| **Lead Agency: SHORT TITLE**  **Reference Number; Title of Reg/Agency Action** | **Agency release date; due date for comments** | **Agency’s Summary of Action** | **Notes:** |  |
| --- | --- | --- | --- | --- |
| **Open Regulatory Items / Pending Action** | | | | |
| **Stage 3 Definition of Meaningful Use of EHRs**  **HHS (no reference number)**  Request for Comment  Regarding the Stage 3 Definition of  Meaningful Use of Electronic Health  Records (EHRs) | **Released:** 11/26/2012  **Due date**: **1/14/2013** | This notice announces the request of the Health Information Technology (HIT) Policy Committee, HHS Office of the National Coordinator for Health Information Technology (ONC), for comments on its draft recommendations for meaningful use Stage 3. | Comments will not be filed. |  |
| **FEHBP Coverage for Certain Intermittent Employees**  **OPM RIN 3206-AM74**  Federal Employees Health Benefits Program Coverage for Certain Intermittent Employees | **Released: 11/14/2012**  **Due date: 1/14/2013** | This interim final rule amends Federal Employees Health Benefits Program (FEHBP) regulations to make certain employees who work on intermittent schedules qualify for enrollment in a health benefits plan under FEHBP. This rule is intended to allow agencies such as the Federal Emergency Management Agency (FEMA) to apply to OPM for authorization to offer FEHBP coverage to intermittent employees engaged in emergency response functions. |  |  |
| **Compliance with Individual and Group Market Reforms**  **CMS-10430**  PRA Request for Comment | **Released:** 11/21/2012  **Due date**: **1/22/2013** | 1. *Type of Information Collection Request*: Reinstatement of a previously approved collection; *Title*: Information Collection Requirements for Compliance with Individual and Group Market Reforms under Title XXVII of the Public Health Service Act; *Use*: The provisions of title XXVII of the Public Health Service Act (PHS Act) promote access to health insurance and reduce allowable limitations on coverage. Sections 2723 and 2761 of the PHS Act direct CMS to enforce title XXVII with respect to health insurance issuers when a state has notified CMS that it has not enacted legislation to enforce or that it is not otherwise enforcing a provision (or provisions) of the individual and group market reforms with respect to health insurance issuers, or when CMS has determined that a state is not substantially enforcing one or more of those provisions. This collection also pertains to notices issued by individual and group health insurance issuers and self-funded non-Federal governmental plans. **This collection includes the issuance of certificates of creditable coverage**; notification of preexisting condition exclusions; **notification of special enrollment rights;** and review of issuer filings of individual and group market products or similar Federal review in cases in which a state is not enforcing a title XXVII individual or group market provision. | Prepare comments after comments are considered for CMS-9972-P  Doneg to prepare first draft by 1/15/2013. |  |
| **MACPro: New CMS Online System for State Plan Amendments, Waivers, etc.**  **CMS-10434** | **Released 12/21/2012**  **Due date:**  **1/22/2012, 5:00 pm** | *Type of Information Collection Request:* New collection (request for a new OMB control number). *Title of Information Collection:* Medicaid and CHIP Program (MACPro). *Use:* Medicaid, authorized by Title XIX of the Social Security Act and, CHIP, reauthorized by the Children’s Health Insurance Program Reauthorization Act of 2009 (CHIPRA), play an important role in financing health care for approximately 48 million people throughout the country. By 2014, it is expected that an additional 16 million people will become eligible for Medicaid and CHIP as a result of the Affordable Care Act (Pub. L. 111–148). In order to implement the statute, CMS must provide a mechanism to ensure timely approval of Medicaid and CHIP state plans, waivers and demonstrations, and provide a repository for all Medicaid and CHIP program data that supplies data to populate Healthcare.gov and other required reports. Additionally, 42 CFR 430.12 sets forth the authority for the submittal and collection of state plans and plan amendment information. Pursuant to this requirement, CMS has created the MACPro system.  Generally, MACPro will be used by both state and CMS officials to: Improve the state application and federal review processes, improve federal program management of Medicaid programs and CHIP, and standardize Medicaid program data. More specifically, it will be used by state agencies to (among other things): (1) Submit and amend Medicaid state plans, CHIP state plans, and Information System Advanced Planning Documents, and (2) submit applications and amendments for state waivers, demonstration, and benchmark and grant programs. It will be used by CMS to (among other things): (1)  Provide for the review and disposition of applications, and (2) monitor and track application activity. A paper-based version of the MACPro instrument would be sizable and time consuming for interested parties to follow as a paper-based instrument. In our effort to provide the public with the most efficient means to make sense of the MACPro system, we held four webinars in lieu of including a paper based version of MACPro. | One issue is whether the requirements to consult with Tribes is identified clearly and easily in MACPro.  Jennifer to prepare initial draft by 1/15/2013. |  |
| **~~Fiscal Soundness Reporting Requirements~~**  **~~CMS-906~~**  ~~PRA Request for Comment~~  [~~http://www.gpo.gov/fdsys/pkg/FR-2012-12-21/pdf/2012-30749.pdf~~](http://www.gpo.gov/fdsys/pkg/FR-2012-12-21/pdf/2012-30749.pdf) | **~~Released:~~** ~~12/21/2012~~  **~~Due date: 1/22/2013~~** | ~~1.~~ *~~Type of Information Collection Request~~*~~: Revision of a currently approved collection;~~ *~~Title~~*~~: The Fiscal Soundness Reporting Requirements;~~ *~~Use~~*~~: CMS oversees the ongoing financial performance for all Medicare Advantage Organizations (MAO), Prescription Drug Plan (PDP) sponsors, and Program of All-Inclusive Care for the Elderly (PACE) organizations. CMS needs the requested collection of information to establish that contracting entities within those programs maintain fiscally sound organizations. The revised fiscal soundness reporting form combines MAO, PDP, 1876 Cost Plans, Demonstration Plans, and PACE organizations. Entities contracting in these programs currently submit all of the documentation requested. Specifically, all contracting organizations must submit annual independently audited financial statements one time per year. MAOs with a net loss, a negative net worth, or both must file three quarterly statements. Currently, approximately 44 MAOs file quarterly financial statements. PDPs also must file three unaudited quarterly financial statements. PACE organizations must file 3 quarterly financial statements for the first three years in the program, and PACE organizations with a net loss, a negative net worth, or both must file statements as well. The revised information request includes one additional data element for PACE organizations, Total Subordinated Liabilities.~~ |  |  |
| **~~Report of a Hospital Death Associated with Restraint or Seclusion~~**  **~~CMS-10455~~**  ~~PRA Request for Comment~~ | **~~Released:~~** ~~11/21/2012~~  **~~Due date~~**~~:~~ **~~1/22/2013~~** | ~~2.~~ *~~Type of Information Collection Request~~*~~: New collection;~~ *~~Title~~*~~: Report of a Hospital Death Associated with Restraint or Seclusion; Use: A CMS rule published on May 16, 2012 (77 FR 29034), included a reduction in the reporting requirement related to hospital deaths associated with the use of restraint or seclusion. Under this rule, hospitals no longer have to report to CMS deaths where no use of seclusion occurred and the only restraint involved 2-point soft wrist restraints. This will reduce the volume of reports submitted by an estimated 90 percent for hospitals. In addition, this rule replaced the previous requirement for reporting via telephone to CMS with a requirement that allows submission of reports via telephone, facsimile, or electronically. This rule also reduced the amount of information that CMS needs for each death report.~~ |  |  |
