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Subject: Letter to Issuers on Federally-facilitated and State Partnership Exchanges

The Centers for Medicare & Medicaid Services (CMS) is issuing this draft Letter to Issuers on Federally-facilitated and State Partnership Exchanges (Letter). This Letter provides Qualified Health Plan (QHP) issuers in Federally-facilitated Exchanges (FFE) and Federally-facilitated SHOPs (FF-SHOP), including State Partnership Exchanges, with operational and technical guidance to help them successfully participate in Exchanges.

As indicated in previous guidance, State Plan Management Partnership Exchanges have flexibility to apply certification standards and adjust processes. Throughout the Letter we identify the areas in which states participating in a State Plan Management Partnership Exchange have flexibility to follow a different approach from the approach articulated in this guidance. For purposes of this Letter, references to State Plan Management Partnership Exchanges also apply to states performing plan management functions in an FFE. We note that the policies articulated in this Letter apply to the 2014 coverage year and beyond. In the future, CMS will issue similar letters to provide operational updates to QHP issuers, but we do not intend to issue these letters more than annually.

CMS has previously provided guidance on market-wide and QHP certification standards, eligibility and enrollment procedures, and other Exchange-related topics in several phases. A list of the most relevant regulations and guidance documents is included in Appendix A. These materials provide the basis for much of the operational guidance included in this Letter. Issuers are advised to consult these materials in conjunction with the Letter to ensure full compliance with the requirements of the Patient Protection and Affordable Care Act and Health Care and Education Reconciliation Act (together referred to as the Affordable Care Act), as implemented. These and other regulatory and guidance materials are available at <http://cciio.cms.gov/resources/regulations/index.html>.

Comments

We welcome comments on this proposed guidance. Please send comments to FFEcomments@cms.hhs.gov by March 15, 2013. Comments will be most helpful if commenters organize them by subsections of this document.

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Chapter 1: Certification Standards for Qualified Health Plans

The Affordable Care Act and the applicable Exchange regulations establish that health plans must meet a number of standards to be certified as qualified health plans (QHPs). Several of these certification standards apply to insurance offered in the individual and small group markets plans that are not QHPs; the remaining standards are specific to QHPs seeking certification from an Exchange. In the Guidance on State Partnership Exchanges,¹ CMS stated its intent not to duplicate state review of potential QHPs conducted under state authority or as part of a state's enforcement of 2014 market reforms (e.g., essential health benefits and actuarial value standards). CMS expects that states will enforce 2014 market reforms; accordingly, CMS expects to rely on states' reviews of market reforms as part of its QHP certification process, provided that such state reviews are consistent with federal regulatory standards and operational timelines.² Issuers should follow state guidance regarding the review processes and criteria for state-conducted reviews.

The following sections describe CMS's approach to reviewing plans against standards that apply only to QHPs seeking certification from an Exchange. The reviews described in these sections will be conducted either by a state participating in a State Partnership Exchange in plan management as a part of the state's recommendation to CMS, or by CMS as a part of the process of certifying a QHP in the applicable FFE. Each section describes CMS's planned approach to evaluating QHPs against a certification standard in a non-Partnership FFE. As noted in previously released guidance, State Partnership Exchanges have flexibility in their application of QHP certification standards, provided that the state's application is consistent with the parameters outlined in CMS regulations and guidance. States where a State Partnership Exchange is operating may use CMS's planned approach to conduct QHP certification reviews and arrive at certification recommendations, or adopt another approach to developing a recommendation that is consistent with the federal regulatory standards in consultation with CMS. More information on the QHP certification process in State Partnership Exchanges is included in Chapter 2. Issuers seeking certification in State Partnership Exchanges should refer to state direction in addition to this guidance. State-based Exchanges will conduct their own reviews for QHP-specific standards.

¹ Guidance on State Partnership Exchange Options in the Federally-facilitated Exchange (January 3, 2013), available at <http://cciio.cms.gov/resources/files/partnership-guidance-01-03-2013.pdf>.

² States are the primary regulators of health insurers and are responsible for enforcing the market reform provisions in title XXVII of the Public Health Service (PHS) Act both inside and outside the Exchanges. Under §§ 2723 and 2761 of the PHS Act and existing regulations, 45 C.F.R. Part 150, CMS is responsible for enforcing the provisions of Parts A and B of title XXVII of the PHS Act in a state if a state notifies CMS that it has "not enacted legislation to enforce or that it is not otherwise enforcing" one or more of the provisions, or if CMS determines that the state is not substantially enforcing the requirements. As necessary, CMS will provide additional information on enforcement.

SECTION 1. NETWORK ADEQUACY AND INCLUSION OF ESSENTIAL COMMUNITY PROVIDERS

This section addresses how CMS will review health plans applying as QHPs for compliance with network adequacy and Essential Community Provider (ECP) standards. States participating in a State Partnership Exchange may use a similar approach.

In collaboration with states, CMS will monitor QHPs for network adequacy and ECP sufficiency. Issuers seeking certification of their health plans as QHPs and issuers offering QHPs are encouraged to view the network adequacy and ECP standards set forth in 45 C.F.R. §§ 156.230 and 156.235 and explained in this Letter as the minimum requirements; CMS urges issuers to offer provider networks with robust ECP participation.

i. Network Adequacy

45 C.F.R. § 156.230(a)(2) requires a QHP issuer to maintain a network that is sufficient in number and types of providers, including providers that specialize in mental health and substance use disorder services, to assure that all services will be accessible without unreasonable delay. CMS recognizes that many states conduct network adequacy reviews as part of the issuer licensure process under their existing authority. As a result, for the 2014 coverage year, when CMS is evaluating applications for QHP certification, CMS will rely on state analyses and recommendation when the state has the authority and means to assess issuer network adequacy. CMS's approach to reviewing network adequacy will vary based on whether the state assesses network adequacy in a sufficient manner and uses standards at least as stringent as those identified in 45 C.F.R. § 156.230(a).

In states with sufficient network adequacy reviews, CMS will use a state's findings as part of its evaluation.

In states without sufficient network adequacy review, CMS will accept an issuer's accreditation (commercial or Medicaid) from an HHS-recognized accrediting entity. Unaccredited issuers will be required to submit an access plan as part of the QHP Application.³ The access plan must demonstrate that an issuer has standards and procedures in place to maintain an adequate network consistent with § 156.235(a).

CMS will monitor network adequacy, for example, via complaint tracking or gathering network data from any QHP issuer at any time to determine whether the QHP's network(s) continues to meet these certification standards.

³ The access plan in the QHP Application was developed based on the National Association of Insurance Commissioners' (NAIC) Managed Care Plan Network Adequacy Model Act. The Model Act is available at: <http://www.naic.org/>.

ii. *Essential Community Providers*

45 C.F.R. § 156.235 establishes requirements for inclusion of ECPs in provider networks and provides an alternate standard for issuers that provide a majority of covered services through employed physicians or a single contracted medical group.

As defined in the statute and regulation, ECPs include providers described in section 340B of the PHS Act and section 1927(c)(1)(D)(i)(IV) of the Social Security Act. Because the number and types of ECPs available varies significantly by location, CMS will use the following approach to evaluate QHP issuer applications for sufficient inclusion of ECPs for the 2014 coverage year. CMS interprets the sufficiency standard found in 45 C.F.R. § 156.235 as being met by the safe harbor standard or minimum expectation described in the following paragraphs. CMS notes that contracted ECPs are subject to applicable issuer credentialing standards for network providers.

- **Safe Harbor Standard:** An issuer application that demonstrates compliance with the standards outlined in this paragraph will be determined to meet the regulatory standard established by 45 C.F.R. § 156.235(a) without further documentation. First, the issuer application demonstrates that at least 20 percent of available ECPs in the plan's service area participate in the issuer's provider network(s). In addition to achieving 20 percent participation of available ECPs, the issuer offers contracts during the coverage year to:
 - All available Indian providers in the service area, using the model QHP Addendum for Indian providers developed by CMS; and
 - At least one ECP in each ECP category (see Table 2.1) in each county in the service area, where an ECP in that category is available.

CMS may verify the offering of contracts after certification.

- **Minimum Expectation:** An issuer application that demonstrates that at least 10 percent of available ECPs in the plan's service area participate in the issuer's provider network(s) will be determined to meet the regulatory standard, provided that the issuer includes as part of its application a narrative justification describing how the issuer's provider network(s), as currently designed and after taking into account new 2014 enrollment, provides an adequate level of service for low-income and medically underserved enrollees.
- **Examples:**
 - Issuer A proposes a service area in which 80 ECPs are available. Issuer A's network includes 16 ECPs, and attests in its narrative justification that it has offered contracts to available Indian providers and one ECP in each major ECP category per county, where an ECP in that category is available. Issuer A meets the safe harbor standard; no additional documentation is required.

- Issuer B also proposes a service area in which 80 ECPs are available. Issuer B’s network includes 8 ECPs. Issuer B meets the minimum expectation by providing a narrative justification explaining why its network includes only 8 ECPs and how it will ensure service for low-income and medically underserved enrollees.

