Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation
Summary of Proposed Rule
CMS-9980-P; RIN 0938-AR03

The Department of Health and Human Services (HHS) published in the *Federal Register* on November 26, 2012 a Notice of Proposed Rulemaking (NPRM) titled "Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation" (77 *FR* 70644-70676). **Comments are due by 5 pm Eastern Standard Time, December 26, 2012**.

The proposed rule addresses several policies required in the implementation of the Affordable Care Act:

- Standards related to required coverage of essential health benefits (EHB) including annual limits on cost-sharing and actuarial value (AV) of benefits.
- Standards for whether an employer-sponsored plan offers minimum essential coverage based on the AV of the plan. This standard is part of what determines if an employee of that employer is eligible to purchase a qualified health plan through the Exchange, and whether an applicable large employer may be subject to a financial penalty if the employee receives a subsidy in the Exchange.
- A timeline for qualified health plans (QHPs) to be accredited in Federally-facilitated Exchanges and for recognition of accrediting entities.

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I. Background

HHS sets out the provisions in the Affordable Care Act (ACA) that provide for the establishment of an EHB and AV requirements, as well as the accreditation requirements.

HHS notes that the statutory provisions related to the EHB and AV apply to all non-grandfathered health insurance coverage in the individual and small group markets (employers with 100 or fewer employees)[1] as well as to Medicaid benchmark and benchmark-equivalent plans and Basic Health Programs. HHS notes that this NPRM applies only in the individual and small group markets, and that EHB applicability to Medicaid and Basic Health Programs will be defined in a separate regulation.

HHS reviews its process of policy development, including a Department of Labor report on the health benefits market, an Institute of Medicine study commissioned by HHS on setting the EHB, extensive stakeholder consultation and the issuance of several documents outlining for comment its intended regulatory approach. In particular, HHS published on December 16, 2011 an "Essential Health Benefits Bulletin"[2] (the EHB Bulletin) that set out its intended directions on EHBs with opportunity for comments. HHS followed up with a series of FAQs and illustrative lists of small group insurance products in each State that could serve as base benchmark plans. HHS published a final rule on July 20, 2012[3] authorizing the collection of data to be used when states select benchmark options to define the EHB. HHS also published on February 24, 2012 an "Actuarial Value and Cost Sharing Reductions Bulletin"[4] (the AV Bulletin) setting out its intended directions on AV calculation and cost-sharing and seeking comment. Other previously issued documents are identified in this summary.

II. Provisions of the Proposed Regulations

Part 147 – Health Insurance Reform Requirements for the Group and Individual Health Insurance Markets

§147.150 Coverage of EHB

HHS proposes in §147.150 to codify the statutory requirement that a health insurance issuer offering coverage in the individual or small group market must ensure that coverage includes the essential health benefits (EHB) package defined in section 1302(a) of the ACA effective for plan or policy years beginning on or after January 1, 2014.

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[1] The Interim Final Rule on the status of plans as grandfathered plans is available at http://cciio.cms.gov/resources/regulations/index.html#gp.
[2] "EHB Bulletin," December 16, 2011. Available at: http://cciio.cms.gov/resources/files/Files2/12162011/essential_health_benefits_bulletin.pdf.
[3] 77 FR 42658 (July 20, 2012).
[4] Actuarial Value and Cost Sharing Reductions Bulletin," February 24, 2012. Available at: http://cciio.cms.gov/resources/files/Files2/02242012/Av-csr-bulletin.pdf.

HHS notes that this requirement for coverage of the EHB includes application of cost-sharing limits and the AV requirements, and that the requirement applies to issuers offering coverage in the individual or small group market inside or outside the Exchange.

HHS also proposes to codify in §147.150 the ACA provision that if a health insurance issuer in the individual market offers health insurance coverage in any level of coverage identified in section 1302(d)(1) of the ACA (the "metal levels"), it must offer coverage in that level to individuals who, as of the beginning of a plan year, have not yet reached the age of 21. HHS notes that this provision for child-only plans could be satisfied by an issuer offering the same product to applicants seeking child-only coverage that it offers to applicants seeking coverage for adults or families including both adults and children, so long as the child-only coverage is priced in accordance with applicable rating rules.

Part 155- Exchange Establishment Standards and other Related Standards under the Affordable Care Act

§155.170 Additional required benefits

Section 1311(d)(3)(B) of the ACA permits a state to require QHPs to offer additional benefits beyond the EHB but requires the state to make payment to defray the cost of these additional benefits.

HHS proposes in §155.170 to codify that explicit permission for a state to require additional benefits. It proposes that state-required benefits enacted on or before December 31, 2011 (even if effective at a later date) may be considered part of the EHB, which means that the state would not need to make payment for such benefits. HHS notes that such benefits would apply to QHP markets in the same way that they apply in the current market. For example, a benefit required in the individual market prior to that date would be considered part of the EHB (and not subject to state payment) only for the individual market, and not the small group market. HHS notes its intent to maintain this policy for state-required benefits as of December 31, 2011 for at least plan years 2014 and 2015.

HHS proposes that the Exchange identify which state-required benefits are in excess of the EHB, and notes that it intends to publish a list of state-required benefits that Exchanges can use as a reference tool. HHS notes, in response to comments on the EHB Bulletin, that it interprets state-required benefits to be specific to the care, treatment and services that a state requires issuers to offer enrollees. State rules related to provider types, cost-sharing or reimbursement methods would not fall under HHS' interpretation of state-required benefits. While plans must comply with such state requirements, there is no federal obligation for states to defray the costs, if any, associated with the requirements.

HHS proposes that the state must make payments to defray the costs of state-required benefits directly to an individual enrollee or directly to the QHP issuer on behalf of such individual. HHS provides no further guidance on this proposal.

HHS proposes that each QHP issuer be responsible for quantifying the costs attributable to each additional state-required benefit and reporting the costs to the Exchange. It proposes that the calculation be prepared by a member of the American Academy of Actuaries based on generally acceptable actuarial principles and methodologies. HHS notes that it considered four possible entities to conduct the calculation: QHP issuers, the state, the Exchange, and HHS. It decided to propose that the QHP issuer quantify the costs because the issuer generates the necessary data typically used to calculate such costs, and builds the costs into the overall premium spread across all enrollees. HHS notes that the calculation must be done prospectively to allow for an offset of an enrollee's share of premium and for purposes of calculating the premium tax credit and reduced cost-sharing. HHS requests comment on whether the state should make the payment based on the statewide average cost or based on each QHP issuer's actual costs.