| **Medicare Uniform Institutional Provider Bill**  **CMS-1450**  PRA Request for Comment | **Released:** 11/21/2012  **Due date**: **1/22/2013** | 1. *Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Medicare Uniform Institutional Provider Bill and Supporting Regulations in 42 CFR 424.5; Use: Section 42 CFR 424.5(a)(5) requires providers of services to submit a claim for payment prior to any Medicare reimbursement. Charges billed are coded by revenue codes. The bill specifies diagnoses according to the International Classification of Diseases, Ninth Edition (ICD-9-CM) code. Inpatient procedures are identified by ICD-9-CM codes, and outpatient procedures are described using the CMS Common Procedure Coding System (HCPCS). These are standard systems of identification for all major health insurance claims payers. Submission of information on CMS-1450 permits Medicare intermediaries to receive consistent data for proper payment. |  |  |
| **Medicare Enrollment Application for Clinics/Group Practice and Certain Other Suppliers**  **CMS-855B**  PRA Request for Comment  <http://www.gpo.gov/fdsys/pkg/FR-2012-12-21/pdf/2012-30749.pdf> | **Released:** 12/21/2012  **Due date: 1/22/2013** | 2. *Type of Information Collection Request*: New collection; *Title*: Medicare Enrollment Application for Clinics/Group Practice and Certain Other Suppliers; *Use*: The CMS-855B enrollment application for Clinics, Group Practices and Certain Other Suppliers serves primarily to gather information from the organization that tells what it is, whether it meets certain qualifications to act as a health care supplier, where it renders services, and information necessary to establish the correct claims payment. The goal of evaluating and revising the CMS-855B enrollment application is to simplify and clarify the information collection without jeopardizing the need to collect specific information. The majority of the revisions are very minor, such as spelling and formatting corrections, removal of duplicate fields, and instruction clarification for the organization/group. The Sections and Sub-Sections within the form are re-numbered and re-sequenced to create a more logical flow of the data collection. In addition, CMS has added a data collection for an address to mail the periodic request for the revalidation of enrollment information (only if it differs from other addresses currently collected). Other than the revalidation mailing address described above, new data being collected in this revision package is a checkbox indicating whether or not an organization is wholly owned or operated by a hospital, the inclusion of a new supplier type (Centralized Flu Biller) and information on, if applicable, where the supplier stores its patient records electronically. |  |  |
| **Medicare Hospital Readiness for EHRs**  **Inpatient Quality Data Reporting**  **CMS-3278-NC**  Medicare Program; Request for  Information on Hospital and Vendor  Readiness for Electronic Health  Records Hospital Inpatient Quality  Data Reporting  <http://www.gpo.gov/fdsys/pkg/FR-2013-01-03/pdf/2012-31582.pdf> | **Released:** 1/3/2013  **Due date: 1/22/2013** | This document requests information from hospitals, electronic health record (EHR) vendors, and other interested parties regarding hospital readiness beginning calendar year 2014 discharges to electronically report certain patient-level data under the Hospital Inpatient Quality Reporting (IQR) Program using the Quality Reporting Document Architecture (QRDA) Category I. |  |  |
| **~~Notice of Special Enrollment Rights Under Group Health Plans~~**  **~~DoL (OMB 1210-0101)~~**  ~~PRA Request for Comment~~  [~~http://www.gpo.gov/fdsys/pkg/FR-2012-12-26/pdf/2012-30964.pdf~~](http://www.gpo.gov/fdsys/pkg/FR-2012-12-26/pdf/2012-30964.pdf) | **~~Released:~~** ~~12/26/2012~~  **~~Due date: 1/23/2013~~** | *~~Type of Information Collection Request~~*~~: Continuation of a currently approved collection;~~ *~~Title~~*~~: Notice of Special Enrollment Rights Under Group Health Plans;~~ *~~Use~~*~~: Under Regulations 29 CFR 2590.701-6(c), a group health plan must provide an individual who is offered coverage under the plan a notice describing the plan’s special enrollment rights at or before the time coverage is offered.~~ |  |  |
| **~~Notice of Pre-Existing Condition Exclusion Under Group Health Plans~~**  **~~DoL (OMB 1210-0102)~~**  ~~PRA Request for Comment~~  [~~http://www.gpo.gov/fdsys/pkg/FR-2012-12-26/pdf/2012-30964.pdf~~](http://www.gpo.gov/fdsys/pkg/FR-2012-12-26/pdf/2012-30964.pdf) | **~~Released:~~** ~~12/26/2012~~  **~~Due date: 1/23/2013~~** | *~~Type of Information Collection Request~~*~~: Continuation of a currently approved collection;~~ *~~Title~~*~~: Notice of Pre-Existing Condition Exclusion Under Group Health Plans;~~ *~~Use~~*~~: An employee group health benefit plan or its issuer that imposes a preexisting condition exclusion period must give, as part of any enrollment application, an employee eligible for coverage a general notice that describes the plan’s preexisting condition exclusion--including that the plan will reduce the maximum exclusion period by the length of an employee’s prior creditable coverage. If no such enrollment materials exist, the notice must be provided as soon after a request for enrollment as is reasonably possible. A plan that uses the alternative method of crediting coverage provided in the applicable regulations must disclose the use of that method at the time of enrollment and describe how the method operates. The plan also must explain that a participant has a right to establish prior creditable coverage through a certificate or other means and to request a certificate of prior coverage from a prior plan or issuer. Finally, a plan or issuer must offer to assist the participant in obtaining a certificate from a prior plan or issuer, if necessary.~~ |  |  |
| **Wellness Programs**  **IRS REG-122707-12**  **DoL RIN 1210-AB55**  **CMS-9979-P**  Incentives for Nondiscriminatory Wellness Programs in Group Health Plans | **Released: 11/26/2012**  **Due date:**  **1/25/2013** | This proposed rule would amend regulations, consistent with the Affordable Care Act, regarding nondiscriminatory wellness programs in group health coverage. This rule would increase the maximum permissible reward under a health-contingent wellness program offered in connection with a group health plan (and any related health insurance coverage) from 20 percent to 30 percent of the cost of coverage. This rule would further increase the maximum permissible reward to 50 percent for wellness programs designed to prevent or reduce tobacco use. In addition, this rule includes other proposed clarifications regarding the reasonable design of health-contingent wellness programs and the reasonable alternatives they must offer to avoid prohibited discrimination.  <http://www.healthcare.gov/news/factsheets/2012/11/wellness11202012a.html> |  |  |
| **CMS Enterprise Identity Management System**  **CMS-10452**  PRA Request for Comment | **Released:** 11/26/2012  **Due date**: **1/25/2013** | 1. *Type of Information Collection Request*: New collection; *Title*: CMS Enterprise Identity Management System; *Use*: The Enterprise Identity Management (EIDM) solution will provide an enterprise-wide solution that will also support the CMS goal to improve the Provider and Health Information Exchange experience by providing an enterprise-wide set of credentials and single sign-on capability for multiple CMS applications. To prove the identity of an individual requesting electronic access to protected information or services, CMS will collect a core set of attributes about that individual. The information collected will be gathered and used solely by CMS and approved contractor(s) and state health insurance exchanges. Information confidentiality will conform to HIPAA and FISMA requirements. |  |  |