For an issuer that does not meet either the safe harbor standard or the minimum expectation, CMS will expect as part of the application a narrative justification describing why the issuer was not able to achieve either standard. Further, the justification should describe how the issuer’s provider network(s) will provide an adequate level of service for low-income and medically underserved enrollees consistent with the regulatory standard. CMS anticipates that it will be difficult for issuers that do not meet the minimum expectation to meet the regulatory standard. Failure to achieve compliance with the regulatory standard will be a basis for not certifying a plan as a QHP.

To assist issuers in identifying these providers, CMS is publishing a non-exhaustive list of available ECPs based on data maintained by CMS and other federal agencies, which will be available soon, and will include identifying and contact information for each provider.

Issuers will indicate which ECPs are included in their provider network(s) by populating a template as part of the QHP Application. CMS will provide detailed instructions to support issuers in completing the template. Issuers that submit a narrative justification will do so as part of the issuer application for QHP certification.

Issuers will be permitted to write in ECPs not on the CMS-developed list for consideration as part of CMS’s certification review (that is, allowable write-ins will count toward the satisfaction of the minimum expectation or safe harbor standard). For example, issuers may write in any providers that are currently eligible to participate in 340B programs that are not included on the CMS-developed list, or not-for-profit or state-owned providers that qualify for 340B program participation but do not receive federal funding under the relevant section of law referred to in section 340B. Such providers include not-for-profit or governmental family planning service sites that do not receive a grant under Title X of the PHS Act.

Table 1.1: ECP Categories and Types in FFEs

Major ECP Category	ECP Provider Types
Federally Qualified Health Center (FQHC)	FQHC and FQHC “Look-Alike” Clinics, Native Hawaiian Health Centers
Ryan White Provider	Ryan White HIV/AIDS Providers
Family Planning Provider	Title X Family Planning Clinics and Title X “Look-Alike” Family Planning Clinics

Indian Providers	Tribal and Urban Indian Organization Providers
Hospitals	DSH and DSH-eligible Hospitals, Children’s Hospitals, Rural Referral Centers, Sole Community Hospitals, Free-standing Cancer Centers, Critical Access Hospitals
Other ECP Providers	STD Clinics, TB Clinics, Hemophilia Treatment Centers, Black Lung Clinics, and other entities that serve predominantly low-income, medically underserved individuals.

iii. Alternate ECP Standard for Integrated Issuers

Issuers that qualify for the alternate ECP standard articulated in 45 C.F.R. § 156.235(a)(2) and (b)⁴ must have a sufficient number and geographic distribution of employed providers and hospital facilities, or providers of its contracted medical group and hospital facilities to ensure reasonable and timely access for low-income, medically underserved individuals in the QHP’s service area, in accordance with the Exchange’s network adequacy standards. CMS interprets this standard as being met by the safe harbor described in this paragraph. Specifically, CMS will review whether the issuer has demonstrated that it has providers located in or contiguous to Health Professional Shortage Areas (HPSA)⁵ and 5-digit zip codes in which 30 percent or more of the population falls below 200 percent of the federal poverty level (FPL). CMS will apply the safe harbor standard and minimum expectation of the regulatory requirements, described above, to these providers. For example, if an issuer’s service area includes 50 available ECPs, the issuer would have five providers in the service area that are also in or contiguous to a HPSA or low-income zip code to meet the minimum expectation, and 10 providers in the service area that are in or contiguous to a HPSA or low-income zip code to meet this safe harbor standard.

As with the general safe harbor, an application that does not meet the ECP safe harbor standard must include a narrative justification to demonstrate compliance with the regulatory standard. An issuer’s explanation should address how the issuer intends to ensure coverage in HPSAs or low-income zip codes where the issuer does not already have provider coverage. For example, an issuer could describe plans to contract with available ECPs, or establish or acquire additional “in-house” providers in the applicable zip codes, or otherwise provide additional access to low-income and underserved populations in such areas. Finally, the explanation should describe the extent to which the issuer’s provider sites are accessible to, and have services that meet the needs of, specific underserved populations, including:

⁴ To qualify for the alternate standard, an issuer must provide a majority of covered professional services through physicians employed by the issuer or through a single contracted medical group.

⁵ More information on Health Professional Shortage Areas is available at: <http://bhpr.hrsa.gov/shortage/>.

- Individuals with HIV/AIDS (including those with co-morbid behavioral health conditions);
- American Indians/Alaska Natives (AI/AN); and
- Low-income and underserved individuals seeking women’s health and reproductive health services.

As stated previously, CMS anticipates that it will be difficult for issuers that do not meet the minimum expectation to meet the regulatory standard. CMS is providing issuers with a database of zip codes listed as HPSAs or where more than 30 percent of the population falls below 200 percent of the federal poverty level. The database is available at <http://cciio.cms.gov/resources/regulations/index.html#pm>. Issuers that qualify for the alternate standard will use the same data template as other issuers to complete this section of the application.

CMS notes that the review standards described above apply to the first year of operations. CMS will continue to assess QHP provider networks, including ECPs, and may revise its approach in later years.

SECTION 2. ACCREDITATION

This section provides additional guidance on accreditation requirements for issuers seeking certification of a QHP in an FFE, including a State Partnership Exchange.

45 C.F.R. § 155.1045 establishes the timeline by which QHP issuers offering coverage in an FFE must be accredited. An issuer’s accreditation status will be displayed to consumers on the Exchange website.⁶ As stated in the preamble to the Essential Health Benefits (EHB)/Accreditation final rule,⁷ CMS is implementing a phased approach to accreditation for QHP issuers in FFEs.

As part of the application for QHP certification, issuers will be asked to provide some information about their accreditation status to determine if the standard in § 155.1045(b) is met. Issuers will be asked if they have any existing health plan accreditation in the commercial, Medicaid, or Exchange markets (i.e., accredited on products under the same legal entity as the one that is offering products in the Exchange). If so, they will be asked to provide information about that accreditation and identify the recognized accrediting entity that issued the accreditation. For certification in 2013 for the 2014 plan year, the National Committee for

⁶ CMS will be responsible for the Exchange website in FFEs, including State Partnership Exchanges.

⁷ Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation, 78 Fed. Reg. 12834 (Feb. 25, 2013) (to be codified at 45 C.F.R. parts 147, 155, & 156).

Quality Assurance (NCQA) and URAC have been recognized as accrediting entities.⁸ The issuer will be asked to enter information for accredited products within the commercial, Medicaid, or Exchange markets, such as accredited product type(s), expiration date(s), and accrediting entity-specific identification information numbers, such as the NCQA Organization Identification Number and Sub-Identification Number(s), and/or the URAC application number(s). Issuers should verify with the applicable accrediting entity before completing the application if they are unsure about their identification numbers. This is important for displaying the appropriate accreditation-related data for the issuer. For certification in future years, the timeline in § 155.1045(b) will be applied by looking at the issuer's accreditation status 90 days prior to open enrollment.

To verify the accreditation information, issuers will also be asked to upload their current and relevant accreditation certificates issued by either NCQA or URAC, or both of these recognized accrediting entities, if applicable. Only data that can be validated will be displayed. All issuers will be required to complete attestations about the accreditation data that will be displayed on the Exchange website in order to demonstrate how the issuer and health plan meet the applicable certification requirements. In addition, information about the issuer's Consumer Assessment of Healthcare Providers and Systems (CAHPS®)⁹ surveys and other data will be requested for CMS to use in determining whether it is in the interest of qualified individuals and qualified employers to certify the health plan as a QHP. Consistent with 45 C.F.R. § 156.275(a)(2), issuers will be asked as part of the application to authorize the release of their accreditation survey data from the recognized accrediting entity to the Exchange, if available.

For open enrollment beginning on October 1, 2013, an Exchange website will display selected CAHPS® survey results from an issuer's accredited commercial product lines when these existing CAHPS® data are available for the same QHP product types and adult/child populations. CMS will display the two CAHPS® Global Ratings for the health plan¹⁰ and health care,¹¹ and results from one access to care measure.¹²

⁸ NCQA and URAC were established as recognized as accrediting entities on an interim basis in Patient Protection and Affordable Care Act; Data Collection to Support Standards Related to Essential Health Benefits; Recognition of Entities for the Accreditation of Qualified Health Plans, 77 Fed. Reg. 42658 (Jul. 20, 2012) (to be codified at 45 C.F.R. part 156). They were formally recognized in a final notice published on November 23, 2012 (77 Fed. Reg. 70163). CMS may recognize additional accrediting entities in the future. See 45 C.F.R. § 156.275(a).

⁹ CAHPS® is a registered trademark of the Agency for Healthcare Research and Quality (AHRQ) of HHS.

¹⁰ Using any number from 0 to 10 where 0 is the worst health plan possible and 10 is the best health plan possible, what number would you use to rate your health plan?

¹¹ Using any number from 0 to 10, where 0 is the worst health care possible and 10 is the best health care possible, what number would you use to rate all your health care (excluding dental and hospital) in the last 12 months?

