

# Patient Protection and Affordable Care Act: Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation

## Summary of Final Rule CMS-9980-F; RIN 0938-AR03

The Department of Health and Human Services (HHS) on February 25, 2013 published in the *Federal Register* (78 FR 12834-12872) final rules on Standards Related to Essential Health Benefits, Actuarial Value and Accreditation. This rule finalizes, with changes, the Department's proposed rule published November 26, 2012 (77 FR 70644-70676).

It finalizes:

- 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.
- 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) as well as to Medicaid benchmark and benchmark-equivalent plans and Basic Health Programs. HHS notes that this final rule 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 (proposed rules for Medicaid were published in the *Federal Register* on January 22, 2013 (78 *FR* 4594-4724).

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.

HHS published on December 16, 2011 an “Essential Health Benefits Bulletin”<sup>1</sup> (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<sup>2</sup> 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”<sup>3</sup> (the AV Bulletin) setting out its intended directions on AV calculation and cost-sharing and seeking comment. As noted earlier, the rule finalizes with changes the Department’s NPRM issued on November 26, 2012.<sup>4</sup>

The Department also released a set of FAQs associated with the final rule<sup>5</sup> along with AV and MV calculators and methodologies.<sup>6</sup>

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<sup>1</sup> “EHB Bulletin,” December 16, 2011. Available at:

[http://cciio.cms.gov/resources/files/Files2/12162011/essential\\_health\\_benefits\\_bulletin.pdf](http://cciio.cms.gov/resources/files/Files2/12162011/essential_health_benefits_bulletin.pdf).

<sup>2</sup> Available at: <http://www.gpo.gov/fdsys/pkg/FR-2012-07-20/pdf/2012-17831.pdf>.

<sup>3</sup> Actuarial Value and Cost Sharing Reductions Bulletin,” February 24, 2012. Available at:

<http://cciio.cms.gov/resources/files/Files2/02242012/Av-csr-bulletin.pdf>.

<sup>4</sup> The NPRM is available at: <http://www.gpo.gov/fdsys/pkg/FR-2012-11-26/pdf/2012-28362.pdf>

<sup>5</sup> Affordable Care Act Implementation FAQs-12. Available at:

<http://cciio.cms.gov/resources/files/Files2/02172012/ehb-faq-508.pdf>

<sup>6</sup> Available at: <http://cciio.cms.gov/resources/regulations/index.html#pm>

## II. Provisions of the Final Regulations

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

#### §147.150 Coverage of EHB

HHS finalizes at §147.150 its proposal 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.

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 markets inside or outside the Exchange.

HHS also finalizes its proposal to codify 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 at 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.

HHS reviews in the preamble its interpretation (along with that of the Departments of Labor and Treasury) of the applicability of different cost-sharing limits in the group market, and issued the previously cited Frequently Asked Questions document <http://cciio.cms.gov/resources/files/Files2/02172012/ehb-faq-508.pdf>. The three Departments intend to engage in future rulemaking but explain in more detail in the preamble and in the FAQs their intended approach.

- **Deductible limits:** the Departments have concluded that the deductible limits under section 1302(c)(2) of the ACA apply only to plans and issuers in the small group market and not to self-insured group health plans, large group health plans, or health insurance issuers offering coverage in the large group market.
- **Annual limits:** the Departments have concluded that the annual limits on cost sharing under section 1302(c)(1) of the ACA apply to all non-grandfathered group health plans.

HHS notes in the preamble that the Departments received comments requesting that self-insured plans be exempt from the annual limits, and expressing operational concerns with applying a single annual limit to any group EHB administered by separate contractors. In

particular, contractors noted the practice of using a pharmacy benefit manager to administer prescription benefits separately from medical benefits.

As a result, while the Departments interpret the provisions to mean that all group health plans, including large group market and self-insured plans, must comply with the annual limitation on out-of-pocket maximums, they find that transitional relief is appropriate, and the FAQ document, in Question 2, establishes that relief.