HHS notes that it expects that there will be few, if any, payments made for state-required benefits because any such benefits enacted prior to December 31, 2012 will be part of the EHB.

§155.1045 Accreditation Timeline

HHS had previously set out in §155.1045 a timeline for QHP accreditation by an approved accrediting entity in state Exchanges. HHS now proposes in §155.1045 a new paragraph (b) to set forth the timeline for QHP accreditation in Federally-facilitated Exchanges, including State Partnership Exchanges. HHS proposes that:

- During an issuer's initial year of QHP certification in a state, an issuer without existing commercial, Medicaid or Exchange health plan accreditation in that state from a recognized accrediting entity must have scheduled or plan to schedule a review with a recognized accrediting entity.
- Prior to a QHP issuer's second and third year of certification, it must be either:
    - accredited by a recognized accrediting entity on the policies and procedures applicable to its Exchange product; or
    - have commercial or Medicaid health plan accreditation in that state from a recognized accrediting entity, and the administrative policies and procedures underlying that accreditation must be the same or similar to the policies and procedures used by the QHP.
- Prior to the QHP issuer's fourth year of certification (and for all subsequent years) it must be accredited by a recognized accrediting entity.

HHS notes that this accommodates new issuers and those not previously accredited, while ensuring that all QHP issuers make a commitment to ensuring the delivery of high quality care.

Part 156 – Health Insurance Issuer Standards under the Affordable Care Act, Including Standards Related to Exchanges

§156.20 Definitions

HHS proposes to add six new definitions to §156.20. It proposes two definitions related to actuarial value:

- Actuarial value (AV) means the percentage paid by a health plan of the percentage of the total allowed cost of benefits.
- Percentage of the total cost of allowed benefits means:
  the anticipated covered medical spending for EHB coverage paid by a health plan for a standard population, computed in accordance with the plan's cost-sharing
  divided by
  the total anticipated allowed charges for EHB coverage provided to a standard population.

HHS notes that, in general, AV can be considered a summary of a health plan's generosity.

HHS proposes three definitions related to benchmark plans for the EHB:

- Base-benchmark plan means the plan that is selected by a state from the options described in §156.100(a) (see below), or a default benchmark plan, as described in §156.100(c), prior to any adjustment made pursuant to the benchmark standards described in §156.110.
- EHB-benchmark plan means the standardized set of essential health benefits that must be met by a QHP.
- EHB package means the scope of covered benefits and associated limits of a health plan offered by an issuer that provides at least the 10 statutory categories of benefits, as described in §156.110(a); provides the benefits in the manner described in §156.115; limits the cost-sharing for such coverage as described in §156.130; and subject to offering catastrophic plans described in section 1302(e) of the ACA, provides distinct levels of coverage as described in §156.140 (these are the bronze, silver, gold and platinum levels of coverage).

Subpart B- Essential Health Benefits Package

§156.100 State selection of benchmark

HHS proposes, consistent with the approach outlined in the EHB Bulletin, that a state may select a base-benchmark plan from among four types of health plans:

- Small group market health plan: the largest health plan by enrollment in any of the three largest small group insurance products in the state's small group market.

- State employee health benefit plan: any of the largest three employee health benefit plan options by enrollment offered and generally available to state employees in the state.
- FEHBP plan: any of the largest three national Federal Employees Health Benefits Program (FEHBP) plan options by aggregate enrollment offered to all health-benefits-eligible federal employees.
- HMO: the coverage plan with the largest insured commercial non-Medicaid enrollment offered by a health maintenance organization operating in the state.

HHS proposes, again consistent with the approach outlined in the EHB Bulletin, that if a state does not make a selection, the default base-benchmark plan will be the largest plan by enrollment in the state's small group insurance market.

HHS proposes that a state-selected base-benchmark plan must meet the requirements for coverage of benefits and limits described in §156.110 (below) in order to become an EHB-benchmark plan; this includes coverage of at least the 10 categories of benefits outlined in the ACA.

HHS makes a number of points about the proposed policy. It will use enrollment data from the first quarter two years prior to the coverage year to determine plan enrollment. HHS has already provided states with data on the largest plans by enrollment in the three largest small group insurance products as of the first quarter of CY 2012.[5] HHS notes that the PHS Act defines "state" to include U.S. territories (Puerto Rico, Guam, the Virgin Islands, American Samoa, and the Northern Mariana Islands), so the EHB requirements apply to the territories. HHS seeks comments as to whether the default base-benchmark plan is an appropriate default for the territories given the smaller size and unique nature of their insurance markets, or whether one of the other four options, such as the largest FEHBP plan, would be more appropriate.

HHS notes that states were encouraged to submit their proposed benchmark selections for 2014 and 2015 by October 1, 2012, and that a state may submit a selection or revise its previous selection by the end of the comment period of the proposed rule (December 26, 2012). HHS sets out in Appendix A its current list of proposed benchmarks either selected by states or, for states that have not selected, the default benchmark under the proposed rule. HHS notes that issuers have commented that early selection is important to provide them with sufficient time to develop and receive certification for QHPs. HHS, in Appendix B to the proposed rule, makes available benefit data for the largest Federal Employees Dental and Vision Insurance Program (FEDVIP) dental and vision plans.

HHS notes that it received a number of comments on the EHB Bulletin about the ACA requirement for periodic review and update of the EHB definition. Some favored annual updates, while others recommended less frequent updates, including waiting until 2016 or 2017. HHS proposes that the state's benchmark plan selection in 2012 would be

[5] Available at http://cciio.cms.gov/resources/files/largest-smgroup-products-7-2-2012.pdf.PDF

applicable for the 2014 and 2015 benefit years. HHS notes that it chose to establish a consistent set of benefits for two years to reflect current market offerings and limit market disruption in the initial years of Exchanges. HHS notes that it intends to revisit the policy in future years, and invites comments on the process it should use for updating the EHB.

HHS also notes that it intends to use existing enforcement authorities at 45 CFR part 159 to ensure that plans adhere to the EHB standards. That generally provides that states have primary enforcement authority, but allows HHS to take enforcement actions against issuers if a state has notified HHS that it has not enacted legislation to enforce, or that it is not otherwise enforcing, or when HHS has determined that a state is not substantially enforcing the PHS Act. HHS notes that the ACA extended this enforcement authority to apply to the enforcement of title I of the ACA, including section 1302 (the EHB requirements).

