

HEALTH POLICY MONITOR

Polsinelli
Shughart

Update for January 30, 2013

Top News

CMS, IRS Issue Proposed Rules on Health Insurance Mandate, Minimum Essential Coverage

CMS and the IRS on January 30 issued proposed rules that address the Affordable Care Act's (ACA) minimum essential coverage requirement. Beginning in 2014, the ACA requires that each individual have basic health insurance, qualify for an exemption, or pay a penalty when filing a federal income tax return. This "shared responsibility payment" does not apply to taxpayers who cannot afford health insurance coverage or have a "good cause" for being uninsured for a short time. To implement this principal, the rule enumerates several situations in

which an exemption would apply. For example, the penalty would not apply to who would be eligible for Medicaid but for a state's decision not to expand eligibility. The proposed rule includes nine categories of individuals who are exempt from the penalty: individuals who cannot afford coverage; taxpayers with income below the filing threshold; members of Indian tribes; hardship; individuals who experience short coverage gaps; religious conscience; members of a health care sharing ministry; incarcerated individuals; and individuals who are not lawfully present.



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The regulations also provide details on a verification and eligibility determination process for these categories of exemptions, an option for state-based exchanges to use a federally-managed service for conducting eligibility determinations for exemptions (instead of the exchange handling this independently), procedures for addressing changes in eligibility for exemptions during a calendar year, exchange reporting to IRS, and other supporting functions.

The regulations also detail that minimum essential coverage includes the following types of coverage: employer-sponsored coverage (including COBRA coverage and retiree coverage), coverage purchased in the individual market Medicare Part A coverage, Medicaid coverage, Children's Health Insurance Program (CHIP) coverage, certain types of Veterans health coverage, and TRICARE. Comments on the Treasury proposed regulations are due by May 2, 2013, and a public hearing will be held May 29, 2013. Comments on the HHS proposed regulations are due by March 18, 2013. Additional details are available [here](#).

Insurers Weigh Options for Exchange Participation

Like other health insurers, United Health Group and WellPoint are considering their options for participating in the health reform law's insurance exchanges. During recent earnings calls with investors, the insurers said they were investigating the marketplace to determine where to operate. United Health Group CEO Stephen Hemsley said that he expects United will broadly participate in the exchanges and estimated it will compete in 10 to 25 exchanges. However, he said that any decision to participate in an exchange would be based on local market conditions. WellPoint Executive Vice President Kenneth Goulet said the insurer will investigate participating in state exchanges where it already operates a Blues plan but would not commit to

competing in all state exchanges. "We're working with our regulators in each market. It ultimately does come down to a decision on how we work with our regulators, but we do anticipate using our advantages in all markets," he said.

Quality Improvements in Care Transitions Show a Significant Reduction in Re-hospitalizations

A CMS pilot program that facilitated care transition for beneficiaries discharged from hospitals helped lower readmission rates, according to a study recently published in the Journal of the American Medical Association. The study compared 14 selected communities against 50 similar communities and compared re-hospitalization outcomes to determine if state-based Quality Improvement Organizations could improve community-wide quality by working with hospitals and other providers to improve care transitions. The study found that "all-cause 30-day re-hospitalizations" and "all-cause hospitalizations" were about 6 percent lower in the intervention communities. The study, "Association Between Quality Improvement for Care Transitions in Communities and Rehospitalizations Among Medicare Beneficiaries" is available [here](#).



Pew Charitable Trust Proposes Compounding Quality Standards

Congress should direct the FDA to develop quality standards for compounding that bridge the gap between the drug manufacturing standards and the less stringent U.S. Pharmacopeia (USP) standards that some states use. The FDA is soliciting input on developing and enforcing quality standards for “non-traditional” high risk compounding. According to Pew, the USP standards may not be suitable for the high-risk, large-scale compounding that the FDA is focusing on. In comments to the FDA, Pew wrote: “Congress should direct the FDA to establish minimum standards for quality and safety in compounding, which may vary depending on the risk-level of compounding activity. Application of the [Current Good Manufacturing Practice standards] may be appropriate for some activities, but there may also be a need to establish standards that, while not requiring the full GMP, set uniform requirements that are stronger than existing standards such as USP 797.”