“The Departments have determined that, only for the first plan year beginning on or after January 1, 2014, where a group health plan or group health insurance issuer utilizes more than one service provider to administer benefits that are subject to the annual limitation on out-of-pocket maximums under section 2707(a) or 2707(b), the Departments will consider the annual limitation on out-of-pocket maximums to be satisfied if both of the following conditions are satisfied:

- (a) The plan complies with the requirements with respect to its major medical coverage (excluding, for example, prescription drug coverage and pediatric dental coverage); and
- (b) To the extent the plan or any health insurance coverage includes an out-of-pocket maximum on coverage that does not consist solely of major medical coverage (for example, if a separate out-of-pocket maximum applies with respect to prescription drug coverage), such out of pocket maximum does not exceed the dollar amounts set forth in section 1302(c)(1).”

However, the FAQ further notes that, under the Mental Health Parity and Addiction Equity Act of 2008, plans and issuers are prohibited from imposing an annual out-of-pocket maximum on all medical/surgical benefits and a separate out-of-pocket maximum on all mental health and substance use disorder services.

## **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 finalizes at §155.170 without change its proposal related to state requirements to offer additional benefits beyond the EHB. State-required benefits enacted on or before December 31, 2011 (even if effective at a later date) are considered part of the EHB, which means that the state will not need to make payment for such benefits. HHS notes that some concerns were expressed about costs, but that most favored this policy and that research indicated that the majority of state-required benefits would have a negligible impact on premiums. HHS notes that such benefits will 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 will 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.

Exchanges will identify which state-required benefits are in excess of the EHB. HHS maintains a list of state-required benefits that Exchanges can use as a reference tool. Current information for each state is at: <http://cciio.cms.gov/resources/data/ehb.html>. HHS notes, in response to comments, that it interprets state-required benefits to be specific to the care, treatment and services that a state requires issuers to offer enrollees. HHS reiterates that state rules related to provider types, cost-sharing or reimbursement methods will 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.

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. While some comments suggested that payments to the enrollee not be permitted, HHS maintains this as a state option based on its reading of the statutory requirement.

Each QHP issuer is responsible for quantifying the costs attributable to each additional state-required benefit and reporting the costs to the Exchange. The calculation must be prepared by a member of the American Academy of Actuaries based on generally acceptable actuarial principles and methodologies. HHS noted in the proposed rule 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 notes that it will provide states the option for making the payments based on the statewide average cost of the state-required benefit or based on each QHP issuer's actual costs.

### **§155.1045 Accreditation Timeline**

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

- 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 in response to comments that that this policy 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. It further notes in response to comments that:

- This phased approach is designed to align with the earliest possible time that issuers are able to report performance data on their QHP population (for example, in 2015 for the 2014 performance year).
- It is requiring performance-level reporting at the product level as part of accreditation required in 2016.
- States may align with the proposed Federally-facilitated Exchange timeline, but are not required to do so.
- Issuers participating in Exchanges need to meet a range of other standards, and HHS anticipates future rulemaking on QHP issuer quality reporting requirements.
- It considers issuers to have existing accreditation if accredited for the product type at issue (such as a PPO) under the same legal entity that is offering that product in the Exchange, and the accreditation in that case will extend to multiple QHPs of that product type in the Exchange.
- The standards require that all QHP issuers be accredited according to the phasing schedule, including CO-OPs and Medicaid managed care. As noted in the Exchange Establishment Final Rule, to the extent that accreditation standards for stand-alone dental plans do not exist, such plans are not required to meet the accreditation timeline.
- HHS will be issuing guidance on operationalizing these requirements, such as when in a certification year a QHP must be accredited.
- The Office of Personnel Management (OPM) will set the standards for accreditation of multi-state plans (see OPM's December 5, 2012 proposed rules at 77 FR 72582).

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

### **§156.20 Definitions**

HHS finalizes new definitions at §156.20 with only technical changes. Two definitions relate 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 noted in the proposed rule that, in general, AV can be considered a summary of a health plan's generosity.