| **Medicare Part C Explanation of Benefits**  **CMS-10453**  PRA Request for Comment | **Released:** 11/26/2012  **Due date**: **1/25/2013** | 2. *Type of Information Collection Request*: New collection; *Title*: The Medicare Advantage and Prescription Drug Program: Part C Explanation of Benefits CFR 422.111(b)(12); *Use*: CMS seeks OMB approval for the information collection requirements referenced in the April 15, 2011, final rule revising the Medicare Advantage (MA) and Part D programs for calendar year 2012. The rule revised the MA disclosure requirements by adding the authority for CMS to require MA organizations to furnish a written explanation of benefits directly to enrollees. This information collection request would require MA organizations to furnish directly to enrollees, in the manner specified by CMS and in a form easily understandable to such enrollees, a written explanation of benefits. |  |  |
| **Expedited Review of Denial of COBRA Premium Reduction**  **DoL (OMB 1210-0135)**  PRA Request for Comment | **Released:** 11/27/2012  **Due date**: **1/25/2013** | *Type of Information Collection Request*: Continuation of a previously approved collection; *Title*: Request to the Department of Labor for Expedited Review of Denial of COBRA Premium Reduction; *Use*: ARRA section 3001 provides an assistance eligible individual with the right to pay reduced health benefits premiums under the Consolidated Omnibus Budget Reconciliation Act of 1986 (COBRA) for as long as 9 months. If an individual requests treatment as an assistance eligible individual and is denied such treatment because of COBRA continuation coverage ineligibility, ARRA section 3001(a)(5) requires the Secretary of Labor to provide for expedited review of the denial upon application to the Secretary in the form and manner the Secretary provides. The Application to the Department of Labor for Expedited Review of Denial of COBRA Premium Reduction is the form used by individuals to file their expedited review appeals. Such individuals must complete all information requested on the Application in order to file their review requests with the EBSA. This information collection request relates to the Application. |  |  |
| **Establishing Creditable Coverage Under Group Health Plans**  **DoL (OMB 1210-0103)**  PRA Request for Comment  <http://www.gpo.gov/fdsys/pkg/FR-2012-12-26/pdf/2012-30964.pdf> | **Released:** 12/27/2012  **Due date: 1/28/2013** | *Type of Information Collection Request*: Continuation of a currently approved collection; *Title*: Establishing Creditable Coverage Under Group Health Plans; *Use*: This request covers information collection requirements imposed under Regulations 29 CFR 2520.104b-1 and 2590.701-5 in connection with the alternative method of crediting coverage established by the regulations. The regulations permit a plan to adopt, as its method of crediting prior health coverage, provisions that impose different pre-existing condition exclusion periods with respect to different categories of benefits, depending on prior coverage in that category. In such a case, the regulations require the former plan to provide additional information upon request to the new plan in order to establish an individual’s length of prior creditable coverage within that category of benefits. |  |  |
| **National Partnership for Action to End Health Disparities**  **HHS-OS-17378-30D**  PRA Request for Comment  <http://www.gpo.gov/fdsys/pkg/FR-2012-12-28/pdf/2012-31196.pdf> | **Released:** 12/28/2012  **Due date: 1/28/2013** | *Type of Information Collection Request*: New collection; *Title*: Evaluation of the National Partnership for Action to End Health Disparities; *Use*: The Office of Minority Health (OMH) in the Office of the Assistant Secretary for Health (OASH), Office of the Secretary (OS) seeks approval for new data collection activities for the Evaluation of the National Partnership for Action to End Health Disparities (NPA). NPA, officially launched in April 2011, seeks to mobilize a nationwide, comprehensive, community-driven, and sustained approach to combating health disparities and to move the nation toward achieving health equity. The goal of the NPA evaluation is to determine the extent to which NPA has contributed to the elimination of health disparities and the attainment of health equity in our nation. OMH will use the collected data to inform the various stakeholders involved in implementation of NPA and the National Stakeholder Strategy about progress, results, lessons learned, and necessary mid-course adjustments. The evaluation team will facilitate meetings to reflect and discuss the findings with OMH’s leadership, staff, and the implementation and communications teams that support NPA. The meetings will focus on the lessons learned and their implications on strategy improvement and implementation. OMH also will include information from the evaluation in its biennial report to Congress. |  |  |
| **Survey Regarding Patient Experiences With Emergency Department Care**  **CMS-4169-NC**  Medicare Program; Request for Information To Aid in the Design and Development of a Survey Regarding Patient Experiences With Emergency Department Care | **Released:** 11/30/2012  **Due date: 2/1/2013** | This notice is a request for information regarding consumer and patient experiences with emergency department (ED) care. CMS has begun to review potential topic areas, as well as publicly available instruments and measures, for the purpose of developing a consumer and patient experience survey that will enable objective comparisons of ED experiences across the country. The principal focus is to develop a survey for consumers and patients ages 18 and older, but CMS also is interested in how a survey could also be developed for pediatric patients. CMS seeks submission of suggested topic areas (such as “communication with providers,” “pain control” or “waiting time”), as well as publicly available instruments for capturing patient experiences with ED care. In addition, CMS is interested in instruments and items that can measure quality of care from the patient’s and caregiver’s perspective, including pediatric patients, and track changes over time. |  |  |
| **~~MLR and Rebate Calculation Report and MLR Rebate Notices~~**  **~~CMS-10418~~**  ~~PRA Request for Comment~~ | **~~Released:~~** ~~12/4/2012~~  **~~Due date~~**~~:~~ **~~2/4/2013~~** | ~~1.~~ *~~Type of Information Collection~~*~~: Revision of a currently approved collection;~~ *~~Title~~*~~: Annual MLR and Rebate Calculation Report and MLR Rebate Notices;~~ *~~Use~~*~~: Under Section 2718 of the Affordable Care Act and implementing regulation at 45 CFR part 158, a health insurance issuer (issuer) offering group or individual health insurance coverage must submit a report to the Secretary concerning the amount the issuer spends each year on claims, quality improvement expenses, non-claims costs, federal and state taxes and licensing and regulatory fees, and the amount of earned premium. An issuer must provide an annual rebate if the amount it spends on certain costs compared to its premium revenue (excluding federal and states taxes and licensing and regulatory fees) does not meet a certain ratio, referred to as the medical loss ratio (MLR).~~ |  |  |
| **Fees for the Patient-Centered Outcomes Research Trust Fund**  **TD 9602**  Fees on Health Insurance Policies and  Self-Insured Plans for the Patient-  Centered Outcomes Research Trust  Fund  <http://www.gpo.gov/fdsys/pkg/FR-2012-12-06/pdf/2012-29325.pdf> | **Released:** 12/6/2012  **Due date**: None | This final rule implements and provides guidance on the fees imposed by the Affordable Care Act on issuers of certain health insurance policies and plan sponsors of certain self-insured health plans to fund the Patient-Centered Outcomes Research Trust Fund. This final rule affects the issuers and plan sponsors that are directed to pay those fees. | Fees are applicable to self-insured health plans. |  |