State News

Providers File Appeal to Block Medi-Cal Cuts

The California Medical Association filed a request with the Ninth Circuit Court of Appeals to stop California from implementing a 10 percent cut to Medi-Cal provider reimbursement rates. A three-judge panel of the Ninth Circuit ruled that the state could move forward with the rate cuts, which were passed by the legislature in the spring of 2011. The three-judge panel ruling overturned an earlier district court ruling that found that the cuts would irreparably harm Medi-Cal patients. CMA and the other plaintiffs in the case are requesting a rehearing in front of the full Ninth Circuit Court of

Appeals. The other plaintiffs are: California Hospital Association, California Dental Association, California Pharmacists Association, National Association of Chain Drug Stores, California Association of Medical Product Suppliers, AIDS Healthcare Foundation and American Medical Response. Additional details are available [here](#).

Kaiser Survey Finds States Upgrading Medicaid Enrollment Systems

Almost every state is using federal funds made available through the Affordable Care Act to develop or upgrade electronic systems to handle Medicaid eligibility determinations and enrollment, according to a Kaiser Commission on Medicaid and the Uninsured. The annual survey found that states are implementing a number of improvements to streamline Medicaid enrollment regardless of whether or not the state intends to participate in the Affordable Care Act’s Medicaid expansion. As of January 1, 47 states had submitted applications to CMS to implement enrollment system upgrades. Forty-two states have started upgrading their enrollment systems to facilitate online applications for Medicaid or CHIP. “Our survey shows that the states already are making significant advances to modernize the Medicaid enrollment



process in 2014 to lower barriers to coverage and reduce administrative burdens for both families and states,” said Kaiser Family Foundation Executive Vice President Diane Rowland. The report is available [here](#).

Regulatory News

CMS Updating Manuals, Plans Education Campaign, on Improvement Standard Settlement

CMS is revising its policy manuals to reflect a recent court settlement that ended the use of the improvement standard for processing claims for skilled home care, therapy and nursing home care. The settlement, which was finalized by a U.S. District Court in Vermont on January 24, ended CMS’ unofficial policy that a beneficiary’s condition must continually improve for Medicare to pay for such care. The manual update is expected to take six months and will emphasize that the improvement standard is not CMS policy and should not be enforced by its contractors. Once the manual is updated, CMS will conduct an education campaign that will include written communications with contractors, all levels of the Medicare appeals system, Quality Improvement Organizations, and providers to clarify the situation. CMS also will sample claims to ensure that contractors and Medicare Advantage plans are complying with the update. “The whole purpose of the education campaign is to drum into the providers and contractors” that the improvement standard does not exist, said Gill Deford, with the Center for Medicare Advocacy.

HHS, Treasury, and Labor Department Posts FAQs Regarding ACA Implementation

HHS, the Labor Department and the Treasury Department posted a set of frequently asked questions to a website that addresses questions related to the employer notice of coverage options, health reimbursement arrangements, disclosure of information related to firearms, employer group waiver plans supplementing Medicare Part D, fixed indemnity insurance and payment of PCORI fees. The FAQs are available [here](#).

HHS Offers Guidelines for HIPAA Compliance

HHS’ Office of Civil Rights published guidelines for the preparation of business associate agreements to comply with the new HIPAA requirements that were released earlier this month. The HIPAA Rules generally require that covered entities and business associates enter into contracts with their business associates to ensure that the business associates will appropriately safeguard protected health information. The guidelines are available [here](#). A summary of the HIPAA Privacy Rule is available [here](#).



Additional Reading

- *GAO (report): [Private Health Insurance: Expiration of the Health Coverage Tax Credit Will Affect Participants' Costs and Coverage Choices as Health Reform Provisions are Implemented](#)*
- *GAO (report): [Expiration of the Health Coverage Tax Credit Will Affect Participants' Costs and Coverage Choices as Health Reform Provisions Are Implemented](#)*
- *Kaiser Health News: [Long-Term Care Ombudsmen Face Challenges to Independence](#)*
- *Kansas Health Institute: [Lawmakers and Providers Assess KanCare Transition](#)*
- *Kansas City Star: [Health Law Means Free Clinics Have to Accept Payments](#)*
- *MedPage Today: [Patients Suffer if Hospitalists Overworked](#)*
- *Missouri Hospital Association: [\\$4 Billion In Cuts Would Damage Hospitals, Harm Missouri Communities](#)*
- *New York Times: [Biotech Firms, Billions at Risk, Lobby States to Limit Generics](#)*
- *Stateline (Pew Center on the States): [Future of Health Law is Largely in State Hands](#)*
- *St. Louis Beacon: [Nixon Uses State of the State to Press for Medicaid Expansion, More Education Spending](#)*
- *Washington Post: [Health Care Among the Early Leaders as 'Obamacare' Starts to Become a Reality](#)*
- *Washington Post: [Legislators Worry About Costs as They Weigh Expanding Medicaid to Cover Low-Income Adults](#)*