§156.105 Determination of EHB for Multi-State Plans

HHS proposes that multi-state plans meet benchmark standards set by the Office of Personnel Management (OPM). HHS notes that OPM will promulgate regulations and guidance related to its Multi-State Plan Program.

§156.110 EHB Benchmark Plan Standards

§156.110(a) proposes to codify the ACA's requirement that an EHB-benchmark plan must provide coverage of at least the following 10 categories of benefits:

- Ambulatory patient services;
- Emergency services;
- Hospitalization;
- Maternity and newborn care;
- Mental health and substance use disorder services, including behavioral health treatment;
- Prescription drugs;
- Rehabilitative and habilitative services and devices;
- Laboratory services;
- Preventive and wellness services and chronic disease management; and
- Pediatric services, including oral and vision care.

HHS notes that several states asked for a definition of the age of coverage of pediatric services, and that it interprets pediatric services to mean services for an individual under the age of 19 years. This interpretation is consistent with the age stated in the ACA's prohibition on preexisting conditions for children and the age limit for eligibility in the Child Health Insurance Program. HHS notes that states have the flexibility to extend pediatric coverage beyond the proposed 19 year age limit.

§156.110(b) proposes standards for supplementing a base-benchmark plan that does not provide coverage of one or more of the 10 categories listed. HHS proposes, as a general

supplementation methodology, that the base-benchmark plan be supplemented by the addition of the entire category of missing benefits offered under any other of the four benchmark plan options described in §156.100.

HHS then proposes policy for two categories of benefits that may not currently be included in some major medical benefit plans: pediatric oral and vision services.

To supplement a base-benefit plan that does not include the category of pediatric oral services, HHS proposes that it must be supplemented by one of two options: the FEDVIP dental plan with the largest national enrollment (identified in Appendix B as the MetLife Federal Dental Plan-High), or by the benefits available under that state's separate CHIP plan, if a separate CHIP plan exists, to the eligibility group with the highest enrollment.

To supplement a base-benefit plan that does not include the category of pediatric vision services, HHS also proposes two options for supplementation: the FEDVIP vision plan with the largest national enrollment (identified in Appendix B as the BCBS Association FEP BlueVision – High), or by the benefits available under that state's separate CHIP plan, if a separate CHIP plan exists, to the eligibility group with the highest enrollment. HHS notes that this second option, use of the state's CHIP plan for supplementing pediatric vision services, was not included in the EHB Bulletin, but was added to provide states additional flexibility in selecting the EHB benchmark plan.

HHS will make benefit data available to facilitate any supplementation by states with FEDVIP dental and vision plans prior to the publication of the final rule.

§156.110(c) proposes that a default base-benchmark plan for a state that lacks any of the 10 categories of required benefits will be supplemented by HHS in the following order, to the extent that any of the plans offer benefits in the missing EHB category:

- The largest plan by enrollment in the second largest product in the state's small group market (except for pediatric oral and vision benefits).
- The largest plan by enrollment in the third largest product in the state's small group market (except for pediatric oral and vision benefits).
- The largest national FEHBP plan by enrollment across states (except for pediatric oral and vision benefits).
- The FEDVIP dental and vision plans with the largest national enrollment for pediatric oral and vision benefits, respectively.
- A habilitative benefit determined by the plan or the state under the habilitative benefit provisions that follow.

§156.110(d) proposes that the EHB not include discriminatory benefit design defined in §156.125 (see below). HHS notes that the standard would apply to benefit designs that limit enrollment and those that prohibit access to care for enrollees. HHS further notes that it believes it unlikely that an EHB-benchmark plan will include discriminatory offerings, but that this section proposes that if such a plan does include discriminatory benefit design the design must be adjusted to eliminate such discrimination. HHS solicits

comments on potential approaches to ensuring that EHB-benchmark plans do not include discriminatory design.

§156.110(e) proposes that the EHB-benchmark plan ensure an appropriate balance among the benefit categories to ensure that benefits are not unduly weighted toward any category. HHS solicits comments on potential approaches to ensuring that EHB-benchmark plans achieve appropriate balance.

§156.110(f) HHS notes that its research on employer-sponsored benefits and state-required benefits indicates that many health insurance plans do not identify habilitative services as a distinct group of services. HHS proposes, as a transition policy, that if a base-benchmark plan does not include habilitative services, the state may determine which services to include in that category. HHS notes that this policy, which provides additional flexibility beyond that outlined in the EHB Bulletin, will provide an opportunity for states to lead the development of policy in this area, and HHS welcomes comments on this proposed approach. HHS further notes that if states do not define the habilitative services category, plans must provide these benefits as set out in §156.115 (below).

HHS notes that it is requesting public comment on all possible EHB-benchmark plans, not just those included as proposed benchmarks. This includes potential base-benchmark plans as well as potential combinations of benefits used to supplement the base-benchmark plan.

§156.115 Provision of the EHB

§156.115(a) proposes that provision of an EHB means that a health plan provides benefits that meet the following standards:

- Benefits must be substantially equal to those covered by the EHB-benchmark plan, including covered benefits, limitations on coverage including benefit amount, duration and scope; and prescription drug benefits that meet the requirements of §156.120.
- Mental health and substance abuse services, including behavioral health treatment services, must comply with the requirements of §146.136, which are the parity standards implementing the Mental Health Parity and Addiction Equity Act of 2008.
- An EHB must include provision of all preventive services mandated under the ACA, without cost sharing, and codified under §147.130. HHS notes that it believes that setting this requirement for the EHB is necessary because EHB-benchmark plans are based on 2012 designs that could include a grandfathered plan not subject to the codified ACA requirement for coverage of certain preventive benefits without cost sharing.
- If the EHB-benchmark plan does not include habilitative services and the state has not taken advantage of the option under §156.110(f) to define those services, HHS proposes that a health plan must either:

- Provide parity by covering habilitative services benefits similar in scope, amount and duration to covered rehabilitation services; or
- Determine its coverage of habilitative services and report on that coverage to HHS.

HHS notes that it intends to evaluate the habilitative reported benefits and further define the benefit in the future. HHS believes that this would provide a valuable window of opportunity for review and development of policy and welcomes comments on the proposed approach.