| **Revisions to the 2014 EHR Certification Criteria and EHR Incentive Program**  **CMS-0046-IFC**  Health Information Technology:  Revisions to the 2014 Edition  Electronic Health Record Certification  Criteria; and Medicare and Medicaid  Programs; Revisions to the Electronic  Health Record Incentive Program  <http://www.gpo.gov/fdsys/pkg/FR-2012-12-07/pdf/2012-29607.pdf> | **Released:** 12/7/2012  **Due date**: **2/5/2013** | This interim final rule with comment period replaces the Data Element Catalog (DEC) standard and the Quality Reporting Document Architecture (QRDA) Category III standard adopted in the final rule published on September 4, 2012, in the Federal Register with updated versions of those standards. This rule also revises the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs by adding an alternative measure for the Stage 2 meaningful use (MU) objective for hospitals to provide structured electronic laboratory results to ambulatory providers; correcting the regulation text for the measures associated with the objective for hospitals to provide patients the ability to view online, download, and transmit information about a hospital admission; and making the case number threshold exemption for clinical quality measure (CQM) reporting applicable for eligible hospitals and critical access hospitals (CAHs) beginning with FY 2013. This rule also provides notice of CMS’ intention to issue technical corrections to the electronic specifications for CQMs released on October 25, 2012. |  |  |
| **Consumer Assessment of Healthcare Providers and Systems Survey**  **CMS-10450**  PRA Request for Comment  <http://www.gpo.gov/fdsys/pkg/FR-2012-12-07/pdf/2012-29627.pdf> | **Released:** 12/7/2012  **Due date: 2/5/2013** | 1. *Type of Information Collection Request*: New collection; *Title*: Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey for Physician Quality Reporting; *Use*: The Physician Quality Reporting System (PQRS), established in 2006 as a voluntary “pay for-reporting” program that allows physicians and other eligible health care professionals to report information to Medicare about the quality of care provided to beneficiaries who have certain medical conditions, provides incentive payments to physicians who report quality data; consumers do not have access to this data. CMS launched the Physician Compare Web site in December 30, 2010, to meet requirements set forth by Section 10331 of the Affordable Care Act (ACA), which requires the site to contain information on physicians enrolled in the Medicare and other eligible professionals who participate in the Physician Quality Reporting Initiative. By January 1, 2013 (and for reporting periods beginning no earlier than January 1, 2012), CMS must implement a plan to make information on physician performance publicly available through Physician Compare. A key component of the reporting requirements under ACA is public reporting on physician performance that includes patient experience measures, and the collection and reporting of a Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey for Physician Quality Reporting will fulfill this requirement. This survey will provide patient experience of care data that will serve as essential component of assessing the quality of services delivered to Medicare beneficiaries and will permit beneficiaries to have this information to help them choose health care providers that offer services meeting their needs and preferences, thus encouraging providers to improve quality of care for beneficiaries. |  |  |
| **~~Hospital Wage Index Occupational Mix Survey~~**  **~~CMS-10079~~**  ~~PRA Request for Comment~~  [~~http://www.gpo.gov/fdsys/pkg/FR-2012-12-07/pdf/2012-29627.pdf~~](http://www.gpo.gov/fdsys/pkg/FR-2012-12-07/pdf/2012-29627.pdf) | **~~Released:~~** ~~12/7/2012~~  **~~Due date: 2/5/2013~~** | ~~2.~~ *~~Type of Information Collection Request~~*~~: Revision of a currently approved collection;~~ *~~Title~~*~~: Hospital Wage Index Occupational Mix Survey and Supporting Regulations in 42 CFR, Section 412.64;~~ *~~Use~~*~~: Section304(c) of Public Law 106-554 amended section 1886(d)(3)(E) of the Social Security Act to require CMS to collect data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in Medicare to construct an occupational mix adjustment to the wage index for application beginning October 1, 2004 (the FY 2005 wage index). The purpose of the occupational mix adjustment is to control for the effect of hospitals’ employment choices on the wage index.~~ |  |  |
| **Consumer Assistance Program Grants CMS-10333**  PRA Request for Comment  <http://www.gpo.gov/fdsys/pkg/FR-2012-12-07/pdf/2012-29626.pdf> | **Released:** 12/7/2012  **Due date: 2/7/2013** | 1. *Type of Information Collection Request*: Revision of a currently approved collection; *Title*: Consumer Assistance Program Grants; *Use*: Section 1002 of the Affordable Care Act (ACA) provides for the establishment of consumer assistance (or ombudsman) programs (CAPs), starting in FY 2010. Federal grants will support CAPs, which will assist consumers with filing complaints and appeals; assist consumers with enrollment into health coverage, collect data on consumer inquiries and complaints to identify problems in the marketplace; educate consumers on their rights and responsibilities; and with the establishment of the new Exchange marketplaces, resolve problems with premium credits for Exchange coverage. ACA requires CAPs to report data to the Secretary of HHS “on the types of problems and inquiries encountered by consumers” (Sec. 2793 (d)). Analysis of this data reporting will help identify patterns of practice in the insurance marketplaces and uncover suspected patterns of noncompliance. HHS must share program data reports with the Departments of Labor and Treasury and state regulators. Program data also can offer CCIIO one indication of the effectiveness of state enforcement, affording opportunities to provide technical assistance and support to state insurance regulators and, in extreme cases, inform the need to trigger federal enforcement. The 60-day Federal Register notice published on July 27, 2012, resulted in 21 comments, the majority of which involved feedback on providing CAPs with more flexibility in collecting and reporting data, and CMS addressed those comments in this notice. |  |  |
| **ICD-10 Industry Readiness Assessment**  **CMS-10381**  PRA Request for Comment  <http://www.gpo.gov/fdsys/pkg/FR-2012-12-07/pdf/2012-29626.pdf> | **Released:** 12/7/2012  **Due date: 2/7/2013** | 2. *Type of Information Collection Request*: Revision of a currently approved collection; *Title*: ICD-10 Industry Readiness Assessment; *Use*: Congress addressed the need for a consistent framework for electronic transactions and other administrative simplification issues in the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191, enacted on August 21, 1996. Through subtitle F of title II of HIPAA, the Congress added to title XI of the Social Security Act (the Act) a new Part C, entitled “Administrative Simplification,” which defines various terms and imposes several requirements on HHS, health plans, health care clearinghouses, and certain health care providers concerning the transmission of health information. Specifically, HIPAA requires the Secretary of HHS to adopt standards that covered entities are required to use in conducting certain health care administrative transactions, such as claims, remittance, eligibility, and claims status requests and responses. CMS will use findings from the ICD-10 industry readiness assessment to understand each sector’s progress toward compliance and to determine what communication and educational efforts can best help affected entities obtain the tools and resources they need to achieve timely compliance with ICD-10. CMS will use findings for education and outreach purposes only, not for policy purposes. |  |  |