¹² In the last 12 months, how often was it easy to get the care, tests, or treatment you needed?
[Never/Sometimes/Usually/Always]

If CAHPS[®] commercial data are not available through existing accreditation for an issuer's same QHP product types (e.g., HMO, PPO) and adult/child populations, CMS will display CAHPS[®] survey results available from an issuer's accredited Medicaid product lines if these data are available for the same QHP product types and adult/child populations. If applicable CAHPS[®] data are not available through existing accreditation, the Exchange website will display a neutral statement such as "No data available." For issuers with relevant Medicaid CAHPS[®] data to be displayed, the Exchange website will display Medicaid CAHPS[®] 2012 data at the beginning of open enrollment until Medicaid CAHPS[®] 2013 data are available (anticipated in mid-November 2013).

For the 2014 coverage year, the Exchange website will also display the accreditation status of a QHP issuer ("Accredited by NCQA," "Accredited by URAC," "Accredited by NCQA and URAC," or "Not yet accredited") if an issuer is accredited on *any* of its existing products (e.g., HMO, PPO) in the commercial, Medicaid, or Exchange markets by one of the currently recognized accrediting entities. If the QHP issuer is accredited by NCQA with "Excellent," "Commendable," "Accredited," and/or "Interim" status, the Exchange website will display the issuer as accredited. If the QHP issuer is accredited by URAC with "Full," "Provisional," and/or "Conditional," status, the Exchange website will display the issuer as "Accredited." An issuer will not be displayed as accredited if the accreditation review is scheduled or in process. If the issuer does not have this existing accreditation from a currently recognized accrediting entity, neutral language such as "Not yet accredited" will be displayed.

In addition to displaying CAHPS[®] data attained through accreditation and accreditation status as explained above, all states participating in an FFE (including a State Partnership Exchange) have the option of requesting that the Exchange website display a link to existing quality data available for the commercial and/or Medicaid market in that state. We interpret 45 C.F.R. § 155.205(c) to apply to such linked websites and materials when the linked sites are provided as part of the FFE provision of comparable data about QHPs and QHP issuers.

SECTION 3. REVIEW OF RATES

This section addresses how CMS will work with states to review rate increases for QHPs. States participating in a State Partnership Exchange may use a similar approach.

i. Consideration of Rate Increases

45 C.F.R. § 155.1020 requires an Exchange to consider all rate increases when certifying plans as QHPs. For the 2014 plan year, CMS will take into consideration issuers' data and actuarial justifications provided in the Unified Rate Template, other information submitted as part of the Effective Rate Review program and any recommendations provided to CMS by the applicable

state regulator about patterns or practices of excessive or unjustified rate increases and whether or not particular issuers should be excluded from participation in the Exchange. In future years, CMS may also take into account other factors such as rate growth inside and outside the Exchange market.

As discussed above and in the Guidance on State Partnership Exchanges, CMS does not plan to duplicate reviews that a state is already conducting as a matter of state law, and will take into consideration reviews conducted on behalf of a state under the Effective Rate Review program as described in the Final Market Rules.¹³ CMS anticipates integrating state and other CMS rate reviews into its QHP certification processes, provided that states provide information to CMS consistent with federal standards and agreed-upon timelines.

For rate increases not being reviewed by an Effective Rate Review program or by CMS on behalf of a state:

- The QHP issuers' justification for all rate increases, will be captured in the submission of Part I of the rate filing justification (Unified Rate Review Template).
- To ensure consumer transparency, issuers must publish information from Part I of the rate filing justification by either: (1) posting a link directly on the issuer's website to the Exchange's website (or HealthCare.gov), or (2) posting the information directly on the issuer's website.¹⁴

i. Review of QHP Rates

Rates that are too high or too low could have undesirable consequences for consumers. If rates are too high, consumers may be overpaying for services. If rates are too low, consumers may purchase a plan whose pricing is not sustainable over time, potentially leading to significant rate increases in future years. Such increases could be disruptive to consumers who remain in the plan and to consumers who switch to more effectively priced plans but experience changes in covered benefits or provider networks. In addition, QHP rates – specifically, the rate for the second lowest cost silver plan in an Exchange – directly impact the value tax credit for health insurance as well as federal outlays.

¹³ Patient Protection and Affordable Care Act; Health Insurance Market Rules; Rate Review, 78 Fed. Reg. 13406 (Feb. 27, 2013) (to be codified at 45 C.F.R. parts 144, 147, 150, 154, & 156).

¹⁴ Section 1311(e)(2) of the Affordable Care Act directs issuers to “prominently post” justifications for any rate increases. CMS notes that information that is not part of the justification that is protected by the Freedom of Information Act or the Trade Secrets Act (such as trade secrets or confidential financial information) will not be publicly posted by CMS.

As detailed above, CMS does not plan to duplicate reviews that a state is already conducting as a matter of state law. CMS intends to implement a process that, in collaboration with existing state rate review processes, will help ensure that QHP rates are reasonable. Specifically, CMS will conduct an outlier test on QHP rates to identify rates that are relatively high and low compared to other QHP rates in the same rating area.

CMS recognizes that identification of a QHP rate as an outlier does not necessarily indicate inappropriate rate development. CMS will notify the appropriate state entity of the results of its outlier test. If the state confirms that the rate is justified, CMS expects to certify the QHP (assuming that the QHP meets all other standards).

SECTION 4. BENEFIT DESIGN REVIEW

This section addresses how CMS will review health plans applying for QHP certification. States participating in a State Partnership Exchange may use a similar approach.

i. Non-discrimination

The law directs that, as a condition of participating in Exchanges, QHPs must not employ cost-sharing designs that will have the effect of discouraging the enrollment of individuals with significant health needs (45 C.F.R. § 156.225).¹⁵ To ensure non-discrimination in benefit design, CMS will perform an outlier analysis on QHP cost sharing (e.g., co-payments and co-insurance) as part of its QHP certification reviews. Identification as an outlier does not necessarily indicate that a QHP benefit design is discriminatory; rather, CMS will use the outlier analysis to target QHPs for more in-depth reviews.

CMS's outlier analysis will array and compare QHPs with comparable cost-sharing structures to identify outliers. For example, CMS will array and compare silver level QHPs with coinsurance-based benefit designs. In 2014, CMS's analysis will identify cost-sharing outliers for specific benefits, including:

- i. Inpatient hospital stays,
- ii. Inpatient mental/behavioral health stays,
- iii. Specialist visits,
- iv. Pregnancy and newborn care,
- v. Specific conditions including behavioral health conditions such as mental health disorders and substance abuse, and
- vi. Prescription drugs.

¹⁵ Non-discrimination in benefit design with respect to EHB and marketing are market-wide consumer protections that apply inside and outside of Exchanges.

Issuers of QHPs flagged as outliers may be asked to modify benefit designs that have the effect of discouraging the enrollment of individuals with significant health needs.

CMS will also review information contained in the “explanations” and “exclusions” sections of the plans and benefits template with the objective of identifying discriminatory practices or wording. As part of this review, CMS expects to flag any language that indicates a reduction in the generosity of a benefit in some manner for subsets of individuals that is not based on clinically indicated, reasonable medical management practices (e.g., language indicating that the coinsurance rate for enrollees with certain health issues).

Finally, CMS will collect attestations that issuers’ QHPs will not discriminate against individuals on the basis of health status, race, color, national origin, disability, age, sex, gender identity or sexual orientation, consistent with 45 C.F.R. § 156.200(e).

ii. Supporting Informed Consumer Choice

CMS has previously stated its intention to certify as a QHP any plan that meets all certification standards. CMS believes that this approach has important benefits, including increased consumer choice and competition. However, CMS also wishes to ensure that consumers can make an informed selection among plan choices that the consumer can readily differentiate and compare,¹⁶ and that one issuer does not impede competition by submitting a number of very similar QHPs that monopolize virtual “shelf space.”

To balance these priorities, CMS will conduct a benefit package review for all QHPs offered by an issuer. The goal of this review is to identify QHPs that are not meaningfully different from other QHPs offered by the same issuer and with the same plan characteristics. As in other areas, CMS will use this review to target QHPs for additional review and discussion with the issuer.

CMS expects this review to consist of two parts:

- **Part One:** Whether the health plan’s benefit package and plan costs are substantially different from other potential Exchange plan offerings in that state from that issuer. CMS will take into account the extent to which each potential QHP is substantially different from other QHPs of its plan type¹⁷ with respect to key characteristics such as metal level

¹⁶ Research suggests that consumers may prefer more limited arrays of choices. See Iyengar, S.; Lepper, M. *Journal of Personality and Social Psychology*, Vol 79(6), Dec 2000, 995-1006.

¹⁷ Plan types are defined as preferred provider organization (PPO), health maintenance organization (HMO), point of service (POS), or exclusive provider organization (EPO). QHPs with multiple in-network tiers will also be considered a different plan type for purposes of a meaningful difference review.

(that is, bronze, silver, gold or platinum), service areas covered, provider networks, premiums, cost sharing, benefits offered, or formulary structure; and

- **Part Two:** Whether consumers would likely be able to distinguish the particular plan from other QHP offerings from the same issuer in a given service area.

Given the uniqueness of the stand-alone dental plan market, CMS will not perform such a review of stand-alone dental plans as part of the certification of those plans.

Examples of QHPs that might be flagged for follow-up as part of CMS’s benefit package review include:

- A \$50 difference in the annual deductible, when the two potential QHPs have otherwise identical cost sharing and nearly identical covered benefits.
- A \$100 difference in annual maximum out-of-pocket limit, when the two potential QHPs have otherwise identical cost sharing and nearly identical covered benefits.
- A slight difference in covered benefits, when the two potential QHPs have nearly identical cost sharing. A slight difference would be for “immaterial benefits” that do not materially impact the monthly premium.