Three definitions relate to 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.
- Essential Health Benefits or 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 finalizes its proposal (with one clarification noted below as to the default benchmark plan in the case of the territories) 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.

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.

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 will use enrollment data from the first quarter two years prior to the coverage year to determine plan enrollment. HHS has 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.<sup>7</sup>

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. In response to comments about the markets in the territories, HHS in the final rule sets the default base benchmark plan for all of the territories except for Puerto Rico as the largest FEHBP plan. The default benchmark plan for Puerto Rico will be the largest small group plan by enrollment.

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 rule. HHS sets out in Appendix B benefit data for the largest Federal Employees Dental and Vision Insurance Program (FEDVIP) dental and vision plans.

HHS notes in response to comments that the benchmark approach for defining EHB balances the statutory 10 categories of benefits and affordability while providing states, as the primary regulators of health insurance markets, with flexibility, and that the benchmark options reflect the scope of benefits typically offered in the employer market in that state.

HHS also notes that it continues to look first to states for enforcement of the EHB. The preamble to the proposed rule referred to enforcement under existing 45 CFR part 159 to ensure that plans adhere to the EHB standards. That rule 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 noted in the proposed rule that the ACA extended this enforcement authority to apply to the enforcement of title I of the ACA, including section 1302 (the EHB requirements). HHS in the final rule notes that it anticipates releasing additional guidance on enforcement.

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<sup>7</sup> Available at <http://cciio.cms.gov/resources/files/largest-smgroup-products-7-2-2012.pdf>

HHS also notes that it is reviewing options for updating the EHB in 2016 and anticipates releasing additional guidance on that issue.

### **§156.105 Determination of EHB for Multi-State Plans**

HHS finalizes its proposal 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**

HHS finalizes at §156.110(a) its proposal 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.

Pediatric services mean services for an individual under the age of 19 years, which 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.

HHS finalizes its proposal at §156.110(b) for supplementing a base-benchmark plan that does not provide coverage of one or more of the 10 categories listed. The base-benchmark plan is 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 finalizes with technical edits the approach to supplementation for two categories of benefits that may not currently be included in some major medical benefit plans: pediatric oral and vision services.

- A base-benefit plan that does not include the category of pediatric oral services 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.

- A base-benefit plan that does not include the category of pediatric vision services must be supplemented by one of two options: 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 finalizes at §156.110(c) its proposal 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.

HHS finalizes at §156.110(d) its proposal that the EHB not include discriminatory benefit design defined in §156.125 (see below). HHS notes that the standard will apply to benefit designs that limit enrollment and those that prohibit access to care for enrollees.

HHS finalizes at §156.110(e) its proposal 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 finalizes at §156.110(f) its proposed policy regarding habilitation benefits. HHS’ 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 finalizes its proposal that if a base-benchmark plan does not include habilitative services, the state may determine which services to include in that category. If states do not define the habilitative services category, plans must provide these benefits as set out in §156.115 (below).

## **§156.115 Provision of the EHB**

HHS finalizes at §156.115(a), with one change from its proposed rule noted below, 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. In response to comments requesting clarification, HHS retains the substantially equal standard as written to allow for flexibility in plan design.
- 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. HHS confirms in response to comments that plans must comply with parity standards in both the individual and small group markets, and that states will not have to defray any costs associated with bringing plans into compliance because any benefits added to ensure parity will be considered part of the EHB package.
- An EHB must include provision of all preventive services mandated under the ACA, without cost sharing, and codified under §147.130.
- 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, 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 in response to comments that this is a transitional policy and that HHS intends to monitor coverage of habilitative benefits.
- HHS adds in response to comments a clarification that an EHB plan may not exclude an enrollee from any EHB category except for pediatric services.

HHS finalizes at §156.115(b) its proposal, with one change noted below, that benefit substitution be allowed under specified conditions:

- 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. In response to comments, HHS notes that this option is retained in order to provide greater consumer choice and promote plan innovation. It is up to each state to set the criteria for benefit substitution within these constraints.
- 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.