| **Home Health Change of Care Notice CMS-10280**  PRA Request for Comment  <http://www.gpo.gov/fdsys/pkg/FR-2012-12-12/pdf/2012-29951.pdf> | **Released:** 12/12/2012  **Due date: 2/11/2013** | 1. *Type of Information Collection Request*: New collection; *Title*: Home Health Change of Care Notice (HHCCN); *Use*: Home health agencies (HHAs) must provide written notice to original Medicare beneficiaries under various circumstances involving the initiation, reduction, or termination of services, and the Home Health Advance Beneficiary Notice (HHABN) (CMS-R-296) has served as the notice used in these situations. In 2006, CMS added three interchangeable option boxes to HHABN: Option Box 1 addressed liability, Option Box 2 addressed change of care for agency reasons, and Option Box 3 addressed change of care due to provider orders. To streamline, reduce, and simplify notices issued to Medicare beneficiaries, CMS will replace HHABN Option Box 1 with the existing Advanced Beneficiary Notice of Noncoverage (ABN) (CMS-R-131), which providers and suppliers other than HHAs use to inform fee for service (FFS) beneficiaries of potential liability for certain items/services billed to Medicare. CMS will introduce HHCCN (CMS-10280) as a separate, distinct document to provide change of care notice in compliance with HHA conditions of participation. HHCCN will replace both HHABN Option Box 2 and Option Box 3. CMS has designed the single page format of HHCCN to specify whether the change of care results from agency reasons or provider orders. |  |  |
| **Advanced Beneficiary Notice of Noncoverage**  **CMS-R-131**  PRA Request for Comment  <http://www.gpo.gov/fdsys/pkg/FR-2012-12-12/pdf/2012-29951.pdf> | **Released:** 12/12/2012  **Due date: 2/11/2013** | 2. *Type of Information Collection Request*: Revision of a currently approved collection; *Title*: Advance Beneficiary Notice of Noncoverage (ABN); *Use*: Certain Medicare providers and suppliers use the Advanced Beneficiary Notice of Noncoverage (ABN) (CMS-R-131) to inform fee for service (FFS) beneficiaries of potential liability for certain items/services billed to the program. Under section 1879 of the Social Security Act, Medicare beneficiaries can have financially responsibility for items or services usually covered under the program, but denied in an individual case under specific statutory exclusions, if beneficiaries are informed that Medicare likely will deny payment prior to furnishing the items or services. When required, Part B paid physicians, providers (including institutional providers, such as outpatient hospitals), practitioners (such as chiropractors), and suppliers, as well as hospice providers and Religious Non-Medical Health Care Institutions paid under Part A, deliver ABN. The revised ABN in this information collection request incorporates expanded use by HHAs, with no substantive changes to the form or changes that will affect existing ABN users. |  |  |
| **Early Retiree Reinsurance Program Survey of Plan Sponsors**  **CMS-10408**  PRA Request for Comment  <http://www.gpo.gov/fdsys/pkg/FR-2013-01-11/pdf/2013-00468.pdf> | **Released:** 1/11/2013  **Due date: 2/11/2013** | 1. *Type of Information Collection Request*: Reinstatement with change of a previously approved collection; *Title*: Early Retiree Reinsurance Program Survey of Plan Sponsors; *Use*: Under ACA and implementing regulations at 45 CFR Part 149, employment-based plans that offer health coverage to early retirees and their spouses, surviving spouses, and dependents are eligible to receive tax-free reimbursement for a portion of the costs of health benefits provided to such individuals. The statute limits the use of the reimbursement funds and requires the Secretary of HHS to develop a mechanism to monitor the appropriate use of such funds. The survey in this information collection request serves as part of that mechanism. CMS published a 60-day FR Notice on September 28, 2012, and received no comments. |  |  |
| **ACA Internal Claims and Appeals and External Review Procedures for Issuers CMS-10338**  PRA Request for Comment  <http://www.gpo.gov/fdsys/pkg/FR-2013-01-11/pdf/2013-00468.pdf> | **Released:** 1/11/2013  **Due date: 2/11/2013** | 2. *Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Affordable Care Act Internal Claims and Appeals and External Review Procedures for Non-grandfathered Group Health Plans and Issuers and Individual Market Issuers; *Use*: As part ACA, Congress added PHS Act section 2719, which provides rules relating to internal claims and appeals and external review processes. On July 23, 2010, interim final regulations (IFR) set forth rules implementing PHS Act section 2719 for internal claims and appeals and external review processes. With respect to internal claims and appeals processes for group health coverage, PHS Act section 2719 and paragraph (b)(2)(i) of the interim final regulations provide that group health plans and health insurance issuers offering group health insurance coverage must comply with the internal claims and appeals processes set forth in 29 CFR 2560.503-1 (the DOL claims procedure regulation) and update such processes in accordance with standards established by the Secretary of Labor in paragraph (b)(2)(ii) of the regulations. The DOL claims procedure regulation requires an employee benefit plan to provide third-party notices and disclosures to participants and beneficiaries of the plan. In addition, paragraphs (b)(3)(ii)(C) and (b)(2)(ii)(C) of the IFR add an additional requirement that non-grandfathered group health plans and issuers of non-grandfathered health policies provide to the claimant, free of charge, any new or additional evidence considered, or generated by the plan or issuer in connection with the claim. Paragraph (b)(3)(i) of the IFR requires issuers offering coverage in the individual health insurance market to also generally comply with the DOL claims procedure regulation as updated by the Secretary of HHS in paragraph (b)(3)(ii) of the IFR for their internal claims and appeals processes.  Furthermore, PHS Act section 2719 and the IFR provide that non-grandfathered group health plans, issuers offering group health insurance coverage, and self-insured nonfederal governmental plans (through the IFR amendment dated June 24, 2011) must comply either with a state external review process or a federal external review process. The IFR provides a basis for determining when such plans and issuers must comply with an applicable state external review process and when they must comply with the federal external review process. Plans and issuers required to participate in the Federal external review process must have electronically elected either the HHS-administered process or the private accredited IRO process as of January 1, 2012, or, in the future, at such time as the plans and issuers use the federal external review process. Plans and issuers must notify HHS as soon as possible if any of the above information changes at any time after it is first submitted. The election requirements associated with this ICR are articulated through guidance published June 22, 2011. The election requirements are necessary for the federal external review process to provide an independent external review as requested by claimants. |  |  |
| **IHS Forms to Implement the Privacy Rule**  **IHS-810, IHS-912-1, IHS-912-2, IHS-913, and IHS-917**  PRA Request for Comment  <http://www.gpo.gov/fdsys/pkg/FR-2013-01-11/pdf/2013-00363.pdf> | **Released:** 1/11/2013  **Due date: 2/11/2013** | *Type of Information Collection Request*: Extension, without revisions, of currently approved information collection; *Title*: 0917-0030, “IHS Forms to Implement the Privacy Rule (45 CFR parts 160 164)”; *Use*: This collection of information is made necessary by the HHS Rule entitled “Standards for Privacy of Individually Identifiable Health Information” (Privacy Rule), which implements the privacy requirements of the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996, creates national standards to protect individual’s personal health information, and gives patients increased access to their medical records. This rule requires the collection of information to implement these protection standards and access requirements. |  |  |
| **Telehealth Resource Center Performance Measurement Tool**  **HRSA (OMB 0915-xxxx)**  PRA Request for Comment  <http://www.gpo.gov/fdsys/pkg/FR-2013-01-10/pdf/2013-00292.pdf> | **Released:** 1/10/2013  **Due date: 30 days (approx. 2/11/2013)** | *Type of Information Collection Request*: New collection; *Title*: Telehealth Resource Center Performance Measurement Tool; *Use*: To ensure the best use of public funds and to meet GPRA requirements, the Office for the Advancement of Telehealth (OAT) in collaboration with Telehealth Resource Centers (TRCs) has developed a set of performance metrics to evaluate the technical assistance services provided by TRCs. The TRC Performance Indicator Data Collection Tool contains the data elements that TRCs would need to collect to report on the performance metrics. This tool can translate easily into a web-based data collection system (PIMS). Also, it will allow TRCs to report to OAT around their projects’ performance progress and will allow OAT to demonstrate to Congress the value added from the TRC Grant Program. |  |  |