If CMS flags a potential QHP for follow-up based on this review, we anticipate that the issuer will be given the opportunity to amend or withdraw its submission for one of the identified health plans. Alternatively, the issuer may submit supporting documentation to CMS explaining how the potential QHP is substantially different from others offered by the issuer for QHP certification and, thus, is in the interest of consumers to certify as a QHP. For example, an issuer may make the case that one QHP is an Accountable Care Organization. This additional information will factor into the determination of whether it is in the interest of the qualified individuals and qualified employers to certify the plan as a QHP (*see* 45 C.F.R. § 155.1000).

CMS anticipates its approach related to meaningful difference may be updated in future years.

iii. Annual Limitation on Cost Sharing

Section 1302(c)(1) of the Affordable Care Act sets an annual limitation on cost sharing (commonly referred to as a maximum out-of-pocket limit) as part of the EHB package that non-grandfathered policies sold in the individual and small group markets must offer. As provided in 45 C.F.R. § 156.130(c), cost sharing for benefits provided outside of a health plan’s network do not count towards the annual limitation on cost sharing when the health plan uses a provider network. For plan or policy years beginning after January 1, 2014, this limit will be the out-of-pocket limit for high deductible health plans (HDHP), adjusted by the Consumer Price Index (CPI-U), and set by the Internal Revenue Service (IRS) pursuant to section 223(c)(2)(A)(ii) of

the Internal Revenue Code.¹⁸ Issuers of stand-alone dental plans should consult Chapter 4 of this Letter for more information on stand-alone dental plans.

CMS anticipates that the IRS will publish the HDHP limit for 2014 in the spring of 2013. IRS's publication of these limits cannot occur earlier because of the statutorily required method for computing and adjusting the HDHP limit. To assist issuers in designing health plans for the 2014 plan year, CMS has estimated that the annual limitation on cost sharing for the 2014 plan year will be approximately \$6,400 for self-only coverage and \$12,800 for family coverage.¹⁹ These are estimates only, though we think it is unlikely that the actual numbers will differ.

In the FFE, if IRS-published limits are below \$6,400/\$12,800, CMS will flag QHP applications with out-of-pocket maximums above the allowed amount. Affected issuers will be permitted to revise their out-of-pocket maximums during the resubmission window built into the QHP certification process. CMS will allow issuers to adjust other associated data elements for affected plans if necessary. For example, issuers will be permitted to modify other cost-sharing parameters in order to maintain an actuarial value (AV) consistent with the standards of 45 C.F.R. § 156.140.

CMS encourages states, particularly those participating in a State Partnership Exchange, to use this approach to allow updates during the revision window. States may instruct issuers to follow an alternate process to correct deficiencies of this type of issue.

Once CMS's QHP certification determinations are complete, CMS's Health Insurance Oversight System (HIOS) will send all final QHP application data to the NAIC's System for Electronic Rate and Form Filing (SERFF) for use as a final state record.

SECTION 5. COST-SHARING REDUCTION PLAN VARIATIONS AND ADVANCE PAYMENT ESTIMATES

This section addresses how CMS will review plans for QHP certification. States participating in a State Partnership Exchange may use a similar approach.

¹⁸ Beginning in 2015, a different methodology set by CMS will be used as set forth in section 1302(c)(1)(B) of the Affordable Care Act. This methodology will be discussed in the Notice of Benefit and Payment Parameters for 2015. 45 C.F.R. § 156.130(a)(2).

¹⁹ For reference, the limit set by the IRS for the 2013 calendar year is \$6,250 for self-only coverage or \$12,500 for family coverage. IRS Rev. Proc. 2012-26, available at <http://www.irs.gov/pub/irs-drop/rp-12-26.pdf>. This \$6,400/\$12,800 estimate is approximately a 2 percent increase from the limit set by IRS for the 2013 benefit year (\$6,250). By way of comparison, a 0 percent increase in the limit would result in an annual limit for 2014 of \$6,250, and a 6 percent increase would result in an annual limit of \$6,650. Over the past 20 years, CPI has always been below 6 percent.

CMS plans to review the estimated advance payment amounts for QHP issuers in all Exchanges – whether or not operated by CMS – to ensure that these payments are consistent with the methodology identified in § 156.430, and set forth in the Final Payment Notice²⁰ for the 2014 benefit year. If any estimates are identified as inconsistent with the methodology, issuers will be notified, and advance payment amounts may be modified. Finalized advance payment amounts will be identified for Exchanges to include enrollment information transferred to QHPs.

²⁰ Patient Protection and Affordable Care Act; CMS Notice of Benefit and Payment Parameters for 2014, RIN 0938-AR51 (displayed Mar. 1, 2013) (to be codified at 45 C.F.R. parts 153, 155, 156, 157, & 158).

Chapter 2: Qualified Health Plan Certification Process in FFEs, including State Partnership Exchanges

This Chapter provides an overview of the QHP certification process in FFEs, including State Partnership Exchanges, and describes the timing, data submission by issuers, and communication processes. High-level graphics summarizing the certification process in non-Partnership FFEs and State Partnership Exchanges are included in Appendix B.

As described in the Guidance on State Partnership Exchanges, states participating in a State Partnership Exchange will evaluate health plans against QHP certification standards as part of the state's traditional regulatory role for the insurance industry and/or enforcement of Title 27 of the PHS Act, or otherwise for state purposes. Based upon the state's analysis and review, the state will recommend QHPs for certification to CMS, and CMS will decide whether to certify the QHPs. Similarly, CMS anticipates integrating state regulatory activities conducted independently of a Partnership Exchange into its decision-making for QHP certification recommendations in the FFE, provided that states make these determinations and provide information to HHS consistent with federal standards and FFE timelines. These principles underlie the discussion in this Letter about the QHP certification process.

CMS will review the state's recommendations or findings to confirm that they are consistent with federal regulatory standards, and will communicate to the state any concerns that would preclude CMS's implementation of the state's recommendations or findings according to the process and timeline outlined in the State Partnership Exchange guidance. CMS will be responsible for QHP certification decisions in each FFE or State Partnership Exchange.

SECTION 1. QHP APPLICATION AND CERTIFICATION PROCESS IN NON-PARTNERSHIP FFEs

This section describes how CMS will conduct QHP certification. States and issuers participating in a State Partnership Exchange should refer to Section 2.

In accordance with 45 C.F.R. part 155 subpart K, CMS will review and approve or deny applications from issuers that are applying to offer QHPs in a non-Partnership FFE. Table 2.1 presents a high-level overview of key dates in the certification process. Each major component of the process is described in greater detail in the subsections that follow.

Table 2.1 Key Dates: QHP Certification in an FFE (Non-Partnership)

Note: all dates are subject to minor changes.

Expected Date (all dates in 2013)	Activity
Already in process	Issuers Submit Requests for Plan IDs (for plans intended

	for the Exchange) to HIOS
April 1 – April 30	Issuers Submit QHP Applications in HIOS
May 1 – June 16	CMS Reviews QHP Applications
June 17	CMS Releases QHP Application Results to Issuers
June 17 – June 21	Issuers Revise QHP Applications Based on any Identified Deficiencies and Resubmit to HIOS
July 31	As Applicable, HHS Receives Final State Evaluation Findings in HIOS
August	CMS Review of State Evaluation Findings and Recommendations
August 22 – August 26	Issuers Review Data During Plan Preview Period and Submit Data Corrections
September 4	CMS Notifies all Issuers of QHP Certification Decisions for the FFEs
September 5 – September 9	Issuers Sign Agreements with CMS
October 1	Open Enrollment Begins

i. Registration and Application

To offer QHPs in non-Partnership FFEs for the 2014 plan year, health insurance issuers will complete QHP Applications electronically through HIOS. Before submitting an application, issuers must gain access to HIOS and define user roles (such as data submitter, data validator, and attester), and obtain HIOS user IDs.

We expect that between April 1 and April 30, 2013, the issuers will access the QHP Application in HIOS to submit all information necessary for certification of health plans as QHPs. The QHP Application will collect both issuer-level and plan-level benefit and rate data and information, largely through standardized data templates. Applicants will also be required to attest to their adherence to the regulations set forth in 45 C.F.R. parts 155 and 156 and other programmatic requirements necessary for the operational success of an Exchange, and provide requested supporting documentation. These attestations will also apply to vendors and contractors of the issuer or company.

ii. Issuer Data Collection and Coordination with States

CMS expects that states will review potential QHPs for compliance with EHB and AV standards under state regulatory authority consistent with the PHS Act. To the extent permissible by law, CMS intends to utilize state results from reviews conducted under state authority in these and other areas (including network adequacy), and will review and incorporate these results into its

certification decisions. Regardless of whether a state conducts reviews under its own authority, issuers will submit a complete copy of the QHP Application and any supporting data in HIOS.