§156.115(b) proposes, consistent with the EHB Bulletin, that benefit substitution be allowed under specified conditions:

- HHS proposes that issuers may substitute a benefit that is actuarially equivalent to the benefit that is being replaced, and is within the same essential health benefits category, and is not a prescription drug benefit. HHS notes that this means that substitution could only occur within, not between, benefit categories.
- HHS proposes that issuers must submit evidence of actuarial equivalence to the state. This certification must be conducted by a member of the American Academy of Actuaries, in accordance with generally accepted actuarial principles and methodologies, and use a standardized population.
- HHS proposes that actuarial equivalence be determined without regard to cost-sharing, which it notes will be considered in the AV calculation under 156.135.

HHS notes that the resulting plan benefits, after any such substitution, would still be subject to the non-discrimination requirements. HHS notes that states have the option to enforce a stricter standard on benefit substitution, or can prohibit substitution completely. HHS notes that a plan may not exclude an enrollee from coverage in an entire EHB category covered by the plan, citing as an example that a plan may not exclude dependent children from the category of maternity and newborn coverage.

HHS notes that it seeks additional comment on the tradeoff between comparability of benefits and opportunities for innovation and benefit choice.

§156.115(c) proposes to clarify that a plan does not fail to provide an EHB solely because it does not offer the services described in §156.280(d), which is the definition of abortion services for which public funding is prohibited. HHS notes that that provision applies to all services under ACA section 1303, including pharmacological services.

§156.115(d) proposes that a plan offering EHB may not include as EHB routine non-pediatric dental, routine non-pediatric eye exam services, long-term or custodial nursing home care benefits, or cosmetic orthodontia. HHS notes that the ACA requires the EHB to include at least the 10 listed categories of benefits and be equal in scope to a typical employer plan. HHS notes that the benefits it proposes for exclusion often qualify as "excepted benefits."[6] HHS notes that it proposes that issuers may not include these

[6] See 26 CFR 54.9831-1; 29 CFR 2590.732; 45 CFR 146.145 and 148.220.

benefits as EHB pursuant to the statutory direction that benefits be equal in scope to a typical employer plan, and solicits comments on the exclusion of these benefits from EHB coverage.

§156.120 Prescription drug benefits

§156.120(a) proposes that, with the exception noted in (b), a health plan must cover, at a minimum, the greater of:

- One drug in every U.S Pharmacopeia (USP) category and class, or
- The same number of drugs in each category and class as the EHB-benchmark plan.

HHS proposes that the health plan must submit its drug list to the Exchange, the state, or OPM.

HHS notes that in the EHB Bulletin it indicated that it was considering an option to require coverage of at least one drug in every USP category and class. Specific drugs could vary, as long as a drug in each category and class was covered. HHS received a large number of comments. Many indicated that the requirement of just one drug in each category and class could result in insufficient access to medications for individuals with certain conditions. Some recommended that HHS adopt for the EHB the standards used in Medicare Part D, including coverage of substantially all FDA-approved drugs in certain protected categories and classes. Other commenters emphasized the importance of flexibility for issuers in designing benefits that maximize value.

HHS notes that its revised proposal for coverage of the greater of one drug in every USP category and class, or the same number of drugs in each category and class as the EHB-benchmark plan, reflects the comments and the need to balance access with affordability. It notes that it is consistent with coverage in the small group market today.

HHS discusses that it is considering using the most recent version of the USP classification system as a common organizational tool for plans to report drug coverage. It is publicly available, widely used and comprehensive. Directing plans to submit their drug list using the same classification system would facilitate review, analysis and comparison of the number of drugs on a QHP's list with the number of drugs on the EHB-benchmark plan's list.

HHS notes that each EHB plan would be able to choose different drugs, but that those drugs must be presented using the USP classification system. HHS believes that this permits plan flexibility in benefit design and medical management, while ensuring that plans offer drug coverage consistent with that of the typical employer plan.

HHS notes that, if adopted in the final rule, it will continue to assess the need for and value of the use of the USP system and it intends to work with states and the National Association of Insurance Commissioners (NAIC) to facilitate use of the USP system.

HHS also notes that the proposed required use of the USP classification system applies only to the submission of the formulary for review and certification. Plans may continue to use any classification system they choose in marketing and other plan materials.

HHS also notes that it also proposes (although not in the proposed regulatory language) that drugs listed be chemically distinct, a concept described in the Medicare Part D Manual.[7] HHS cites as an example that offering two dosage forms or strengths of the same drug would not be offering drugs that are chemically distinct, nor would offering a brand name drug and its generic equivalent. Such offerings would not count toward meeting the standard of offering the same number of drugs in a USP category and class as the EHB-benchmark.

§156.115(b) proposes that a health plan does not fail to provide EHB prescription drug benefits solely because it does not offer drugs for services described in §156.280(d), which is the definition of abortion services for which public funding is prohibited.

§156.115(c) proposes that a health plan must have procedures in place to allow an enrollee to request clinically appropriate drugs not covered by the health plan. HHS notes that this proposal is made to ensure access to clinically appropriate drugs prescribed by a provider that are not included in the plan's drug list, and is consistent with private plan practice today. HHS solicits comments on this proposal.

HHS notes that §156.125 (below) directs the Secretary to ensure that EHBs not be designed in a discriminatory manner. HHS encourages states to monitor and identify discriminatory benefit design or implementation, and to test for such discriminatory design. HHS notes that it will use information on complaints and appeals, and data on drug lists, to refine its prescription drug benefit policy in future years.

§156.125 Prohibition on discrimination

HHS proposes that an issuer does not provide EHB if its benefit design or implementation of that design discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions. Further, HHS proposes that issuers must comply with the requirements of §156.200(e), which prohibits discrimination based on factors including but not limited to race, disability and age, and §156.225, which prohibits marketing practices and benefit design that results in discrimination against individuals with significant or high cost health care needs.

HHS comments on a number of provisions in section 1302 of the ACA that it interprets, collectively, as a prohibition on discrimination by issuers. HHS sought stakeholder feedback and considered guidance provided by the IOM. Commenters expressed concern about the potential for benefit designs that discriminate against populations with significant health needs, and some recommended that HHS establish an explicit non-

[7] More information is available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads//Chapter6.pdf.

discrimination policy. HHS notes that, based on the input, it proposes an approach that would allow states to monitor and identify discriminatory benefit design or implementation. It notes that it would not prohibit issuers implementing the EHB standards from applying utilization management techniques, but issuers could not use such techniques to discriminate against certain groups of people. For example, HHS says that an issuer could use prior authorization, but could not determine when prior authorization is required or granted in a manner that discriminates on the basis of factors including age, disability, or length of life.