- Actuarial equivalence is 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, will 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 finalizes at §156.115(c) its proposal 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. In response to comments, HHS notes that the provision applies to QHPs in the Exchange and non-Exchange markets.

HHS finalizes at §156.115(d), with one technical change noted below, its proposal 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 non-medically necessary orthodontia. (The proposed rule had referred to “cosmetic” orthodontia, and HHS changed it to “non-medically necessary” in response to comments about industry standards.) HHS notes that these benefits often qualify as “excepted benefits.”<sup>8</sup> HHS notes that plan offerings are not restricted to EHB, so plans may offer additional benefits.

#### **§156.122 Prescription Drug Benefits (was §156.120 in the proposed rule)**

HHS finalizes at §156.122(a) its proposal 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.

The health plan must submit its drug list to the Exchange, the state, or OPM.

HHS notes in response to comments that it is finalizing this as a transition policy for 2014 and 2015 and will study and take into consideration the effects of the policy on typical drug coverage in the market. It notes that the majority of benchmark plans already meets the regulatory standard, or will have to cover only one or two additional drugs to meet the standard, so the final rule will have a negligible effect on premiums. HHS also notes that the section does not require that drugs be covered on a particular tier. Specific drugs can vary, as long as a drug in each category and class is covered.

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<sup>8</sup> See 26 CFR 54.9831-1; 29 CFR 2590.732; 45 CFR 146.145 and 148.220.

HHS notes in response to comments that the prohibition on discrimination finalized at §156.125 means that an issuer's benefit design, and implementation of that design, may not discriminate based on age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions. Issuers may use reasonable medical management techniques that are evidence-based. The states and Exchanges are responsible for monitoring compliance.

HHS notes that, while there were concerns expressed about the mandatory use of the USP, no universal system was identified as an alternative. HHS reiterates that it chose the current version USP Model Guidelines because it is publicly available, is familiar to pharmacy benefit managers, and best fits the needs for 2014 and 2015 as a transitional policy. HHS intends to work with issuers, states and the National Association of Insurance Commissioners (NAIC) to facilitate state use. HHS noted in the proposed rule that the 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 notes that drugs listed on issuer formularies must be chemically distinct, a concept described in the Medicare Part D Manual. 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 will not count toward meeting the standard of offering the same number of drugs in a USP category and class as the EHB-benchmark.

HHS finalizes at §156.122(b) its proposal 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. It includes a clarification, in response to comments, that it refers to exempted drugs approved by the Food and Drug Administration.

HHS finalizes at §156.122(c), with one clarification, its proposal that a health plan must have procedures in place to allow an enrollee to request clinically appropriate drugs not covered by the health plan (a type of exceptions process). In response to comments, HHS clarifies the language to include specific reference to procedures to allow an enrollee to request "and gain access to" clinically appropriate drugs. HHS notes that additional guidance for the required exceptions process is forthcoming in sub-regulatory guidance.

### **§156.125 Prohibition on discrimination**

HHS finalizes at §156.125, with two changes, its proposal 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, 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.

In the final rule, HHS deletes a cross-reference to §156.225, which prohibits marketing practices and benefit design that results in discrimination against individuals with significant or high cost health care needs.

Finally, HHS codifies in the final rule a comment in the preamble to the proposed rule specifying that nothing in the rule should be construed to prevent an issuer from appropriately using reasonable medical management techniques.

HHS notes in response to comments expressing concern about including benefit implementation in the prohibition against discrimination that the range of prohibited discrimination set out in Section 1302(b)(4) of the ACA implicitly encompasses not just the benefit design but the implementation of that benefit design.

HHS reiterates, in response to comments, its previously noted policy that states have primary enforcement authority, and that HHS can 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, if a state benchmark plan includes a discriminatory benefit design, non-discrimination regulations require issuers to meet the benchmarks in a nondiscriminatory manner.