| **Provisions Related to Eligibility and Enrollment for Exchanges, Medicaid and CHIP, and Medicaid Cost Sharing**  **CMS-2334-P**  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  <http://www.ofr.gov/OFRUpload/OFRData/2013-00659_PI.pdf> | **Released:** 1/15/2013 (expected)  **Due date: 2/13/2013** | This proposed rule would implement provisions the ACA and the Children’s Health Insurance Program Reauthorization Act of 2009 (CHIPRA). This proposed rule reflects new statutory eligibility provisions; proposes changes to provide states more flexibility to coordinate Medicaid and the Children’s Health Insurance Program (CHIP) eligibility notices, appeals, and other related administrative procedures with similar procedures used by other health coverage programs authorized under ACA; modernizes and streamlines existing rules, eliminates obsolete rules, and updates provisions to reflect Medicaid eligibility pathways; revises the rules relating to the substitution of coverage to improve the coordination of CHIP coverage with other coverage; implements other CHIPRA eligibility-related provisions, including eligibility for newborns whose mothers were eligible for and receiving Medicaid or CHIP coverage at the time of birth; amends certain provisions included in the “State Flexibility for Medicaid Benefit Packages” final rule published on April 30, 2010; and implements specific provisions including eligibility appeals, notices, and verification of eligibility for qualifying coverage in an eligible employer-sponsored plan for Affordable Insurance Exchanges. This rule also proposes to update and simplify the complex Medicaid premiums and cost sharing requirements, to promote the most effective use of services, and to assist states in identifying cost sharing flexibilities. |  |  |
| **~~Effect of Reducing Falls on Acute~~**  **~~and Long-Term Care Expenses~~**  **~~HHS-OS-18280-60D~~**  ~~PRA Request for Comment~~  [~~http://www.gpo.gov/fdsys/pkg/FR-2012-12-27/pdf/2012-31113.pdf~~](http://www.gpo.gov/fdsys/pkg/FR-2012-12-27/pdf/2012-31113.pdf) | **~~Released:~~** ~~12/27/2012~~  **~~Due date: 2/25/2013~~** | *~~Type of Information Collection Request~~*~~: Extension of a currently approved collection;~~ *~~Title~~*~~: The Effect of Reducing Falls on Acute and Long-Term Care Expenses;~~ *~~Use~~*~~: The Office of the Assistant Secretary for Planning and Evaluation (ASPE) within the HHS Office of Secretary has begun a demonstration and evaluation of a multi-factorial fall prevention program to measure its impact on health outcomes for the elderly, as well as acute and long-term care use and cost. The study involves a sample of individuals who are ages 75 and older and have private long-term care insurance using a multi-tiered random experimental research design to evaluate the effectiveness of the proposed fall prevention intervention program. The project began in spring 2008 and will end in December 2014. The project will provide information to advance Departmental goals of reducing injury and improving the use of preventive services to impact positively Medicare use and spending.~~ |  |  |
| **New Safe Harbors and Special Fraud Alerts**  **OIG-121-N**  Solicitation of New Safe Harbors and  Special Fraud Alerts  <http://www.gpo.gov/fdsys/pkg/FR-2012-12-28/pdf/2012-31107.pdf> | **Released:** 12/28/2012  **Due date: 2/26/2013** | In accordance with section 205 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), this annual notice solicits proposals and recommendations for developing new and modifying existing safe harbor provisions under the Federal anti-kickback statute (section 1128B(b) of the Social Security Act), as well as developing new OIG Special Fraud  Alerts. |  |  |
| **~~Interest Rate on Overdue Debts~~**  **~~HHS (no reference number)~~**  ~~Notice of Interest Rate on Overdue~~  ~~Debts~~  [~~http://www.gpo.gov/fdsys/pkg/FR-2012-12-28/pdf/2012-31284.pdf~~](http://www.gpo.gov/fdsys/pkg/FR-2012-12-28/pdf/2012-31284.pdf) | **~~Released:~~** ~~12/28/2012~~  **~~Due date:~~** ~~None~~ | ~~Section 30.18 of HHS claims collection regulations (45 CFR part 30) provides that the Secretary shall charge an annual rate of interest, which is determined and fixed by the Secretary of the Treasury after considering private consumer rates of interest on the date that HHS becomes entitled to recovery. The rate must equal or exceed the Department of Treasury’s current value of funds rate or the applicable rate determined from the “Schedule of Certified Interest Rates with Range of Maturities” unless the Secretary waives interest in whole or part, or a different rate is prescribed by statute, contract, or repayment agreement. The Secretary of the Treasury may revise this rate quarterly. HHS publishes this rate in the Federal Register. The current rate of 10 3⁄8%, as fixed by the Secretary of the Treasury, is certified for the quarter ended September 30, 2012. This interest rate is effective until the Secretary of the Treasury notifies the HHS of any change.~~ |  |  |
| **Medicare Rural Hospital Flexibility**  **Grant Program**  **HRSA (OMB 0915-xxxx)**  PRA Request for Comment  <http://www.gpo.gov/fdsys/pkg/FR-2012-12-31/pdf/2012-31399.pdf> | **Released:** 12/31/2012  **Due date: 60 days (approx. 3/1/2013)** | *Type of Information Collection Request*: New collection; *Title*: Medicare Rural Hospital Flexibility Grant Program Performance Measure Determination; *Use*: The Medicare Rural Hospital Flexibility Program (Flex), authorized by Section 4201 of the Balanced Budget Act of 1997 (BBA) and reauthorized by Section 121 of the Medicare Improvements for Patients and Providers Act of 2008, seeks to support improvements in the quality of health care provided in communities served by Critical Access Hospitals (CAHs); to support efforts to improve the financial and operational performance of the CAHs; and to support communities in developing collaborative regional and local delivery systems. This program also assists in the conversion of qualified small rural hospitals to CAH status. For this program, HRSA developed performance measures to provide data useful to the program and to allow the agency to provide aggregate program data required by Congress under the Government Performance and Results Act (GPRA) of 1993. These measures cover principal areas of interest to the Office of Rural Health Policy, including: (a) Quality reporting; (b) quality improvement interventions; (c) financial and operational improvement initiatives; and (d) multi-hospital patient safety initiatives. |  |  |
| **Additional Medicare Tax**  **IRS REG-130074-11**  Rules Relating to Additional Medicare  Tax  <http://www.gpo.gov/fdsys/pkg/FR-2012-12-05/pdf/2012-29237.pdf> | **Released:** 12/5/2012  **Due date: 3/5/2013** | This document contains proposed regulations relating to Additional Hospital Insurance Tax on income above threshold amounts (“Additional Medicare Tax”), as added by the Affordable Care Act. Specifically, these proposed regulations provide guidance for employers and individuals relating to the implementation of Additional Medicare Tax. This document also contains proposed regulations relating to the requirement to file a return reporting Additional Medicare Tax, the employer process for making adjustments of underpayments and overpayments of Additional Medicare Tax, and the employer and employee processes for filing a claim for refund for an overpayment of Additional Medicare Tax. This document also provides notice of a public hearing on these proposed rules. |  |  |