Federal Register

AHRQ published a notice regarding a proposed collection of information project entitled “Evaluating the Knowledge and Educational Needs of Students of Health Professions on Patient-Centered Outcomes Research” that has been submitted to the OMB for review and approval. Comments will be accepted for 60 days following publication. The notice, available [here](#), appeared in the January 28 Federal Register.

AHRQ published a notice regarding a proposed collection of information project entitled “Applying Novel Methods to Better Understand the Relationship Between Health IT and Ambulatory Care Workflow Redesign.” Comments will be accepted for 60 days following publication. The notice, available [here](#), appeared in the January 28 Federal Register

AHRQ published a notice soliciting nominations for both a time-limited work group and a standing work group to be convened by an AHRQ contractor. The work groups will be comprised of individuals with knowledge of the AHRQ Quality Indicators (QIs), their technical specifications, and associated methodological issues. The goals of each group are to provide feedback to AHRQ regarding refinements to the QIs. To ensure consideration, nominations must be received no later



than March 15, 2013. The notice, available [here](#), appeared in the January 28 Federal Register.

CDC published a notice regarding a proposed collection of information project entitled “Management Information System for Comprehensive Cancer Control Programs” that has been submitted to the OMB for review and approval. Comments will be accepted for 30 days following publication. The notice, available [here](#), appeared in the January 25 Federal Register.

CDC published a notice announcing an upcoming public meeting of the Advisory Committee on Immunization Practices. The meeting will be held February 20-21, 2013 in Atlanta, GA and via webcast. The notice, available [here](#), appeared in the January 25 Federal Register.

CDC published a notice announcing an upcoming public meeting of the Clinical Laboratory Improvement Advisory Committee. The meeting will be held March 6-7, 2013 in Atlanta, GA. Preregistration is required. The notice, available [here](#), appeared in the January 30 Federal Register.

CDC published a notice regarding a proposed collection of information project entitled “The National Hospital Care Survey” that has been submitted to the OMB for review and approval. Comments will be accepted for 30 days following publication. The notice, available [here](#), appeared in the January 30 Federal Register.

CMS published a notice regarding a proposed collection of information project entitled “Standards Related to Reinsurance, Risk Corridors and Risk Adjustment” that has been submitted to the OMB for review and approval. Comments will be accepted for 60 days following publication. The notice, available [here](#), appeared in the January 25 Federal Register.

CMS published a notice soliciting information regarding hospital outpatient surgery departments and ambulatory surgery centers, as well as patient-reported outcomes from surgeries or other procedures performed in these settings. CMS is developing a standardized Hospital Outpatient Surgical Department/Ambulatory Surgical Center Experience of Care Survey to evaluate the care received in these facilities from the patient's perspective. To ensure consideration, information solicited in this notice must be received by March 26, 2013. The notice, available [here](#), appeared in the January 25 Federal Register.

CMS published a notice soliciting information regarding patient and family member or close friend experiences with hospice care. CMS is in the process of reviewing potential topic areas, as well as publicly available instruments and measures, for the purpose of developing a Hospice Survey that will enable objective comparisons of hospice experiences across the country. The information solicited in this notice must be received by March 26, 2013. The notice, available [here](#), appeared in the January 25 Federal Register.



CMS published a notice regarding a proposed collection of information project entitled “Data Collection to Support Eligibility Determinations and Enrollment for Employees in the Small Business Health Options Program” that has been submitted to the OMB for review and approval. Comments will be accepted for 30 days following publication. The notice, available [here](#), appeared in the January 29 Federal Register.