HHS that issuers implementing the EHB standards can apply medical 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. It cites as an example that a reasonable management technique would be to require preauthorization for coverage of the shingles vaccine in persons less than 60 years of age, consistent with the Advisory Committee on Immunization Practices.

HHS notes that the policy is intended to develop a framework and legal standard 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 with special characteristics.

### **§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 non-grandfathered issuers offering coverage in the individual or small group market inside or outside the Exchange. Cost-sharing was previously 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.

HHS finalizes at §156.130(a) that the annual limitation on cost-sharing, which 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.

<b>§156.130(a) Annual limits on cost sharing</b>		
	<b>Self-only coverage</b>	<b>Coverage other than self-only coverage</b>
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)(II) 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.		

As noted in the review of §147.150 and the Department’s FAQ document, HHS and the Departments of Labor and Treasury are providing transitional relief for 2014 for this annual limits on cost sharing for certain group health plans and issuers (see p. 4 of this summary).

HHS finalizes at §156.130(b) its proposal 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).

<b>§156.130(b) Annual limits on deductibles for plans in the small group market</b>		
	<b>Self-only coverage</b>	<b>Coverage other than self-only coverage</b>
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)

A health plan's annual deductible may exceed the annual deductible 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 policy 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 intends to provide sub-regulatory guidance outlining options related to such plan designs, and reiterates that the deductible limits as finalized only apply to issuers and QHPs that must offer the EHB.

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 interprets section 1302(c)(2)(A) as permitting but not requiring that FSAs be taken into account, and therefore finalizes its proposal to standardize the maximum deductible for the small group market at the statutory levels noted above and not increase the deductible levels by the amount available under an FSA. HHS notes in response to comments that this is due to operational considerations in determining the FSA amounts in time for open enrollment, and that it will revisit the policy in future years.

HHS finalizes at §156.130(c) its proposal 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. In response to comments, HHS notes that it is retaining this approach based on research that generally, health spending occurs in network, and that this approach reflects its focus on the long term balance between affordability and comprehensiveness of coverage. HHS notes that nothing in the rule 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 finalizes at §156.130(d) its proposal 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.

HHS finalizes at §156.130(e) its proposal 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 noted in the proposed rule 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.

HHS finalizes at §156.130(f) its proposal 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).

HHS is not finalizing §156.130(g), which had proposed that the structure of cost sharing must conform to the nondiscrimination requirements in §156.125. HHS is dropping this from the final rule in response to concerns that applying the nondiscrimination requirements to cost sharing would limit a health plan's ability to control costs through the use of utilization management. This paragraph is deleted in the final rule and the subsequent paragraph relabeled accordingly.

HHS finalizes at §156.130(g) (which was originally (h) in the proposed rule), consistent with section 1302(b)(4)(e) of the ACA, its proposal 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. 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 finalizes at §156.135(a) its proposal that issuers calculate the AV of a health plan using the AV calculator developed and made available by HHS. The AV calculator has been developed using a set of claims data weighted to reflect the standard population projected to enroll. Plans will input their own information on cost sharing parameters.

HHS notes that it considered technical comments on the proposed calculator and made revisions as appropriate in developing the final AV calculator and methodology document, which are at <http://cciio.cms.gov/resources/regulations/index.html#pm>. 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 also notes in response to comments about specific additional functionalities and benefit inputs that the calculator was developed to accommodate the vast majority of plan designs, and that it balances the need to accommodate a wide range of plan designs with the need to provide a tool that is accessible to the user with a manageable number of inputs.

HHS notes in response to comments that the use of a consistent methodology and standard population 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 notes in response to comments suggesting other approaches, such as micro simulation models, that it is using the continuance table model because it is common, popular and well understood by the actuarial community. HHS further notes in response to comments 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, and that this approach was supported by the American Academy of Actuaries.

HHS noted in the proposed rule 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 finalizes at §156.135(b) its proposed exceptions to the use of the AV calculator, if an issuer's plan design is not compatible with the AV calculator. In that case, 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 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.