| **~~Test Tools and Procedures for the ONC HIT Certification Program~~**  **~~HHS ONC (no reference number)~~**  ~~Notice of Availability: Test Tools and~~  ~~Test Procedures Approved by the~~  ~~National Coordinator for the ONC HIT~~  ~~Certification Program~~  [~~http://www.gpo.gov/fdsys/pkg/FR-2013-01-02/pdf/2012-31484.pdf~~](http://www.gpo.gov/fdsys/pkg/FR-2013-01-02/pdf/2012-31484.pdf) | **~~Released:~~** ~~1/2/2013~~  **~~Due date:~~** ~~None~~ | ~~This notice announces the availability of test tools and test procedures approved by the National Coordinator for Health Information Technology (the National Coordinator) for the testing of EHR technology to the 2014 Edition EHR certification criteria under the ONC HIT Certification Program. The approved test tools and test procedures appear on the ONC Web site at:~~ [~~http://www.healthit.gov/policy-researchers-implementers/2014-edition-final-test-method~~](http://www.healthit.gov/policy-researchers-implementers/2014-edition-final-test-method)~~.~~ |  |  |
| **MAC Satisfaction Indicator (MSI) Participant Information Form**  **CMS-10457**  PRA Request for Comment  <http://www.gpo.gov/fdsys/pkg/FR-2013-01-08/pdf/2013-00065.pdf> | **Released:** 1/8/2013  **Due date: 3/11/2013** | *Type of Information Collection Request*: New collection; *Title*: MAC Satisfaction Indicator (MSI) Participant Information Registration Form; *Use*: Section 1874(A)(b)(3)(B) of the Social Security Act requires provider satisfaction to serve as a performance standard for the work of Medicare Administrative Contractors (MACs). To gain provider feedback regarding their satisfaction with their MACs, CMS requires accurate contact information to: select from a random sample for a survey, forward the survey to the appropriate respondents, and increase response rates. The survey will have a different control number via an Interagency Agreement. |  |  |
| **Research on Outreach for Health Insurance Marketplace**  **CMS-10458**  PRA Request for Comment  <http://www.gpo.gov/fdsys/pkg/FR-2013-01-11/pdf/2013-00467.pdf> | **Released:** 1/11/2013  **Due date: 3/12/2013** | *Type of Information Collection Request*: New collection; *Title*: Consumer Research Supporting Outreach for Health Insurance Marketplace; *Use*: CMS seeks approval for two surveys to aid in understanding levels of awareness and customer service needs associated with the Health Insurance Marketplace established by ACA. One survey will include individual consumers most likely to use the Marketplace, and another will include small employers most likely to use the Small Business Health Options portion of the Marketplace. These brief surveys, conducted quarterly, will give CMS the ability to obtain a rough indication of the types of outreach and marketing needed to enhance awareness of and knowledge about the Marketplace for individual and business customers. CMS’ biggest customer service issue likely will involve providing education sufficient for consumers to: (a) take advantage of the Marketplace and (b) know how to access CMS’ customer service channels. The surveys will provide information on media use, concept awareness, and conceptual or content areas where education for customer service delivery needs improvement. Awareness and knowledge gaps are likely to change over time based not only on effectiveness of CMS’ marketing efforts, but also of those of state, local, private sector, and nongovernmental organizations. |  |  |
| **Matching Grants to States for the Operation of High Risk Pools**  **CMS-10078**  PRA Request for Comment  <http://www.gpo.gov/fdsys/pkg/FR-2013-01-11/pdf/2013-00473.pdf> | **Released:** 1/11/2013  **Due date: 3/12/2013** | *Type of Information Collection Request*: Reinstatement without change of a previously approved collection; *Title*: Program for Matching Grants to States for the Operation of High Risk Pools; *Use*: CMS requires the information in this information collection request as a condition of eligibility for grants authorized in the Trade Act of 2002, the Deficit Reduction Act of 2005, and the State High Risk Pool Funding Extension Act of 2006. CMS needs the information to determine if a state applicant meets the necessary eligibility criteria for a grant as required by law. The respondents will include states that have a high risk pool as defined in sections 2741, 2744, or 2745 of the Public Health Service Act. The grants will provide funds to states that incur losses in the operation of high risk pools. |  |  |
| **Shared Responsibility for Employers**  **Regarding Health Coverage**  **REG-138006-12**  Shared Responsibility for Employers  Regarding Health Coverage  <http://www.gpo.gov/fdsys/pkg/FR-2013-01-02/pdf/2012-31269.pdf> | **Released:** 1/2/2013  **Due date: 3/18/2013** | This document contains proposed regulations providing guidance under section 4980H of the Internal Revenue Code (Code) with respect to the shared responsibility for employers regarding employee health coverage. These proposed regulations would affect only employers that meet the definition of “applicable large employer” as described in these proposed regulations. As discussed in section X of this preamble, employers may rely on these proposed regulations for guidance pending the issuance of final regulations or other applicable guidance. This document also provides notice of a public hearing on these proposed regulations. | IRS FAQ doc on shared responsibility --  <http://www.irs.gov/uac/Newsroom/Questions-and-Answers-on-Employer-Shared-Responsibility-Provisions-Under-the-Affordable-Care-Act> |  |
| **State Partnership Exchange**  **CCIIO (no reference number)**  Guidance on the State Partnership Exchange  <http://cciio.cms.gov/resources/files/partnership-guidance-01-03-2013.pdf> | **Released:** 1/3/2013  **Due date:** None | This guidance provides a framework and basic roadmap for states considering a State Partnership Exchange, a hybrid model through which States may assume primary responsibility for many of the functions of the Federally-facilitated Exchange permanently or as they work towards running a State-based Exchange. For example, states may carry out many plan management functions through what is referred to throughout this guidance as a State Plan Management Partnership Exchange. In addition, states can choose to assume responsibility for in-person consumer assistance and outreach, through what is referred to throughout this guidance as a State Consumer Partnership Exchange. States also have the option to assume responsibility for a combination of these main Exchange activities.  With a State Partnership Exchange, states can continue to serve as the primary points of contact for issuers and consumers, and will work with HHS to establish an Exchange that best meets the needs of state residents. This guidance also describes how HHS will work with states independent of State Partnership Exchange. |  |  |
| **Semiannual Regulatory Agenda**  **HHS OS (no reference number)**  Semiannual Regulatory Agenda  <http://www.gpo.gov/fdsys/pkg/FR-2013-01-08/pdf/2012-31671.pdf> | **Released:** 1/8/2013  **Due date:** None | The Regulatory Flexibility Act of 1980 and Executive Order 12866 require HHS semiannually to issue an inventory of rulemaking actions under development to provide the public a summary of forthcoming regulatory actions. This information will help the public more effectively participate in HHS’ regulatory activity, and the Department welcomes comments on any aspect of this agenda. |  |  |
| **Health-related Agency Actions Pending at OMB** | | | | |
| Part II--Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction (CMS-1367-P) | Received at OMB: 8/2/2012 | No detail provided. |  |  |
| Requirements for Long-Term Care Facilities: Hospice Services (CMS-3140-F) | Received at OMB: 12/2/2011 | No detail provided. |  |  |
| Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules – Final Rule (RIN: [0945-AA03](http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=null&RIN=0945-AA03) ) | Received at OMB: 3/24/2012 | No detail provided. |  |  |
| Transparency Reports and Reporting of Physician Ownership of Investment Interests (CMS-5060-F) | Received at OMB: 11/27/2012 | This final rule requires applicable manufacturers of drugs, devices, biologicals, or medical supplies covered by Medicare, Medicaid, or CHIP to report annually to the Secretary certain payments or transfers of value provided to physicians or teaching hospitals (“covered recipients”). In addition, applicable manufacturers and applicable group purchasing organizations (GPOs) are required to report annually certain physician owner-ship or investment interests. The Secretary is required to publish applicable manufacturers’ and applicable GPOs’ submitted payment and ownership information on a public Web site. |  |  |