We expect that states will establish the timeline, communication process, and resubmission window for any reviews under state authority, and that CMS will have access to state's recommendations through HIOS by July 31, 2013. Issuers that wish to prohibit CMS from sharing QHP Application information with the relevant state department of insurance should do so by notifying CMS in writing (email is permitted). Issuers should defer to any state-specific guidelines for review and resubmission of state-reviewed standards. CMS notes that issuers may be required to submit additional data to state regulators, if required by a state, and must comply with any requests for resubmissions from the state or from CMS in order to be certified. CMS will coordinate with states to ensure that any state-specific review guidelines and procedures are consistent with applicable federal law and operational deadlines. We note that all QHP issuers must be licensed and in good standing to offer health insurance coverage in each state where the issuer offers health insurance coverage.

iii. FFE review of QHP Applications

Between May 1 and June 16, 2013, CMS expects to review QHP Applications. On or around June 17, 2013, CMS expects to notify issuers of the results of all reviews conducted in this initial period by CMS, including any deficiencies or requests for additional documentation. During a single resubmission window, issuers will submit corrections or clarifications into HIOS in response to CMS's notification. During this period, issuers may also receive requests for resubmission or other communications from states conducting reviews under state authority. Issuers will be able to alter only data explicitly identified as deficient in CMS's notice or by a state. CMS expects to review the revised data, verify and confirm findings and results submitted by a state, and inform issuers of its final certification determination by September 4, 2013.

iv. Plan Preview

The Plan Preview period will allow issuers to review their QHP data before the data become public and to correct any discrepancies between the issuer's Application data and the data for display as appropriate. Plan Preview will occur concurrently with CMS's final certification reviews; therefore, display during Plan Preview is not a guarantee that a QHP will be certified. After receiving final QHP data from issuers, CMS will load QHP data into a plan preview portal for issuer review. Accreditation status and CAHPS[®] survey data will also be part of Plan Preview on the FFE website, as applicable. Issuers will review plan data as the data will appear to consumers on the Exchange website, and will have an opportunity to submit corrections if necessary. Issuers will not have an opportunity to submit substantive changes (that is, changes that would require CMS to re-evaluate an issuer's Application) to 2014 QHP Applications during the Plan Preview period. At a later date, issuers will also have the opportunity to review the

updated Medicaid CAHPS[®] 2013 data when these data become available and prior to posting on the FFE website. More information about CAHPS[®] data is included in Chapter 1, Section 2 of this Letter.

SECTION 2. QHP CERTIFICATION PROCESS IN A PLAN MANAGEMENT STATE PARTNERSHIP EXCHANGE

This section describes how states participating in a State Partnership Exchange will conduct QHP certification. Issuers participating in a non-Partnership FFE should refer to Section 1.

In a Plan Management State Partnership Exchange, issuers will work directly with the state to submit all QHP issuer application data in accordance with state guidance.²¹ CMS anticipates that states will choose to use the SERFF system to collect and review QHP data. The state will review issuer applications for QHP certification for compliance with the standards described above and will provide a certification recommendation for each QHP to CMS. CMS will review and confirm the state’s recommendations, coordinate Plan Preview, make final certification decisions, and load certified QHP plans on the Exchange website for the relevant State Partnership Exchange. CMS will work closely with states in State Partnership Exchanges to coordinate this process.

As indicated in Table 2.2, the certification process in State Partnership Exchanges will align with the process for issuers in states without State Partnership Exchanges, particularly after July 31, 2013. Each major component of the process is described in greater detail in the subsections that follow.

Table 2.2 Key Dates: QHP Certification in a State Partnership Exchange
Note: all dates are subject to minor changes.

Expected Dates (all dates in 2013)	Activities
Already in progress	Issuers Submit Requests for Plan IDs (for plans intended for the Exchange) to HIOS
Beginning approx. April 1	Issuers Submit QHP Applications into State’s Application system
July 31	CMS Receives State Certification Recommendation and Final Reviewed QHP Data from Partner States

²¹ CMS will work with states participating in State Partnership Exchanges to ensure that such guidance is consistent with federal regulatory standards and operational timelines.

August	CMS Review of State Certification Recommendations
August 22 – August 26	Issuers Review Data During Plan Preview Period and Submit Data Corrections
September 4	CMS Notifies all Issuers of QHP Certification Decisions

i. Registration, Application, and State Review

An issuer’s HIOS user ID will be used to link the state and federal records for a given issuer or QHP. Therefore, like an issuer applying in an FFE, an issuer applying in a State Partnership Exchange must access HIOS between March 1, 2013 and the beginning of the state’s QHP certification process to obtain a HIOS user ID, as described in Section 1 above.

Issuers are to submit QHP Applications, typically in SERFF, according to the timeline set by the state. Each state will define the relevant submission window as well as dates and processes for deficiency notices, corrections, and resubmissions. Issuers are to refer to state guidance on this process. We expect that the state will review the QHP Applications and provide final data and recommendations for certification to CMS no later than July 31, 2013.

i. Plan Preview

As described in Section 1 above, CMS will offer a plan preview period for issuers seeking certification in a State Partnership Exchange. The plan preview period will follow the process outlined in Section 1, except that issuers that submitted QHP Applications into SERFF will also submit any data corrections into SERFF.

SECTION 3. QHP AGREEMENT

This section describes how CMS will conclude QHP certification in all FFEs, including State Partnership Exchanges.

A signed QHP Agreement with CMS will complete the certification process in an FFE or State Partnership Exchange. The Agreement will highlight and memorialize many of the QHP issuer’s statutory and regulatory requirements and will serve as an important reminder of the relationship between the QHP issuer and CMS. A single QHP Agreement will cover all of the QHPs offered by a single issuer in an FFE and FF-SHOP (i.e., the state area served by the FFE and FF-SHOP) CMS plans to release a copy of the QHP Agreement in the spring of 2013. In order for QHPs to be displayed in the Exchange to potential enrollees during the initial open enrollment period, we anticipate issuers should submit the signed agreement to CMS by approximately September 9. The QHP Application and agreement should be signed by a representative of the issuer who has the authority to commit the issuer to upholding all statutory and regulatory requirements.

SECTION 4. FFE QHP ANNUAL REVIEW AND RECERTIFICATION

This section describes how CMS will conduct QHP recertification. States participating in a State Partnership Exchange may use a similar approach.

QHP certification in an FFE is valid for one year. Issuers wishing to continue participating in FFEs will be required to apply for recertification. CMS's annual review and recertification process, including the associated data and/or document needs, will be outlined in future guidance. Issues that emerge through issuer audits, monitoring, consumer complaints, and/or concerns raised by states or consumers during the 2014 coverage year will factor into CMS's future certification decisions.

Consistent with a state's role in State Partnership Exchange certification activities, CMS expects that states in State Partnership Exchanges will establish their own QHP recertification processes that are consistent with FFE policies and guidance. CMS will articulate a process for working with states to complete recertification in future guidance.

SECTION 5. CERTIFICATION OF STAND-ALONE DENTAL PLANS

This section provides additional guidance for stand-alone dental plans seeking certification in FFEs, including State Partnership Exchanges.

CMS and states participating in a State Partnership Exchange will use the QHP certification process, with necessary adjustments, to certify stand-alone dental plans. As provided in the Exchange Final Rule,²² stand-alone dental plans seeking Exchange certification must meet all applicable QHP certification standards. Chapter 4 identifies which QHP certification standards will apply to stand-alone dental plans in FFEs, including State Partnership Exchanges, for the 2014 coverage year. CMS anticipates verifying compliance with those requirements by having stand-alone dental plan issuers attest to meeting the applicable certification requirements as part of their QHP Applications. More information is included in Chapter 4.

SECTION 6. CERTIFICATION OF CO-OPs FOR ALL EXCHANGES

This section provides additional guidance for CO-OPs seeking certification in FFEs, including State Partnership Exchanges, and State-based Exchanges.

²² Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers, 77 Fed. Reg. 18310 (Mar. 27, 2012) (to be codified at 45 C.F.R. parts 155, 156, & 157).

Section 1322 of the Affordable Care Act establishes the Consumer Operated and Oriented Plan (CO-OP) Program to provide additional health plan options for consumers in Exchanges. Consistent with this goal, QHPs offered by CO-OPs may be deemed certified to participate in the Exchanges by CMS pursuant to section 1301(a)(2) of the Affordable Care Act.

Under 45 C.F.R. § 156.520(e) of the final rule Patient Protection and Affordable Care Act; Establishment of Consumer Operated and Oriented Plan Program,²³ to be deemed certified to participate in an Exchange, a CO-OP must meet the terms of the CO-OP Program, federal standards for Exchanges, and any state-specific Exchange standards.²⁴ CO-OPs may be deemed certified to participate in the Exchanges for two years by CMS. CMS will work closely with State-based Exchanges and states participating in State Partnership Exchanges to assess whether QHPs offered by a CO-OP meet all certification standards. A State-based Exchange's or state's recommendation regarding whether a CO-OP QHP meets Exchange certification standards will be given consideration in CMS's determination to deem a CO-OPs QHP to be certified to be offered through an Exchange, though the final decision will remain with CMS under the CO-OP rule.

To apply to be deemed certified to participate in FFEs, including State Partnership Exchanges, a CO-OP issuer must generally follow the same application process as other QHP issuers. When registering in HIOS, CO-OP issuers must select the CO-OP indicator on the QHP Application to be considered for deeming. CMS does not expect to collect information beyond the QHP Application from CO-OP issuers in order to complete the deeming process in FFEs, including State Partnership Exchanges.