CMS published a notice regarding a proposed collection of information project entitled “Data Collection to Support Eligibility Determinations and Enrollment for Small Businesses in the Small Business Health Options Program” that has been submitted to the OMB for review and approval. Comments will be accepted for 30 days following publication. The notice, available [here](#), appeared in the January 29 Federal Register.

CMS published a notice regarding a proposed collection of information project entitled “Data Collection to Support Eligibility Determinations for Insurance Affordability Programs and Enrollment through Affordable Insurance Exchanges, Medicaid and Children’s Health Insurance Program Agencies” that has been submitted to the OMB for review and approval. Comments will be accepted for 30 days following publication. The notice, available [here](#), appeared in the January 29 Federal Register.

CMS published a notice correcting the comment period on the proposed rule entitled “Medicaid, Children’s Health Insurance Programs, and Exchanges: Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes for Medicaid and Exchange Eligibility Appeals and Other Provisions Related to Eligibility and Enrollment for Exchanges, Medicaid and CHIP, and Medicaid Premiums and Cost Sharing” that appeared in the January 22 Federal Register. The correct comment period ending date is February 21, 2013. The notice, available [here](#), appeared in the January 30 Federal Register.

CMS published a notice regarding a proposed collection of information project entitled “Report of a Hospital Death Associated with Restraint or Seclusion” that has been submitted to the OMB for review and approval. Comments will be accepted for 30 days following publication. The notice, available [here](#), appeared in the January 30 Federal Register.

CMS published a notice regarding a proposed collection of information project entitled “Prepaid Health Plan Cost Report” that has been submitted to the OMB for review and approval. Comments will be accepted for 60 days following publication. The notice, available [here](#), appeared in the January 30 Federal Register.

CMS published a notice regarding a proposed collection of information project entitled “Medicare Provider Cost Report Reimbursement Questionnaire” that has been submitted to the OMB for review and approval. Comments will be accepted for 60 days following publication. The notice, available [here](#), appeared in the January 30 Federal Register.



FDA published a proposed rule entitled “Medical Devices; Ophthalmic Devices; Classification of the Scleral Plug.” The FDA is proposing to classify the scleral plug into class II (special controls), and proposing to exempt the scleral plugs composed of surgical grade stainless steel from premarket notification (510(k)) and to continue to require premarket notification (510(k)) for all other scleral plugs. Comments will be accepted until April 25, 2013. The notice, available [here](#), appeared in the January 25 Federal Register.

FDA published a notice regarding a proposed collection of information project entitled “Pretesting of Tobacco Communications” that has been submitted to the OMB for review and approval. Comments will be accepted for 30 days following publication. The notice, available [here](#), appeared in the January 25 Federal Register.

FDA published a notice announcing an upcoming meeting of the Vaccines and Related Biological Products Advisory Committee. The meeting will be held on February 27, 2013 in Rockville, MD. The notice, available [here](#), appeared in the January 25 Federal Register.

FDA published a notice announcing the availability of grant funds for the support of the Center for Devices and Radiological Health radiation protection program. The goal of the “2013 Assuring Radiation Protection” will be to coordinate federal, state and tribal activities to achieve effective solutions to present and future radiation control problems. The application due date is April 1, 2013, the anticipated start date is May 1, 2013, the opening date is January 28, 2013, and the expiration date is April 2, 2013. The notice, available [here](#), appeared in the January 28 Federal Register.

FDA published a notice announcing the availability of guidance for industry entitled “Premarket Evaluation in Early-Phase Clinical Studies and Recommendations for Labeling.” This guidance is intended to assist the pharmaceutical industry and other investigators engaged in new drug development in evaluating how variations in the human genome, specifically DNA sequence variants, could affect a drug’s pharmacokinetics (PK), pharmacodynamics (PD), efficacy, or safety. The notice, available [here](#), appeared in the January 28 Federal Register.

FDA published a notice announcing an upcoming public conference entitled “Detecting and Evaluating Drug-Induced Liver Injury; What’s Normal, What’s Not, and What Should We Do About It?” The conference will be held March 20-21, 2013 in Hyattsville, MD. Preregistration is required. The notice, available [here](#), appeared in the January 25 Federal Register.