| Medicaid Eligibility Changes Under the Affordable Care Act--Part II (CMS-2334-P) | Received at OMB: 11/29/2012 | This proposed rule would implement provisions of the Affordable Care Act of 2010 (ACA). ACA expands access to health insurance through improvements in Medicaid, the establishment of Affordable Insurance Exchanges (Exchanges), and coordination between Medicaid, the Children’s Health Insurance Program (CHIP), and Exchanges. This proposed rule would set forth sections of ACA related to appeals, notices, and other Medicaid eligibility changes under ACA and options established by other Federal statutes.  **Approved by OMB 1/10/2013 but not yet published by agency.** |  |  |
| **DoL and IRS/Treasury** |  |  |  |  |
| Procedures for the Handling of Retaliation Complaints under Section 1558 of the Affordable Care Act of 2010 **RIN:** [1218-AC79](http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=null&RIN=1218-AC79) | Received at OMB: 7/21/2012 | **SEC. 1558. PROTECTIONS FOR EMPLOYEES.** The Fair Labor Standards Act of 1938 is amended by inserting after section 18B (as added by section 1512) the following:  **‘‘SEC. 18C** o**29 U.S.C. 218c**.**. PROTECTIONS FOR EMPLOYEES.**  ‘‘(a) PROHIBITION.—No employer shall discharge or in any manner discriminate against any employee with respect to his or her compensation, terms, conditions, or other privileges of employment because the employee (or an individual acting at the request of the employee) has— ‘‘(1) received a credit under section 36B of the Internal Revenue Code of 1986 or a subsidy under section 1402 of this Act;…” |  |  |
| **OPM** |  |  |  |  |
| None. |  |  |  |  |
| **Recently Submitted Comments** | | | | |
| **HRSA**  **Methodology for Designation of**  **Frontier and Remote Areas**  Request for public comment on methodology for designation of frontier and remote areas. | **Released: 11/5/2012**  **Due date: 1/4/2013** | This notice announces a request for public comment on a methodology derived from the Frontier and Remote (FAR) system for designating U.S. frontier areas. This methodology was developed in a collaborative project between the Office of Rural Health Policy (ORHP) in the Health Resources and Services Administration (HRSA); and the  Economic Research Service (ERS) in the U.S. Department of Agriculture (USDA). While other agencies of the Department of Health and Human Services (HHS) and the ERS may in the future choose to use the FAR methodology to demarcate the frontier areas of the U.S., there is no requirement that they do so, and they may choose other, alternate methodologies and definitions that best suit their program requirements. | **Comments filed 1/4/2013.** |  |
| **Multi-State Plan Program for Exchanges**  **OPM RIN 3206-AM47**  Patient Protection and Affordable Care Act; Establishment of the Multi-State Plan Program for the Affordable Insurance Exchanges  <http://www.gpo.gov/fdsys/pkg/FR-2012-12-05/pdf/2012-29118.pdf> | **Released:** 12/5/2012  **Due date**: **1/4/2013** | OPM is issuing a proposed rule to implement the Multi-State Plan Program (MSPP). OPM is establishing the MSPP pursuant to the Affordable Care Act. Through contracts with OPM, health insurance issuers will offer at least two multi-State plans (MSPs) on each of the Affordable Insurance Exchanges (Exchanges). Under the law, an MSPP issuer may phase in the States in which it offers coverage over four years, but it must offer MSPs on  Exchanges in all States and the District of Columbia by the fourth year in which the MSPP issuer participates in the MSPP. OPM aims to administer the MSPP in a manner that is consistent with  State insurance laws and that is informed by input from a broad array of stakeholders. | **Comments filed 1/4/2013.** |  |
| **Health Insurance Market Rules**  **CMS-9972-P**  Patient Protection and Affordable Care Act; Health Insurance Market Rules; Rate Review | **Released: 11/26/2012**  **Due date:**  **12/26/2012** | This proposed rule would implement Affordable Care Act (ACA) policies related to fair health insurance premiums, guaranteed availability, guaranteed renewability, risk pools, and catastrophic plans. This rule would clarify the approach used to enforce the applicable requirements of ACA with respect to health insurance issuers and group health plans that are non-federal governmental plans. In addition, this rule would amend the standards for health insurance issuers and states regarding reporting, utilization, and collection of data under section 2794 of the Public Health Service Act (PHS Act). This rule also revises the timeline for states to propose state-specific thresholds for review and approval by CMS.  <http://www.healthcare.gov/news/factsheets/2012/11/market-reforms11202012a.html> | **Comments filed 12/26/2012.** |  |
| **Notice of Benefit and Payment Parameters for 2014**  **CMS-9964-P**  Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2014  <http://www.gpo.gov/fdsys/pkg/FR-2012-12-07/pdf/2012-29184.pdf> | **Released:** 12/7/2012  Due date: 12/31/2012  Regulation indicates comments due by 5:00 pm; reg.gov indicates comments due by 11:59 p.m. ET. | This proposed rule provides further detail and parameters related to: the risk adjustment, reinsurance, and risk corridors programs; cost-sharing reductions; user fees for a Federally facilitated Exchange; advance payments of the premium tax credit; a Federally facilitated Small Business Health Option Program; and the medical loss ratio program. **The cost-sharing reductions and advanced payments of the premium tax credit**, combined with new insurance market reforms, will significantly increase the number of individuals with health insurance coverage, particularly in the individual market. The premium stabilization programs--risk adjustment, reinsurance, and risk corridors--will protect against adverse selection in the newly enrolled population. These programs, in combination with the medical loss ratio program and market reforms extending  guaranteed availability (also known as guaranteed issue) protections and prohibiting the use of factors such as health status, medical history, gender, and industry of employment to set premium rates, will help to ensure that every American has access to high-quality, affordable health insurance. | **Comments filed 12/31/2012.** |  |
| **Model Qualified Health Plan Addendum (aka Indian Addendum)**  Request for Public Comment on the Draft Model Qualified Health Plan Addendum for Indian Health Care Providers | **Released: 11/20/2012**  **Due date: 12/19/2012** | On November 19, 2012, CMS and IHS jointly issued a Dear Tribal Leader letter seeking consultation on the Model Qualified Health Plan (QHP) Addendum for Indian health care providers. Written comments are due Wednesday, December 19th. Attached is the Dear Tribal Leader letter, the Addendum, and further information outlining the purpose and key provisions of the Addendum. A copy of the letter will be mailed to all 566 tribes and will be posted on the CMS website at <http://www.cms.gov/Outreach-and-Education/American-Indian-Alaska-Native/AIAN/index.html> and the IHS website at [www.ihs.gov](http://www.ihs.gov/)  The Addendum is designed to facilitate the inclusion of Indian health care providers in the QHP provider networks. It was developed in response to comments made during previous tribal consultations as well as with input from the CMS Tribal Technical Advisory Group and the Indian Health Service. We anticipate that the Addendum will enable QHP issuers to contract more efficiently with Indian health care providers to help ensure that American Indians and Alaska Natives (AI/AN)s can continue to be served by their Indian provider of choice. Although the Model QHP Addendum is not required, CMS will strongly encourage its use by QHPs. | **12/19/2012: Submitted by TTAG (and others.)** |  |