HHS notes that the proposal is intended to develop a framework for analysis to facilitate testing for discriminatory benefit designs. HHS believes such analyses could include identification of significant deviation from typical plan offerings, including unusual cost-sharing and limitations on benefits. HHS also notes that Medicare Advantage program cost-sharing is subject to this type of analysis. HHS welcomes comments on its proposed approach to prohibiting discriminatory benefit design.

§156.130 Cost-sharing requirements

HHS notes that the §147.150 requirement for coverage of the EHB (described earlier in this summary) includes application of cost-sharing limits and the AV requirements, and that the requirement applies to issuers offering coverage in the individual or small group market inside or outside the Exchange. HHS also notes that cost-sharing is defined in §156.20 as any expenditure required by or on behalf of an enrollee with respect to essential health benefits, and includes deductibles, coinsurance, copayments or similar charges. It excludes premiums, balance billing for non-network providers, and spending for non-covered services.

§156.130(a) proposes the annual limitation on cost-sharing, and codifies section 1302(c)(1)(A) of the ACA, which ties the annual limitation to the enrollee out-of-pocket limit for high-deductible health plans (HDHP) pursuant to section 223(c)(2)(A)(ii) of the Internal Revenue Code of 1986. The table below summarizes the proposed policy.

§156.130(a) Annual limits on cost sharing		
	Self-only coverage	**Coverage other than self-only coverage**
Plan year beginning in CY 2014	The annual dollar limit described in section 223(c)(2)(A)(ii)(I) of the Internal Revenue Code for self-only coverage in effect for 2014	The annual dollar limit described in section 223(c)(2)(A)(ii)(I) of the Internal Revenue Code for non-self-only coverage in effect for 2014
Plan year beginning in a CY after 2014	The dollar limit for CY 2014 for self-only coverage increased by the annual premium adjustment percentage (defined in paragraph (e) below)	The dollar limit for CY 2014 for non-self-only coverage increased by the annual premium adjustment percentage (defined in paragraph (e) below)
Note: The annual amount if this were in effect for 2013 would be $6,250 for self-only coverage and $12,500 for non-self-only coverage.		

HHS notes that the annual limit ensures that health plans pay for significant health expenses associated with the EHB and that, as a result, the risk of medical debt or bankruptcy is limited. Once the limitation is reached, the enrollee is not responsible for additional cost-sharing for the EHB for the remainder of the plan year.

§156.130(b) proposes to codify the annual limits on deductibles in the small group market established by section 1302(c)(2)(A)(i) and (ii) of the ACA. HHS notes that this limitation is established on QHPs and on non-grandfathered coverage in the small group market (as noted under proposed §147.150 above).

§156.130(b) Annual limits on deductibles for plans in the small group market		
	Self-only coverage	**Coverage other than self-only coverage**
Plan year beginning in CY 2014	$2,000	$4,000
Plan year beginning in a CY after 2014	The dollar limit for CY 2014 ($2,000) for self-only coverage increased by the annual premium adjustment percentage (defined in paragraph (e) below)	The dollar limit for CY 2014 ($4,000) for non-self-only coverage increased by the annual premium adjustment percentage (defined in paragraph (e) below)

HHS also proposes that a health plan's annual deductible may exceed the annual limit if that plan may not reasonably reach the actuarial value of a given level of coverage (defined in §156.140 below) without exceeding the annual deductible limit. HHS notes that it bases this proposal on the ACA's requirement in section 1302(c)(2)(C) that the limit be applied so as not to affect the AV of any plan. HHS notes that it proposes to use this "reasonableness" standard and requests comment on what evidence or factors should be required from an issuer and considered in determining whether this standard is met with respect to health insurance coverage. HHS notes that it may be possible to develop plan designs to meet all of the constraints (maximum deductible, annual limit, and AV), but it believes that it could be difficult to achieve in the future, for example in bronze (60 percent AV) plans. HHS notes that an alternative would be to use the AV calculator (described in §156.135) to determine a reasonable increase in the deductible limits for plans in the small group market. HHS solicits comments on its approach and on whether a specific variation threshold should be identified, and if so, how it should be established.

HHS notes that section 1302(c)(2)(A) of the ACA provides that the deductible maximums can, in certain circumstances, be increased by the maximum amount of reimbursement reasonably available to an employee under a flexible spending arrangement (FSA). HHS considered permitting the maximum deductible to increase by the amount available to each employee under an FSA, but notes that such variability in the maximum deductible by employee would require different deductible plans to be available to different employees based on FSA decisions made during open enrollment.

HHS interprets section 1302(c)(2)(A) as permitting but not requiring that FSAs be taken into account, and therefore proposes to standardize the maximum deductible for the small group market at the statutory levels noted above. HHS notes that it welcomes comments on permitting such an adjustment, including permitting an employer to attest to the amount available to employees in an FSA as the basis for increasing the maximum permissible deductible for employees.

§156.130(c) proposes that, in the case of a plan using a network of providers, cost-sharing for benefits outside of such network shall not count toward the annual limitation on cost sharing under §156.130(a) or the annual limitation on deductibles in §156.130(b). HHS notes that it considers an out-of-network provider to be a provider with whom the issuer does not have a contractual arrangement. An enrollee who utilizes many services could reach the annual limitation on cost sharing, or, in the case of a small group plan the annual deductible, and still be required to pay cost sharing if the enrollee has used services outside of the plan's network. HHS believes that this proposed policy would allow issuers greater flexibility to design innovative benefit structures, and notes that nothing in the proposal prohibits an issuer from establishing a maximum out-of-pocket limit applicable to out-of-network services, or a state from requiring that issuers do so. HHS solicits comments on this approach.

§156.130(d) proposes to codify the ACA requirement that any increase in the annual limits or the annual deductible limits be rounded to the next lowest multiple of $50.

§156.130(e) proposes that the premium adjustment percentage (used for changing the annual limits and the annual deductible limits) is the percentage, if any, by which the average per capita premium for health insurance coverage for the preceding calendar year exceeds the average per capita premium for health insurance for 2013. HHS notes that this ensures that the annual limits change with health insurance market premiums over time. HHS will publish this annual premium adjustment percentage in its annual notice of benefits and payment parameters.