SECTION 7. OPM MULTI-STATE PLANS PARTICIPATING IN ALL EXCHANGES

This section provides additional guidance for multi-State plans seeking certification in FFEs, including State Partnership Exchanges, and State-based Exchanges.

The U.S. Office of Personnel Management (OPM) is responsible for implementing the Multi-State Plan Program (MSPP) as required under section 1334 of the Affordable Care Act. Specifically, OPM is responsible for contracting with at least two health insurance issuers per state to offer individual and small group coverage through multi-State Plans (MSP) made available on Exchanges. In accordance with section 1334(d) of the Affordable Care Act, MSPs offered by MSPP issuers under contract with OPM are deemed to be certified by an Exchange.

²³ Patient Protection and Affordable Care Act; Establishment of Consumer Operated and Oriented Plan Program, 76 Fed. Reg. 77392 (Dec. 13, 2011) (to be codified at 45 C.F.R. 156).

²⁴ CO-OPs are not required to meet state-specific Exchange standards that operate to exclude CO-OPs due to being new issuers or other characteristics inherent in the design of a CO-OP.

Issuers seeking to offer MSPs must apply to participate via OPM's online application portal.²⁵ OPM will evaluate issuer applications and determine which issuers are qualified to become MSPP issuers. OPM plans to work closely with states in reviewing benefits and rates to achieve a viable MSPP and a level playing field for all issuers within a state. In accordance with section 1334(d) of the Affordable Care Act, the contracts between MSPP issuers and OPM will specify each MSP that the issuer will offer and in what state it will be offered. The MSP will thereby be deemed to be certified by the Exchange(s) operating in those states. In order to be deemed certified by an Exchange, an MSP must be offered in the relevant state under contract with OPM in the relevant state.

We expect OPM to issue guidance to MSPP issuers with further details on a number of issues, including data transmissions to Exchanges, reporting requirements, and other matters. In addition, the MSPP contract will set forth performance requirements for MSPP issuers. MSPs offered under contract with OPM will be displayed on the FFE website and included in the display of QHPs made available through consumer tools. CMS plans to display accreditation status, CAHPS[®] data (if applicable), and a link to existing quality data provided by OPM, though OPM will communicate quality requirements for MSPs. OPM will provide additional information via guidance.

²⁵ For more information about the MSPP, including the MSPP application and MSPP regulations, visit <http://www.opm.gov/healthcare-insurance/multi-state-plan-program/>. The MSPP final rule is Patient Protection and Affordable Care Act; Establishment of the Multi-State Plan Program for the Affordable Insurance Exchanges, RIN 3206-AM47 (displayed Mar. 1, 2013) (to be codified at 45 C.F.R. part 800).

Chapter 3: Qualified Health Plan Performance and Oversight

Section 1311 of the Affordable Care Act establishes minimum standards that health plans must meet in order to be certified as QHPs. CMS, in operation of FFEs, is responsible for the ongoing compliance of issuers offering QHPs in all states where FFEs, including State Partnership Exchanges, are operating.

SECTION 1. ACCOUNT MANAGEMENT

This section describes how CMS will monitor QHP performance during the coverage year in all FFEs, including State Partnership Exchanges.

As described in previously released guidance, all issuers participating in FFEs, including State Partnership Exchanges, will be assigned a federal Account Manager. Account Managers will serve as the QHP issuer's primary point of contact with the Exchange and will provide QHP issuers with clarification and other assistance related to issuers' responsibilities and requirements for participating in the Exchange. Particularly in State Partnership Exchanges, the Account Manager will focus on issues that are unique to Exchange participation, such as assisting issuers with questions regarding the Exchange website, enrollment transaction files, and other operational matters. CMS expects that states, regardless of Exchange type, will take the lead in addressing market-wide issues, such as complaints related to market conduct.

SECTION 2. QHP ISSUER COMPLIANCE AND OVERSIGHT

This section describes how CMS will monitor QHP performance during the coverage year in all FFEs, including State Partnership Exchanges.

QHP issuers will be asked to submit a Compliance Plan as part of the QHP Application. The Compliance Plan is largely intended as a means for each issuer to document its efforts to ensure that appropriate processes are in place to maintain adherence with applicable regulations and guidelines, as well as to prevent fraud, waste, and abuse. CMS believes that compliance plans are a key part of an issuer's overall performance. While submission of a compliance plan is not a requirement for QHP certification, we encourage issuers to submit a plan and we anticipate using the plan as part of determining whether a certifying a particular QHP is in the interests of the qualified individuals and qualified employers who are served by the applicable FFE.

CMS will generally look to existing state compliance oversight and enforcement efforts for issues that fall under the state’s regulatory and enforcement authority (e.g., standards that apply to all non-grandfathered individual and small-group market products). CMS will also investigate compliance concerns that are Exchange-specific in nature. CMS intends to use a risk-based approach to monitoring compliance, focusing first on issuers that show signs of potential performance issues or non-compliance. CMS will consider whether to perform periodic compliance reviews to address evident or suspected performance issues or non-compliance, consistent with oversight and enforcement authority.

SECTION 3. QHP MARKETING

This section describes how CMS will monitor QHP performance during the coverage year in all FFEs, including State Partnership Exchanges.

45 C.F.R. § 156.225 requires that in order to be certified, a QHP issuer must comply with all applicable state laws regarding health plan marketing. In addition, a QHP issuer must not employ marketing practices that could discourage the enrollment of individuals with significant health needs.

Because states already regulate health plan marketing materials and other documents under state law, CMS does not intend to review QHP marketing materials for compliance with state standards as described at 45 C.F.R. § 156.225. However, to assist consumers in identifying plans that have been certified by an Exchange, we recommend that all marketing materials distributed to enrollees and to potential enrollees, contain the following disclaimer: “[Insert plan’s legal or marketing name] is a Qualified Health Plan in the [Health Insurance Marketplace].” A logo for the Health Insurance Marketplace will also be made available for use on marketing materials. We note that consumer-facing materials will refer to the Exchange as the “Health Insurance Marketplace.”

In addition to complying with state marketing standards that apply to all issuers, QHP issuers must ensure that all marketing products and materials meet the meaningful access standards described in Chapter 6, Section 6 of this Letter to ensure access for individuals with limited English proficiency and individuals with disabilities (*See* 45 C.F.R. §§ 155.205, 155.230, and 156.250).

Chapter 4: Stand-alone Dental Plans

Stand-alone dental plans are treated uniquely in the Affordable Care Act, particularly with respect to stand-alone dental plan participation in Exchanges. Thus, various statutory and regulatory standards apply differently to stand-alone dental plans from how they apply to QHPs. To provide states, issuers, and other stakeholders with additional clarity on this issue, the following sections cover a number of policy issues unique to stand-alone dental plans.

SECTION 1. REGULATION OF STAND-ALONE DENTAL PLANS

This section clarifies which statutory and regulatory standards apply to stand-alone dental plans participating in any Exchange.

i. Affordable Care Act Provisions that Do Not Apply to Stand-alone Dental Plans

When provided under a separate policy or contract, limited scope dental benefits are excepted benefits, as defined by PHS Act section 2791, and thus not subject to the requirements of the PHS Act. This means that stand-alone dental plans are not subject to the insurance market reform provisions of the Affordable Care Act that amend the PHS Act and generally apply to non-grandfathered health plans in the individual and group markets inside and outside the Exchange, such as guaranteed availability and renewability of coverage.²⁶

There are other provisions of the Affordable Care Act that generally apply to QHPs offered in an Exchange that are not applicable to stand-alone dental plans because of the unique nature of the limited benefits these plans provide. As stated in 45 C.F.R. § 155.1065, issuers of stand-alone dental plans and stand-alone dental plans must meet QHP certification standards, except for any certification requirement that cannot be met because the plan only covers dental benefits. Further, section 1402(c)(5) of the Affordable Care Act, as codified in 45 C.F.R. § 156.440(b), excludes stand-alone dental plans from the cost-sharing reduction (CSR) requirements placed on medical QHP issuers. The provision states that any CSRs that would be applied to the pediatric dental EHB in a comprehensive medical QHP will not be applied if the pediatric dental benefit is provided through a stand-alone plan.

ii. Affordable Care Act Provisions that Apply to Stand-alone Dental Plans

Some market-wide and Exchange-specific provisions in the Affordable Care Act do apply to stand-alone dental plans:

²⁶ Examples of PHS Act reforms that do not apply to stand-alone dental plans include section 2718 medical loss ratio standards, section 2701 rating standards related to age, family size, rating area, and tobacco, section 2702 guaranteed availability standards, and section 2703 guaranteed renewability standards.

- **Prohibition on Annual and Lifetime Dollar Limits:** Section 2711 of the PHS Act (and its implementing regulations at 45 C.F.R. § 147.126) prohibits health insurance issuers in the individual and group markets from placing annual or lifetime limits on the dollar value of benefits for any beneficiary. Under 45 C.F.R. § 155.1065(a)(2), the pediatric dental EHB offered by stand-alone dental plans must be offered without annual and lifetime limits.
- **Annual Limits on Cost-sharing:** Under 45 C.F.R. § 156.150, rather than meeting the specific dollar limits that apply to comprehensive medical QHPs, stand-alone dental plans offered inside an Exchange will be required to demonstrate to the Exchange (FFE or otherwise) that they have a reasonable annual limitation on cost-sharing in place. The final rule also clarified that the Exchange is responsible for determining the level for “reasonable.”