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. In response to comments seeking clarification on the use of these exceptions, HHS notes that it intends to interpret this standard as dependent on whether the AV calculator takes into account or accommodates all material aspects of a plan's cost-sharing structure. 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.

HHS responds to comments that the AV calculator does not address health plans with family cost sharing features such as deductibles that accrue across members of the same family. HHS agrees, and says that plans with such features may be treated as unique plan designs if the family plan design has a material effect on the plan's AV. To address these concerns, HHS establishes as a safe harbor, that the AV of a plan with a deductible and/or out-of-pocket maximum that accumulates at the family level will be considered the same AV as calculated using the AV calculator for the corresponding individual plan, so long as the deductible and/or out-of-pocket limit do not exceed that allowed by a family multiplier to be set by CMS in future guidance.

HHS finalizes at §156.135(c), with clarifications, its proposal 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 will 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.

In response to comments, HHS clarifies the language so that this treatment applies to HSA amounts and amounts made available under an integrated HRA that may be used only for cost sharing. HHS further clarifies that the amounts must be known to the issuer at the time of purchase. HHS notes that it will give further consideration to whether other types of HRA might count towards the AV and that guidance on the treatment of HRAs will be issued as necessary.

HHS notes 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.

HHS finalizes at §156.135(d) its proposal 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. HHS noted in the proposed rule that its criteria are based on its review of a July, 2011 American Academy of Actuaries issue brief.<sup>9</sup> In response to comments suggesting earlier or later implementation of this state option, HHS retains the 2015 date and notes that states and other stakeholders can assess the AV calculator in 2014 and determine whether geographic variations or state-specific claims data would be useful modifications starting in 2015.

HHS finalizes at §156.135(e) its proposal 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 noted in the proposed rule that, because it uses continuance tables to support the AV calculator, it anticipates that states will also submit any state-

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<sup>9</sup> Available at [http://www.actuary.org/pdf/health/Actuarial\\_Value\\_Issue\\_Brief\\_072211.pdf](http://www.actuary.org/pdf/health/Actuarial_Value_Issue_Brief_072211.pdf).

specific data sets in the form of continuance tables, and that HHS intends to provide a template and instructions for these submissions.

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

#### **§156.140 Levels of Coverage**

HHS finalizes at §156.140 its proposal 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 will allow a 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. In response to comments suggesting both a wider and narrower range of de minimus variation, HHS notes that it believes that its final range strikes the right balance between ensuring comparability among plans within each metal level while allowing plans flexibility to use convenient cost-sharing metrics.

#### **§156.145 Determination of Minimum Value (MV)**

This part of the 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. Section 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.

HHS finalizes at §156.145(a), with one addition, its proposal that an employer-sponsored plan provides minimum value (MV) if the percentage of the total allowed cost of benefits provided under the plan is no less than 60 percent. It sets up 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.

In response to comments suggesting a de minimus variation of +/-2 percentage similar to the AV calculator, HHS notes that while the statute allows for a de minimus range with actuarial value there is no similar provision in section 36B of the Internal Revenue Code with regard to minimum value.

In response to comments about why the AV calculator is not used, HHS notes that the MV calculator will 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 will permit an employer-sponsored plan to enter information about the plans cost sharing to determine whether the plan provides MV. However, HHS is adding to the final rule a provision that any plan in the small group market that meets one of the “metal levels” under §156.140 satisfies the MV standard. The MV calculator and accompanying continuance tables and methodology are available at:

<http://cciio.cms.gov/resources/regulations/index.html#pm>.

HHS notes that the safe harbor option will be based on an array of design-based safe harbor checklists published by HHS and the IRS. HHS said, in the proposed rule, that each will 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 option of actuarial certification will 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.

HHS finalizes at §156.145(b) its proposal 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. For calculating MV the plan is permitted to take into account any benefit it offers that is included in any one of the EHB benchmark plan options in any state.

HHS finalizes at §156.145(c) its proposal 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.

