

February 2016 HHS Retrospective Review Update

The Department of Health and Human Services (HHS) continues to make progress in its retrospective review work, as directed by the President's Executive Orders (EOs) 13563 (*Improving Regulation and Regulatory Review*) and 13610 (*Identifying and Reducing Regulatory Burdens*). This February 2016 update highlights three published rules, four rules we anticipate publishing later this year and two new rules. In sum, the update reflects HHS's regulatory accomplishments over the past six months, and highlights its remaining work to improve access to quality of care for the American people while reducing costs.

Published: Medicaid Covered Outpatient Drugs

In January 2016, the Center for Medicare and Medicaid Services (CMS) issued a final rule implementing several provisions of the Affordable Care Act pertaining to prescription drugs under the Medicaid program. The rule revises the rebate formulas for covered outpatient drugs, the definition of average manufacturer price and the Federal Upper Payment Limits for multiple source drugs.

As of 2012, CMS estimated that the rule would save approximately \$17.7 billion for FY 2014, reflecting \$13.7 billion in federal savings and \$4 billion in state savings. These estimates represented the increased percentages of rebates on generic and brand name drugs, the treatment of new formulations, the change in the maximum rebate amounts, the extension of rebate collection for Medicaid managed care organizations, and provides for adequate pharmacy reimbursement.

Published: Hazard Analysis and Risk-Based Preventative Controls for Human Food

In September 2015, FDA published a final rule requiring food facilities to have and implement preventive controls to significantly minimize or prevent the occurrence of hazards that could affect food manufactured, processed, packed, or held by the facility. The final rule is a significant milestone in FDA's ongoing, public health protection efforts. The rule modernizes current good manufacturing practices for food; it is intended to prevent – or at a minimum, quickly identify – food-borne pathogens before entrance into the food supply. The rule includes modified compliance provisions for small and very small businesses and farms.

Published: Medical Examination of Aliens

The Centers for Disease Control and Prevention (CDC), through HHS, issued a final rule in January 2016 to update the definition of “communicable disease of public health significance” by removing three minor and uncommon bacterial sexually transmitted infections (*chancroid*, *granuloma inguinale*, and *lymphogranuloma venereum*). Other changes are technical and administrative in nature and include: updating the notification of the health-related grounds of inadmissibility to include proof of vaccinations to align with existing requirements established by the Immigration and Nationality Act; and clarifying and revising the evaluation requirements for tuberculosis to reflect current terminology and practice.

Anticipated: Flexibility, Efficiency and Modernization of Child Support Enforcement Programs

By Spring 2016, the Administration for Children and Families (ACF) plans to finalize a rule that would make child support program operations and enforcement procedures more flexible and more efficient by recognizing advancements in technology and the move toward electronic communications and document management. The rule advances HHS' department-wide regulatory goal of assisting working families secure the building blocks for success at every stage of life. The rule would improve document management by allowing states to submit and accept information electronically; increase statutory state law exemption approval periods from three to five years; update case closure criteria to increase state flexibility and facilitate effective transfer between states and tribes; and, discontinue the mandate for states to notify other states involved in enforcing a support order when they submit an interstate case for offset.

Anticipated: Programs of All-Inclusive Care for the Elderly (PACE) Update

By Summer 2016, CMS plans to issue a proposed rule updating the PACE regulations published on December 8, 2006. The rule would improve the quality of the existing regulations, provide operational flexibility and modifications, and remove redundancies and outdated information. These updates are intended to ensure the health and safety of PACE participants.

Anticipated: Food Nutrition Labeling

By Spring 2016, FDA plans to issue a proposed rule that would revise and update food labeling regulations to make nutrition information on packaged food more useful to consumers. This rulemaking would modernize the nutrition information found on the Nutrition Facts label, as well as the format and appearance of the label, to help consumers maintain healthy dietary practices. Annualized over 20 years, the labeling cost associated with the proposed rules is \$122 million per year at a 3 percent discount rate and \$165 million per year at a 7 percent discount rate. We estimate benefits annualized over 20 years at \$2.0 billion per year assuming a 3 percent discount rate and \$1.9 billion per year assuming a 7 percent discount rate.

Anticipated: Federal Workplace Drug Testing Hair Mandatory Guidelines

By Spring 2016, the Substance Abuse and Mental Health Services Administration (SAMHSA) plans to issue the final Federal Workplace Drug Testing Oral Fluid Mandatory Guidelines (OFMG). The OFMG will allow Executive Branch agencies and the regulated industry to implement an alternative testing process that is less intrusive and more cost/time effective when compared to the current urine-based testing program. The use of an electronic chain-of-custody form will also reduce the administrative burden of participating in this program. The OFMG will lessen the administrative and financial burden of workplace drug testing, since they will provide flexibility to use oral fluid testing in addition to existing urine testing procedures.

New: Freedom of Information Act Regulations

Before July 2016, HHS, through the Office of the Assistant Secretary for Public Affairs (ASPA) plans to issue proposed revisions to, and republication of, its regulations implementing the Freedom of Information Act (FOIA). The regulations are being revised in order to incorporate changes made to the FOIA by the Openness Promotes Effectiveness in our National Government Act of 2007 (OPEN Government Act) and the Electronic FOIA Act of 1996 (E-FOIA Act). Additionally, the regulations are being updated to reflect changes to the organization, to make the FOIA process easier for the public to navigate, to update HHS's fee schedule, and to make provisions clearer.

New: Increase the Highest Patient Limit for Qualified Physicians to Treat Opioid Use Disorder with Buprenorphine

SAMHSA has announced a proposed rule to increase the highest patient limit for qualified physicians to treat opioid use disorder with buprenorphine. The rule, if finalized, will expand access to medication-assisted treatment (MAT) by allowing eligible practitioners to request a waiver to treat additional patients under Federal law. It provides practitioners with needed flexibility to treat more patients in emergency circumstances. The rule also includes requirements to ensure that patients receive the full array of services composing evidence-based MAT and minimize the risk of misuse, addiction and diversion. SAMHSA plans to issue the proposed rule by Summer 2016.