SECTION 2. OFFERING STAND-ALONE DENTAL PLANS

This section describes how stand-alone dental plans will be treated in FFEs, including State Partnership Exchanges.

i. Certification of Stand-alone Dental Plans

Stand-alone dental plans must meet the applicable standards for certification and to comply with EHB requirements, as outlined in 45 C.F.R. §§ 155.1065 and 156.150. The following chart outlines the certification standards that do and do not apply to stand-alone dental plans seeking certification in the FFEs for the 2014 coverage year. We note that in addition to the following certification standards, issuers of stand-alone dental plans will need to comply with operational processes and standards as well.

Table 4.1: Certification Standards Applicable to Stand-alone Dental Plans

Certification Standard Applies (* denotes modified standard)		Certification Standard Does Not Apply
Essential Health Benefits*	Actuarial Value*	Accreditation
Maximum Out-of-Pocket Limits*	Licensure and Solvency	Cost-sharing Reduction Plan Variations
Network Adequacy	Inclusion of ECPs	Unified Rate Review Template
Marketing	Service Area	
Non-discrimination		

Stand-alone dental plans will generally use the same QHP Application, but will complete and submit the application on an adjusted timeline. However, the benefits template will be modified to accommodate the limited scope of dental plan benefits and the treatment as an excepted benefit. One of the main differences will be how rates are treated.

One modified standard is the limit on out-of-pocket costs. In 45 C.F.R. § 156.150, stand-alone dental plans are directed to demonstrate that they have a reasonable annual limitation on cost-sharing, as determined by the Exchange. For the 2014 coverage year in the FFE, any annual limit on cost sharing that is \$1,000 or below will be considered reasonable for the pediatric dental EHB. Any annual limit above that will receive additional review under 45 C.F.R. §156.150.

ii. Displaying Stand-alone Dental Plan Rates

As articulated in 45 C.F.R. § 155.205(b), the Exchange is required to collect and display premium rate information for all QHPs, including stand-alone dental plans, in a standardized and comparable way. In addition, 45 C.F.R. § 156.210 requires QHP and stand-alone dental plan issuers to submit rate and benefit information to the Exchange as a standard for certification by the Exchange. Due to their excepted benefit status, stand-alone dental plans are not required to meet the rating rules of PHS Act section 2701(a) that underlie the QHP Rating Tables and business rules template. However, stand-alone dental plans will still need to complete these tables, and based on that information, CMS will display basic, comparable rate information for stand-alone dental plans on the web portal. CMS will also calculate the advance payment of the premium tax credit for stand-alone dental plans using the pediatric dental EHB premium allocation.

When a consumer is directed to the stand-alone dental plan issuer to make the initial premium payment to effectuate enrollment, the stand-alone dental plan issuers would have the ability to make any premium adjustments beyond those accounted for in the Rating Tables and based on additional rating factors available to issuers of stand-alone dental plans.

In order to provide the maximum amount of information to consumers during plan selection, stand-alone dental plans will need to indicate whether they are committing to the rates reported in the Rating Tables or if they are reserving the option to charge additional premium amounts. Issuers of stand-alone dental plans would indicate in the templates included in the issuer application for QHP certification whether they are guaranteeing the rate that is completed in the templates. If the issuer indicates that the rates are guaranteed, then the issuer would not charge additional rates beyond what is reported in the rating templates. If the issuer indicates that the rates are not guaranteed, the issuer could charge additional premiums to the consumer. The plan compare function of the FFE website will inform consumers what the different indications mean.

If an issuer of stand-alone dental plans elects to charge an additional premium, CMS would collect that information for the individual market from the issuer during the transmission of enrollment information and acknowledgement process. As with QHPs in the individual market, the enrollee will be billed by and make payments directly to the stand-alone dental plan issuer.

iii. Separately Offering and Pricing Stand-alone Dental Plans

In the discussion of stand-alone dental plans in the preamble to the Exchange final rule, it is noted that each Exchange can require as a condition of certification, comprehensive medical QHPs to offer and price the pediatric dental EHB (if covered) separately, if doing so would be in the best interest of consumers.

For the 2014 coverage year, CMS will not require comprehensive medical QHP issuers that provide pediatric dental coverage to offer and price the pediatric dental EHB separately from the rest of the plan in connection with certification by an FFE.

Additionally, the FFE will not have the capacity to display dental benefits of a QHP as a separate or severable benefit, for example where an issuer offers both health plans and stand-alone dental plans and wishes to “bundle” them in the plan compare website. In order to be displayed on the Exchange website, dental benefits must either be embedded in a comprehensive medical QHP or offered separately through a stand-alone dental plan.

iv. Data Collected through the Stand-alone Dental Plan Voluntary Reporting Program

In order to allow QHP issuers to exercise the statutory option to omit the pediatric dental EHB in an Exchange where a stand-alone dental plan is also offered, CMS established a voluntary reporting program²⁷ to determine in which Exchanges dental issuers are likely to offer stand-alone plans. The voluntary reporting encouraged dental issuers that intend to seek certification of one or more stand-alone plans in an Exchange to communicate their intent to CMS by state, service area, and market (individual or group). The data was published for the FFE states on February 11, 2013 on the CCIIO website.²⁸ The data show that a stand-alone dental plan is expected to be offered throughout each state in which an FFE, including a State Partnership Exchange, will be operating; therefore, QHP issuers participating in FFEs, including State

²⁷ See Patient Protection and Affordable Care Act; Data Collection to Support Standards Related to Essential Health Benefits; Recognition of Entities for the Accreditation of Qualified Health Plans, 77 Fed. Reg. 42,658 (July 20, 2012) (to be codified at 45 C.F.R. part 156) and OMB control number 0938-1174.

²⁸ Issuers of Stand-alone Dental Plans: Intent to Offer in FFE States (Jan. 23, 2013), available at <http://cciio.cms.gov/resources/files/voluntary-dental-reporting-list-1-28-13.pdf>.

Partnership Exchanges, can expect to have the option to omit the pediatric dental EHB. In future years, CMS will publish these data in the Letter.

Chapter 5: Consumer Enrollment and Premium Payment

In the General Guidance on Federally-facilitated Exchanges,²⁹ CMS outlined a high-level approach for implementation of the enrollment process in FFEs. This Chapter provides updated policy, operational, and technical information to assist issuers in their preparations to offer health insurance coverage through the federal Exchange. Specifically, this Chapter addresses the enrollment process, the enrollment transaction and accompanying Companion Guide for issuers, related transactions, enrollment periods, effective dates, changes, terminations, and enrollment reconciliation. Because eligibility and enrollment functions will be conducted by CMS in State Partnership Exchanges, all processes related to eligibility and enrollment described in this Chapter will apply in all State Partnership Exchanges and FFEs. Some of the standards and practices outlined in this Chapter will also apply to State-based Exchanges. However, given the complexity of state laws in this area and additional flexibility authorized for State-based Exchanges, CMS intends to provide similarly detailed guidance to State-based Exchanges and participating issuers in those Exchanges in the future.

Sections 1 – 3 provide a high-level overview of the enrollment process, including premium payment. The policies and procedures outlined in these sections are consistent with the Exchange Final Rule, and are intended to promote issuer readiness to receive and transmit necessary data and process premium payments. If deemed necessary, CMS will publish future guidance addressing nuances associated with applying for coverage via a paper application.

SECTION 1. OVERVIEW OF THE ENROLLMENT PROCESS FOR QUALIFIED INDIVIDUALS

When a qualified individual wishes to purchase health insurance in a qualified health plan or stand-alone dental plan through the FFE, the individual will:

1. Complete the eligibility application for coverage and, if desired, insurance affordability programs through the Exchange,
2. Evaluate available QHPs to compare the options,
3. Make a plan selection,
4. Select the desired amount of APTC, if eligible, and
5. After being re-directed by the Exchange to the appropriate issuer's website, follow instructions provided by the issuer to determine how to make the first premium payment (unless the APTC are greater than the premium) and provide any additional information required by the QHP issuer to process the enrollment, such as a selection of primary care provider. More information about the initial premium payment is provided later in this document.

²⁹ General Guidance on Federally-facilitated Exchanges (May 16, 2012), available at <http://cciio.cms.gov/resources/files/ffe-guidance-05-16-2012.pdf>.

At least once daily, the Exchange and QHP issuers will exchange electronic files containing information about new enrollments, updates for existing enrollees (e.g., address changes), cancellations, and terminations. The enrollment transactions will also include the APTC and CSR amounts for those who are eligible for that assistance. QHP issuers are expected to update their internal records promptly to match the Exchange's records.

