilities

The Department of Homeland Security [extended](#) the comment period for its [proposed rule](#), *Standards To Prevent, Detect, and Respond to Sexual Abuse and Assault in Confinement Facilities*. The proposed rule would seek to curb sexual abuse within DHS confinement facilities, which include longer-term immigration detention facilities and shorter-term holding facilities. However, the rule would not apply to contract detention facilities or to state- and locally-run intergovernmental service agreement facilities. “The proposed rule, if made final, would require prevention planning; prompt and coordinated response and intervention; training and education of staff, contractors, volunteers and detainees; proper treatment for victims; procedures for investigation, discipline and prosecution of perpetrators; data collection and review for corrective action; and audits for compliance with the standards.” [Comments](#) are now due on February 26th.

Consumer Financial Protection Bureau

CFPB, OCC, NCUA, FHFA, & Fed Board Finalize Rule Requiring Appraisals for High-Priced Mortgages

The Consumer Financial Protection Bureau, in conjunction with the Office of the Comptroller of the Currency, National Credit Union Administration, Federal Housing Finance Agency, and the Federal Reserve Board, published a [final rule](#) amending Regulation Z (Truth in Lending). The final rule requires appraisals for “higher-risk mortgages”, pursuant to the requirements of the Dodd-Frank Act. “For mortgages with an annual percentage rate that exceeds the average prime offer rate by a specified percentage, the final rule requires creditors to obtain an appraisal or appraisals meeting certain specified standards, provide applicants with a notification regarding the use of the appraisals, and give applicants a copy of the written appraisals used.”

Agencies

Food and Drug Administration

FDA Seeks Comment on Draft Strategic Plan for Drug Shortages

The Food and Drug Administration published a [notice](#) seeking comments from the public for the FDA’s draft strategic plan for drug shortages. The draft strategic plan will include “Plans for ensuring that drug shortages are considered when the Secretary initiates a regulatory action that could precipitate a drug shortage or exacerbate an existing drug shortage; Plans for effective communication with outside stakeholders, including who the Secretary should alert about potential or actual drug shortages, how the communication should occur, and what types of



information should be shared; [and] Plans for considering the impact of drug shortages on research and clinical trials.” FDA is seeking comments on how to expand manufacturer capacity, incentives FDA can provide to discourage drug shortages, the impact of drug shortages, and any other actions the Agency could be taking to reduce shortages. [Comments](#) are due on March 14th.

FDA Publishes Guidance on Civil Money Penalties for Tobacco Retailers

The Food and Drug Administration published a [notice](#) announcing the availability of a [draft guidance](#) for industry entitled *Civil Money Penalties for Tobacco Retailers: Responses to Frequently Asked Questions*. This draft guidance provides responses to questions FDA has received regarding the issuance of civil money penalties for violations of regulations issued under the Food and Drug Act relating to tobacco products in retail outlets. “In this draft guidance, FDA provides responses to questions relating to civil money penalties for violations of the requirement that tobacco products may not be sold or distributed in violation of FDA’s “Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents”. This draft guidance also provides additional information regarding the complaint procedure used for civil money penalties.” [Comments](#) are due on April 9th.

Environmental Protection Agency

EPA Announces February 27th Meeting of the Clean Air Act Advisory Committee

The Environmental Protection Agency published [notice](#) announcing an open meeting of the Clean Air Act Advisory Committee (CAAAC) on Wednesday, February 27th from 8:30am – 4:00pm. “The Clean Air Act Advisory Committee (CAAAC) is a senior-level policy committee established in 1990 to advise the U.S. EPA on issues related to implementing the Clean Air Act Amendments of 1990. The CAAAC meets three times a year, normally in Washington, D.C. It provides advice and counsel to EPA on a variety of important air quality policy issues.”