§156.130(f) proposes to codify the ACA requirement that the annual deductibles do not apply to preventive services identified in §147.130 (which refers to required coverage of certain preventive services without cost-sharing).

§156.130(g) proposes that the structure of cost sharing must conform to the nondiscrimination requirements in §156.125.

§156.130(h) proposes, consistent with section 1302(b)(4)(e) of the ACA, that emergency department services must be provided without imposing any prior authorization or limitation of coverage where the provider of services is out-of-network that is more restrictive than the requirements or limits that apply to emergency department services provided in network. Further, HHS proposes that if services are provided out-of-network, cost sharing must be limited to the cost sharing for an in-network provider, as provided in previously published rules (§147.138(b)(3)).

§156.135 AV calculation for determining level of coverage

HHS proposes an approach for issuer calculation of the AV that it discussed in the AV Bulletin.

§156.135(a) proposes that issuers calculate the AV of a health plan using the AV calculator developed and made available by HHS. HHS discusses this approach in detail, noting that the AV calculator has been developed using a set of claims data weighted to reflect the standard population projected to enroll. Plans would input their own information on cost sharing parameters. HHS has made available a methodology document at http://cciio.cms.gov/resources/regulations/index.html#pm and notes specifically that the document is incorporated as part of the proposed rule. It includes the logic behind the calculator, a description of the development of the standard population (which is represented in the calculator in continuance tables of aggregated data that, in general, group enrollees by levels of spending). HHS solicits comments on the methodology and the continuance tables.

HHS notes that the consistent methodology in the AV calculation ensures a consistent set of assumptions and methods of AV calculation by all health plans using the calculator, resulting in comparability for the consumer. HHS further notes that its proposal for the calculator only considers in-network utilization, because only a small percentage of total costs come from out-of-network utilization.

HHS notes that the AV calculator will be available for informal and formal calculations, and could, for example be used as a tool to design health plans, allowing issuers to design a compliant plan without the burden of making the assumptions necessary or paying for a separate AV calculation. HHS solicits comments on this proposal. HHS also proposes that the AV calculator will use one or more sets of national claims data reflecting plans of various levels of generosity as the standard population.

HHS considered several alternatives, including distributing a standard set of de-identified individual-level claims data to issuers as the standard population to allow them to estimate the AV of their plans, or distributing only the continuance tables reflecting the standard population to issuers to allow them to make the AV calculation. HHS notes that commenters on the AV Bulletin were generally supportive of the approach it is proposing to develop a publicly available and transparent AV calculator.

§156.135(b) proposes exceptions to the use of the AV calculator, if an issuer's plan design is not compatible with the AV calculator. In that case, HHS proposes that the issuer must submit actuarial certification that it has complied with one of the following methods:

- Calculate the plan's AV by estimating how to fit the plan's design into the parameters of the AV calculator, and submit an actuarial certification by a member of the American Academy of Actuaries that the plan design was fit

appropriately in accordance with generally accepted actuarial principles and methodologies.

- Use the AV calculator to determine the AV for the plan provisions that do fit within the calculator parameters, and have a member of the American Academy of Actuaries calculate appropriate adjustments to the AV identified by the calculator for plan design features that deviate substantially from the parameters of the AV calculator, in accordance with generally accepted actuarial principles and methodologies.

HHS proposes that the calculation methods may include only in-network cost-sharing, including multi-tier networks.

HHS notes that it anticipates that the vast majority of plans will be able to use the AV calculator, but that some may not. For example, it expects that the calculator will not be able to accommodate multiple coinsurance rates as different levels of out-of-pocket spending are met, or a multi-tier network with substantial use expected in tiers other than the lowest-price tier.

§156.135(c) proposes that, for plans other than those in the individual market, annual employer contributions to Health Savings Accounts (HSAs) and amounts newly made available under Health Reimbursement Accounts (HRAs) for the current year in the small group market would be counted toward the total anticipated medical spending of the standard population paid by the health plan. HHS notes if such accounts are not included, it would understate the value of coverage offered. HHS notes that this means, for example, that a plan with a $0 deductible has the same AV as a plan with a $1,000 deductible plus a $1,000 HSA or HRA.

HHS notes that section 1302(d)(2)(B) of the ACA directs the Secretary to include an employer's contributions to an HSA in determining the level of coverage, without reference to an HRA. HHS is interpreting the statue to allow for a similar treatment of HRAs because an HRA integrated with a small group market plan has a similar impact on AV calculation as an HSA. HHS also notes that employee HSA contributions will not count toward AV, nor do the provisions apply in the individual market because HSAs in the individual market are funded directly by the enrollee.

§156.135(d) proposes that, beginning in 2015, states can use a state-submitted data set on a standard population to calculate AV. Approval of the data set by HHS is contingent on it meeting the requirements of §156.135(e) (below) and a determination that it:

- Supports calculation of AVs for the full range of health plans in the market;
- Is derived from a non-elderly population and estimates those likely to be covered by private health plans on or after January 1, 2014;
- Is large enough that demographic and spending patterns are stable over time, and includes a substantial majority of the state's insured population;
- Is a statistically reliable and stable basis for area-specific calculations; and
- Contains claims data on services typically offered in the then-current market.

HHS notes that issuers in such a state would still use the AV calculator's logic, but the underlying data on the standard population would be specific to the state, and that its proposed criteria are based on its review of a July, 2011 American Academy of Actuaries issue brief.[8] HHS notes that commenters on the AV Bulletin generally supported the proposal to allow states the flexibility to provide their own data sets, and some groups commented that the state data would need to be at least as robust as the national data set. HHS believes that the proposed regulatory parameters will ensure that state-specific data are sufficiently robust, and solicits comments on the proposal and criteria.

§156.135(e) proposes that AV will be calculated using the default standard population identified in §156.135 (f) below, unless a state submits and HHS approves a state data set that can support the use of the AV calculator consistent with §156.135(e) above. HHS notes that, because it uses continuance tables to support the AV calculator, it anticipates that states will also submit any state-specific data sets in the form of continuance tables, and HHS intends to provide a template and instructions for these submissions.

HHS notes that it remains open to comments on the use of state data for 2014, but given time constraints, it proposes that the option for states to submit a state-specific standard population will begin for 2015. It expects that submissions will be due the second quarter of the year prior to the benefit year.