FDA published a notice soliciting comments supported by scientific evidence regarding what changes, if any, to the smokeless tobacco product warnings would promote greater public understanding of the risks associated with the use of smokeless tobacco products. To ensure consideration, comments must be received no later than April 1, 2013.



FDA published a notice announcing an upcoming public meeting of the Science Board. The meeting will be held on February 27, 2013 at the FDA White Oak Campus in Silver Spring, MD and via webcast. The notice, available [here](#), appeared in the January 30 Federal Register.

HHS published a notice soliciting nominations for organizations to serve as non-voting liaison representatives to the Chronic Fatigue Syndrome Advisory Committee. Organizations will be designated to occupy the positions for a two-year term to commence during the 2013 calendar year. Nominations of qualified organizations are being sought for three non-voting liaison representative positions. Nominations must be received no later than February 22, 2013. The notice, available [here](#), appeared in the January 25 Federal Register.

HHS published a notice regarding a proposed collection of information project entitled “SF-424 Research & Related (R&R)” that has been submitted to the OMB for review and approval. The SF-424 Research and Related Information Collection is an information collection comprised of a set of standardized forms used for grant applications to research-based entities. Comments will be accepted for 60 days following publication. The notice, available [here](#), appeared in the January 28 Federal Register.

HHS published a notice announcing the following upcoming public meetings of the President’s Advisory Council on Faith-Based and Neighborhood Partnerships. Meetings will be held via conference call on Wednesday, February 13th, 4:00 p.m.-5:30 p.m. (EST); Wednesday, February 27th, 4:00 p.m.-5:30 p.m. (EST.); and Wednesday, March 13th, 4:00 p.m.-5:30 p.m. (EDT). The notice, available [here](#), appeared in the January 29 Federal Register.

HHS published a notice regarding a proposed collection of information project entitled “Voluntary Academic and Industry DHHS Partner Surveys” that has been submitted to the OMB for review and approval. Comments will be accepted for 60 days following publication. The notice, available [here](#), appeared in the January 30 Federal Register.

HRSA published a notice regarding a proposed collection of information project entitled “Opportunities to Apply a Department of Health and Human Services Message Library to Advance Understanding About Toddler and Preschool Nutrition and Physical Activity” that has been submitted to the OMB for review and approval. Comments will be accepted until February 19, 2013. The notice, available [here](#), appeared in the January 29 Federal Register.

IRS published two notices correcting a proposed rule and notice of hearing entitled “Rules Relating to Additional Medicare Tax” that appeared in the December 5, 2012 Federal Register. The notices, available [here](#) and [here](#), appeared in the January 30 Federal Register.

NIH published a notice announcing the requirements and registration



information for the 2013 National Institute of Biomedical Imaging and Bioengineering DEsign by Biomedical Undergraduate Teams (DEBUT) Challenge. The DEBUT Challenge is open to teams of undergraduate students working on projects that develop innovative solutions to unmet health and clinical problems under one of the following categories: 1) Diagnostic Devices/Methods; 2) Therapeutic Devices/Methods; and 3) Technology to Aid Underserved Populations and Individuals with Disabilities. The competition begins January 25, 2013. Entries will be accepted from January 28 through June 6, 2013. The notice, available [here](#), appeared in the January 25 Federal Register.

NIH published a notice extending the comment period on a proposed collection of information project entitled “National Institutes of Health Information Collection Forms to Support Genomic Data Sharing for Research Purposes” that published in the October 5, 2012 Federal Register. The comment period has been extended an additional 30 days. The notice, available [here](#), appeared in the January 29 Federal Register.

SAMHSA published a notice announcing an upcoming public meeting of the Center for Substance Abuse Prevention. The meeting will be held February 11-12, 2013 in Rockville, MD and via telephone conference. Preregistration is required. The notice, available [here](#), appeared in the January 25 Federal Register.



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About Polsinelli Shughart's Health Care Group

The Health Care group has vast national resources and strong Washington, D.C. connections. With highly trained, regulatory-experienced attorneys practicing health care law in offices across the country, we are familiar with the full range of hospital-physician lifecycle and business issues confronting hospitals today. A mix of talented, bright, young attorneys and seasoned attorneys, well known in the health care industry, make up our robust health care team.

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