HHS sets out a new §156.145(d) to reflect in the language of the rule the policy as to the treatment of employer contributions to HSAs and amounts made available under certain

HRAs, to mirror the policy in §156.135(c) for calculating AV. Specifically, employer contributions to an HSA or newly made available under integrated HRAs that may only be used for cost sharing are counted in determining MV.

### **§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.

HHS finalizes at §156.150(a) its proposal 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 notes in response to comments that it will be up to the Exchange to decide what constitutes a reasonable out-of-pocket maximum for stand-alone dental plans and that it anticipates issuing further interpretive guidance for federally-facilitated Exchanges.

HHS finalizes at §156.150(b) with one change its proposal 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 70 percent (this is a reduction from 75 percent in the proposed rule in response to comments); or
- A “high” level of coverage with an AV of 85 percent; and
- With a de minimus variation of plus/minus 2 percentage points.

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 apply only in stand-alone dental plans.

HHS clarifies in response to comments that a plan outside the Exchange may offer EHB that excludes pediatric dental benefits if the issuer is reasonably assured that such coverage is sold only to individuals who purchase Exchange certified stand-alone dental plans.

### **§156.275 Accreditation of QHP Issuers**

HHS established a “phase one” recognition process for accrediting entities at §156.275 that was previously finalized on July 20, 2012 (77 *FR* 42658). 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.

HHS finalizes its proposal to add to §156.275 by providing for an application and review process for phase-one recognition of additional accrediting entities that may become qualified. 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 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.

In a *Federal Register* notice published concurrently with the proposed rule, HHS notified the public that NCQA and URAC are recognized as accrediting entities for the purposes of QHP certification. HHS noted in the proposed rule 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 timing of the 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	Each state has the option to submit state-specific data	\$1,691 per state choosing the option
§156.150(a) Stand-alone Dental Plan inside the Exchange – demonstrate reasonable annual limit	40 issuers	\$77 per plan; \$3,080 total*
§156.275 Accreditation process for phase one accreditation	HHS will revise its previous estimate	HHS will revise estimate accordingly
*Estimate is a component of larger previously estimated ICRs for QHPs		

#### IV. Regulatory Impact Analysis (RIA)

HHS has determined that the 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.<sup>10</sup> 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.

##### 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.

<b>Summary Excerpts from Accounting Table IV.1 from RIA</b>	
<b>Annualized 2013-2016 (expressed in 2011 dollars)</b>	
<b>Benefits</b>	
Annualized monetized	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.
<b>Costs</b>	
Annualized monetized (\$ million / year)	\$3.4 million at a 7% discount rate, \$3.1 million at a 3% discount rate.* Note: costs include costs associated with the information collection requirements as described in section III

<sup>10</sup> RIA available at: <http://cciio.cms.gov/resources/files/Files2/03162012/hie3r-ria-032012.pdf>.

<b>Summary Excerpts from Accounting Table IV.1 from RIA</b>	
<b>Annualized 2013-2016 (expressed in 2011 dollars)</b>	
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.
<b>Transfers</b>	Not estimated
* Includes costs associated with ICRs	

#### Estimated Number of Affected Entities

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

<b>Table IV.2 from Rule: Estimated number of issuers and licensed entities affected by the EHB and AV requirements, by market, 2011</b>				
	<b>Issuers (companies)</b>		<b>Licensed entities</b>	
	<b>Number</b>	<b>% of Total</b>	<b>Number</b>	<b>% of Total</b>
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 24 million Exchange enrollees by 2016, with participation rates lower in the initial years. The EHB and AV

provisions in the 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 rule on small entities. The Secretary certifies that the rule will not have a significant impact on a substantial number of small entities.

**VII. Unfunded Mandates**

HHS reviews the Unfunded Mandates Reform Act and the impact of the 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 rule does not impose substantial direct costs on state and local governments, 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 rule offers substantial discretion to states. HHS notes extensive consultations with key state and local stakeholders.