§156.135(f) proposes that HHS will provide the default standard population and summary statistics, such as continuance tables, in a format that supports the calculation of AV.

HHS solicits comments on the proposal of whether the AV calculator should allow for variation among states, and whether it should consider including up to three regional adjustments for geographic price differences described in the AV Bulletin. That Bulletin set out a proposal to assign each state to one of three health care pricing tiers in calculating the AV.

§156.140 Levels of Coverage

HHS proposes to codify the ACA requirements for levels of coverage based on AV (calculated in accordance with §156.135). Those are:

- Bronze: AV of 60 percent;
- Silver: AV of 70 percent;
- Gold: AV of 80 percent;
- Platinum: AV of 90 percent.

HHS proposes to allow de minimus variation in AV of +/- 2 percentage points. HHS notes that this means that a silver plan could have an AV between 68 and 72 percent, and it believes that this strikes the right balance between ensuring comparability among plans

[8] Available at http://www.actuary.org/pdf/health/Actuarial_Value_Issue_Brief_072211.pdf.

within each metal level while allowing plans flexibility to use convenient cost-sharing metrics. HHS notes that comments on the AV Bulletin were generally supportive of this approach.

§156.145 Determination of Minimum Value (MV)

This part of the proposed rule shifts from EHB and cost sharing requirements. HHS notes that the ACA sets a standard for whether an eligible employer-sponsored plan provides minimum value. This definition is important because individuals eligible for minimal essential coverage, including coverage under an employer-sponsored plan that is affordable and provides minimum value, are not eligible for a premium tax credit in the Exchange. Further, an applicable large employer that offers a health benefit plan that does not provide minimum value may be liable for an assessment if any full-time employee receives a premium tax credit. Sec 36B(c)(2)(C) of the Internal Revenue Code, as added by the ACA, provides that an employer-sponsored plan does not provide minimum value if the plan's share of the total allowed costs of benefits provided under the plan is less than 60 percent of such costs. The IRS, in Treasury Notice 2012-31, "Minimum Value of an Employer-Sponsored Health Plan" (the "MV Bulletin") issued May 14, 2012, described and requested comments on approaches for determining minimum value.

§156.145(a) proposes several methods that a group health plan may use for determining that an employer-sponsored plan provides minimum value:

- The MV calculator to be made available by HHS and the IRS;
- Any safe harbor established by HHS and the IRS; and
- If neither of the first two methods is appropriate, a group health plan may seek certification of MV by a member of the American Academy of Actuaries, based on generally accepted actuarial principles and methodologies.

HHS notes that the MV calculator would be similar in design to the AV calculator, but based on continuance tables and a standard population reflecting typical self-insured employer plans. This approach would permit an employer-sponsored plan to enter information about the plans cost sharing to determine whether the plan provides MV.

HHS notes that the safe harbor option would be based on an array of design-based safe harbor checklists published by HHS and the IRS. Each would describe the cost-sharing attributes that apply to four core categories of benefits and services that comprise the vast majority of group health plan spending (as described in the MV Bulletin): physician and mid-level practitioner care, hospital and emergency room services, pharmacy benefits, and laboratory and imaging services.

HHS notes that the final option would be available only when one of the first two methods is not applicable to the employer-sponsored plan, and that it intends to issue guidance concerning the actuarial analysis required under that option.

§156.145(b) proposes that if a group health plan offers an EHB outside the parameters of the MV calculator, a member of the American Academy of Actuaries can determine the value of that benefit and adjust the result derived from the MV calculator. HHS further proposes that a group health plan will be permitted to take into account all benefits provided by the plan that are included in any of the EHB benchmarks.

HHS notes that there are no EHB standards for employer-sponsored self-insured group health plans or insured large group health plans. It proposes that for calculating MV the plan is permitted to take into account any benefit it offers that is included in any of the EHB benchmarks (this presumably means any of the state-selected or default EHB benchmarks).

§156.145(c) proposes that the standard population for MV will reflect the population covered by self-insured group health plans, and will be developed by HHS for such use.

§156.150 Application to stand-alone dental plans inside the Exchange

HHS notes that the ACA allows the pediatric dental component of the EHB to be offered through a stand-alone dental plan in an Exchange. If a stand-alone dental plan is offered, QHPs offered in that Exchange may exclude coverage of the pediatric dental component of the EHB.

§156.150(a) proposes that a stand-alone dental plan must demonstrate to the Exchange that it has a reasonable annual limit on cost sharing, calculated without regard to EHBs provided by the QHP and without regard to out-of-network services.

HHS discusses a number of alternatives, including applying the full annual limit on cost sharing separately to stand-alone dental plans, or excluding the pediatric dental benefit entirely from calculations of annual limits whether offered through a health plan or a stand-alone dental plan. HHS requests comments on the proposal and on what should be considered a reasonable annual limit on cost sharing. It notes that the annual limit would be applicable to in-network services only.

§156.150(b) proposes that a stand-alone dental plan may not use the AV calculator, and must demonstrate that it offers the pediatric dental EHB at either:

- A "low" level of coverage with an AV of 75 percent; or
- A "high" level of coverage with an AV of 85 percent; and
- With a de minimus variation of plus/minus 2 percentage points.

HHS proposes that the level of coverage must be certified by a member of the American Academy of Actuaries using generally accepted actuarial principles.

HHS notes that the "high" and "low" AV standards would apply only in stand-alone dental plans. HHS requests comments on the proposal, alternative approaches, whether

the de minimus variation standard is feasible for stand-alone dental plans, and on the AV standards for "high" and "low" designation.

§156.275 Accreditation of QHP Issuers

HHS notes by way of background that it proposes to amend the current, or "phase one" recognition process for accrediting entities that was previously finalized on July 20, 2012 (77 *FR* 42658) in order to provide additional accrediting entities the opportunity to apply and demonstrate that they meet the conditions for recognition. HHS notes that its initial survey of the market showed that two entities, the National Committee for Quality Assurance (NCQA) and URAC met the statutory requirements for accreditation. During the public comment period, additional entities indicated that they may soon meet the conditions.

HHS proposes to add to §156.275 by providing for an application and review process for phase-one recognition of accrediting entities. HHS proposes that within 60 days of receiving a complete application, HHS will publish a notice in the *Federal Register* identifying the accrediting entity making the request, summarizing HHS' analysis, and providing no less than a 30 day comment period about whether HHS should recognize the accrediting entity. HHS proposes that it will notify the public in the *Federal Register* after the close of the comment period the names of those recognized and those not recognized as accrediting entities. Finally, HHS proposes to require documentation with the application for review (this would replace the prior time frame for submitting documentation within 60 days of publication of the final rule).

HHS also notes that in a *Federal Register* notice published concurrently with this proposed rule, it is notifying the public that NCQA and URAC are recognized as accrediting entities for the purposes of QHP certification. HHS notes that this recognition of accrediting entities in phase one is effective until rescinded or until the interim phase one process is replaced by the as yet undetermined phase two process.

III. Collection of Information

Information Collection Requirements: HHS presents information collection requirements, which are summarized in the table below.

Requirement	Number affected	Total Cost
§155.170(c) Additional Required Benefits	2,010 issuers in individual market 1,050 issuers in small group market	$1,721,250
§156.100 State Selection of Benchmark, and Benchmark Plan Standards	HHS does not believe that this is a change to information collection requirements already captured in previous requirements	
§156.135(b) AV Calculation for Determining Level of Coverage – alternative for issuers not using the AV Calculator	1,200 issuers will each offer 15 potential QHPs, for a total of 18,000 QHPs. Only 5% will be unable to use the AV calculator and use the alternative	$1,800 per QHP and $1,620,000 total
156.135(d) AV Calculation for Determining Level of Coverage – state option to submit state-specific data		$1,018 per state choosing the option
§156.275 Accreditation process for phase one accreditation	HHS will revise its previous estimate and now estimates that four entities will apply	HHS will revise estimate accordingly

IV. Regulatory Impact Analysis

HHS has determined that the proposed rule is an economically significant regulatory action (economic effects of $100 million or more in any one year). As a result, the regulation was reviewed by the Office of Management and Budget and a regulatory impact analysis (RIA) is required.

Summary

HHS notes that the previously issued Exchange regulations (45 CFR 156.200) established that QHPs will cover essential health benefits, and will be accredited on the basis of local performance. The costs to health plans of participating in the Exchanges and obtaining QHP certification were accounted for in the RIA that accompanied that regulation.[9] This analysis describes incremental costs and benefits and transfers associated with this proposed rule.

HHS notes that that the proposed details for establishment of a timeline for certification by federally facilitated Exchanges do not result in incremental costs, benefits or transfers.

[9] RIA available at: http://cciio.cms.gov/resources/files/Files2/03162012/hie3r-ria-032012.pdf.

Summary Accounting Table

Table IV.1 in the RIA, which is summarized below, summarizes the accounting table for benefits, costs, and transfers, with dollars computed at both 7% and 3% discount rates

Summary Excerpts from Accounting Table IV.1 from RIA in Proposed Rule		
	2012	**2012-2016**
Benefits		
Annualized monetized	Not estimated	Not estimated
Qualitative	(1) Improved coverage in benefit categories less typically available. Expanded access to covered benefits, especially in the individual market, including maternity and prescription drug coverage. (2) Alignment with current consumer and employer choices. Flexibility for states, limited market disruption, allowance for health plan innovation (e.g., substitution within benefit categories, de minimus variation for AV) (3) Efficiency due to greater transparency. Increased transparency and consumer ability to compare coverage.	
Costs		
Annualized monetized ($ million / year)	$1.7 million at a 7% discount rate, $1.5 million at a 3% discount rate. Note: costs include costs associated with the information collection requirements as described in section III.	Not available
Qualitative	(1) Administrative costs. Insurers will incur administrative costs associated with altering benefit packages to ensure compliance with the definition of EHB. Issuers may also incur minor administrative costs related to computing AV. (2) Costs due to higher service utilization. As consumers gain additional coverage for benefits that previously did not meet the standards outlined in the proposed rule (such as pediatric dental or vision coverage) utilization and costs may increase. A portion of this increase will be economically inefficient as insurance coverage creates a tendency to overuse health care. There may be incremental costs to consumers associated with greater service utilization.	
Transfers	Not estimated	Not estimated

Estimated Number of Affected Entities

HHS presents in Table IV.2 (summarized below) the number of issuers affected by the proposed regulation at a company level, as well as at the "licensed entity" level because many issuers are licensed in more than one state.

Table IV.2 from Proposed Rule: Estimated number of issuers and licensed entities affected by the EHB and AV requirements, by market, 2011				
	Issuers (companies)		**Licensed entities**	
	Number	**% of Total**	**Number**	**% of Total**
Total issuers offering comprehensive major medical coverage	446	100%	2,107	100%
By market				
Individual market	355	79.6%	1,663	78.9%
Small group market	366	82.1%	1,039	49.3%
Large group market	375	84.1%	922	43/8%
Individual and/or small group markets	427	95.7%	1,993	94.6%
Individual market only	82	18.4%	904	42.9%
Small group market only	39	8.7%	117	5.6%
Individual and small group markets only	29	6.5%	164	7.8%
All three markets	279	62.6%	545	25.9%
Notes: consult Table IV.2 in the proposed rule for a number of notes about excluded data.				

HHS notes that CBO estimates that there will be approximately 23 million Exchange enrollees by 2016, with participation rates lower in the initial years. The EHB and AV provisions in the proposed rule will also affect enrollees in non-grandfathered individual and small group market coverage outside of the Exchanges.

V. There is no section V.

VI. Regulatory Flexibility Act

HHS reviews the Regulatory Flexibility Act and analyzes the impact of the proposed rule on small entities. The Secretary certifies that the proposed rule will not have a significant impact on a substantial number of small entities. HHS welcomes comment on its analysis.

VII. Unfunded Mandates

HHS reviews the Unfunded Mandates Reform Act and the impact of the proposed rule on state, local or tribal governments and the private sector. It analyzes the impact and does not believe that it imposes costs in excess of the $139 million threshold established by the Act.

VIII. Federalism

HHS reviews the required Federalism implications. HHS believes that while the proposed rule does not impose substantial direct costs on state and local government, it does have implications due to the direct effect on the distribution of power and responsibilities among the states and federal government in determining standards for health insurance coverage in the individual and small group markets. HHS expects that those implications are mitigated as the proposed rule offers substantial discretion to states. HHS notes extensive consultations with key state and local stakeholders.