SECTION 2. PAYMENT OF PREMIUMS

i. Initial Premium Payments

Enrollees in all FFEs (including State Partnership Exchanges) will make premium payments directly to the QHP issuer; the Exchange will not accept premium payment on behalf of issuers. The mechanism of payment must comply with the issuer's payment policies. When a qualified individual makes a QHP selection online, the Exchange will direct the individual to the issuer's website. If the issuer accepts payment electronically, we anticipate that the individual will be able to make the first premium payment on-line using that link to the issuer's website. We expect that QHP issuers will also provide a telephone number that individuals can call to make payment or ask questions. If payment must be made by other means, instructions should be provided on the issuer's website.

In the event that the payment information submitted by the individual is inconsistent with the issuer's payment policies (for example, because it does not clear the issuer's financial institution), QHP issuers are permitted to follow their standard cancellation procedures (for initial premium payments) or termination procedures (for existing enrollees), subject to applicable federal law and regulations. For existing enrollees, coverage may be terminated in accordance with the allowable grace periods set forth at 45 C.F.R. §§ 155.430(b) and 156.270(c). Issuers must develop a process for notifying an enrollee of the termination, communicating the reason for the termination. CMS believes that also providing an explanation of any associated liability for medical claims that may have been incurred would be a best practice for QHP Issuers.

ii. Initial Premium Payment Cut-off Dates and Cancellations

CMS recommends but does not require that issuers establish the following best practices regarding payment cut-off dates and coverage cancellations. The cut-off date set by issuers for premium payment by the enrollee would be no later than the day before the effective date of coverage and would not be earlier than the last possible date of plan selection. For example, if a qualified individual selects a QHP on December 14, 2013, for coverage on January 1, 2014, the premium payment cut-off date would be no earlier than December 15, 2013, and no later than December 31, 2013. Issuers could choose to *cancel* coverage of any qualified individual who

does not make timely payment of the initial premium. Requiring initial premium payment before the effective date of coverage would prevent an individual from using the insurance benefit of covered services without first having made a premium payment, so CMS recommends that issuers follow that practice. If the qualified individual is still in an enrollment period at the time the coverage is cancelled, he or she could go through the plan selection process again and may select the same or another QHP, should the individual be eligible to enroll in coverage at that future date.

If a qualified individual makes a QHP selection but later selects a new QHP before the coverage effective date, the initial QHP selection could be automatically cancelled by the Exchange as part of the transmission of updated enrollment information to QHP issuers. If any premiums were paid to the initial QHP, the issuer would be responsible for refunding the premium. In some instances, such as when cancellation requests are received immediately before the coverage effective date, the process might result in a retroactive cancellation and issuers should ensure their systems can accommodate such transactions.

iii. APTCs and Premium Payments from Qualified Individuals and Enrollees

In order for the Exchange to appropriately administer APTCs, the QHP issuer must report current and accurate information on the status of qualified individual and enrollee premium payments. QHP issuers will provide up-to-date information on the last premium payment date for every enrollee. In accordance with 45 C.F.R. §§ 155.270, 162.925 and 162.1502, QHP issuers will use Version 5010 Technical Report Type 3 Benefit Enrollment and Maintenance Transaction (ASC X12 834), adopted by the Secretary of Health and Human Services on January 23, 2009.

SECTION 3. EFFECTIVE DATE OF COVERAGE

When a qualified individual enrolls in a QHP, enrollment effective dates follow the dates established by 45 C.F.R. §§155.410(c)(1) and 155.420(b)(1)–(2); CMS will not attempt to negotiate alternative (earlier) effective dates for FFEs. Although most coverage effective dates are either the first of the following month or the first of the second following month, there are exceptions for certain special enrollments (such as those for birth, adoption, placement of adoption, marriage and loss of minimum essential coverage), which allow a qualified individual or enrollee to make a plan selection outside of the initial or annual open enrollment period.

Special enrollment period coverage effective dates depend on the type of event, the date of request for a special enrollment period, and the date of plan selection. CMS will determine enrollee eligibility for all special enrollment periods. Table 5.1 depicts certain triggering events and their corresponding effective enrollment dates, assuming the individual selects a plan and makes a timely premium payment.

Table 5.1: Examples of Effective Dates of Coverage for Individuals

Triggering Event	Triggering Event Date	Eligibility Determination Date	Enrollment Period		Plan Selection Date Examples	Enrollment Effective Dates (first available date depending on the plan selection date)
			Start	End		
Initial Open Enrollment Period		10/1/13	10/1/13	3/31/14	10/1/13	1/1/2014
					3/16/14	5/1/2014
Annual Open Enrollment Period (example for years subsequent to 1/1/2015)		9/10/15	10/15/15	12/7/15	12/7/15	1/1/16
Special Enrollment Periods last 60 days from the triggering event per 45 C.F.R. § 155.420(c). ³⁰ Enrollment Period start dates below indicate the earliest date an individual could select a plan.						
Relocation	4/1	4/10	4/10	5/30	4/15	5/1
	4/10			6/10	4/16	6/1
	3/20			5/20	5/16	7/1
Birth	6/1	7/20	7/20	7/30	7/29	6/1
Loss of Minimum Essential Coverage	4/28	4/28	4/28	6/28	4/29	5/1
	4/15			6/15	5/2	6/1
Marriage	4/12	5/28	5/28	6/12	5/28	5/1
Loss of employer-sponsored insurance	8/30	8/5	8/5	10/30	8/5	9/1

³⁰ In Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Small Business Health Options Program; Proposed Rule; CMS-9964-P2 (displayed Mar. 1, 2013) (to be codified at 45 C.F.R. parts 155 & 156), we propose amending the duration of certain special enrollment periods for the SHOP.

SECTION 4. TRANSMISSION OF ENROLLMENT INFORMATION BETWEEN THE FFE AND QUALIFIED HEALTH PLANS

45 C.F.R. § 155.270 requires Exchanges to use standards, implementation specifications, operating rules, and code sets adopted by the Secretary under the HIPAA and the Affordable Care Act when conducting certain electronic transactions with a covered entity such as an issuer.

The transaction standard CMS and issuers will use to exchange electronic enrollment files will be the ASC X12 834, adopted by the Secretary of CMS on January 23, 2009, and required for use by HIPAA covered entities – like issuers and health plans - on January 1, 2012. CMS released a Companion Guide³¹ for certain fields and data elements for use by Exchanges and issuers to include data elements not otherwise provided in the ASC X 12 834 standard transaction, such as APTCs. Most issuers currently use Companion Guides to provide direction to their trading partners when conducting any type of HIPAA-compliant data exchange such as enrollment, claims processing, eligibility inquiries, and claim status inquiries. Issuers offering QHPs through an FFE, including a State Partnership Exchange, must use ASC X12 834 with the CMS Companion Guide for purposes of QHP enrollment transactions. The CMS Companion Guide is available for use by issuers and Exchanges to begin programming and internal testing.

In some situations, it may be necessary to accept an enrollment file in a non-electronic data interface (EDI) format (e.g., natural disaster, or serious technical problems). CMS will work with QHP issuers to evaluate and determine appropriate alternate paths to transmit enrollment data as necessary under those circumstances, which may include CD, tapes, or online processes.

The ASC X12 Version 5010 834 Benefit Enrollment and Maintenance Transaction TR3 may be purchased from ASC X12, at <http://store.x12.org/store/>.

i. Enrollment Transaction Acknowledgement Files (ASC X12 999)

When the issuer receives the daily enrollment file, in accordance with 45 C.F.R. § 155.400(b)(2), it must acknowledge receipt of information to the FFE by transmitting an ASC X12 Version 5010 999 Implementation Acknowledgement for Health Care Insurance transaction (ASC X12 999 Acknowledgement). This transaction informs the submitter that the file (the ASC X12 Version 5010 834 Benefit Enrollment and Maintenance Transaction TR3) arrived at the destination and can be processed. The ASC X12 999 Acknowledgement may include the number

³¹ Standard Companion Guide Transaction Information Companion Guide Version Number: 1.0 (January 31, 2013). Available at: <http://cciio.cms.gov/resources/files/companion-guide-for-ffe-enrollment-transaction-v1.pdf>.<http://cciio.cms.gov/resources/files/companion-guide-for-ffe-enrollment-transaction-v1.pdf>.

of transactions received, the number of transactions processed, and any errors detected. CMS will provide future guidance as to the other content required in the ASC X12 999 Acknowledgement.

ii. Enrollment Confirmation Transaction

Issuers will use the ASC X12 834 as a confirmation transaction for certain enrollment actions. For example, when a qualified individual submits full payment to the issuer for any applicable initial premium due, the issuer will send the Exchange a full ASC X12 834 “confirmation” record. Additionally, in response to the Exchange sending a file to an issuer containing changes for multiple enrollees, once the issuer has made those changes or effectuated an enrollment, the issuer will send the Exchange a full ASC X12 834 “confirmation” record for each individual affected. The confirmation file provides CMS, in operation of the FFEs, assurance that the issuer has effectuated enrollment, terminations, cancelations, and updates (e.g., a name change) consistent with the information received from the Exchange and also provides the Exchange with the data necessary to reconcile any pending transactions.

iii. Identifiers within the Enrollment Transaction

Both CMS and issuers will utilize several identifiers in the enrollment transaction, including unique identifiers designating the subscriber, enrollee, issuer, and Exchange. Some of these identifiers will be created and provided to the issuer by the Exchange, and some will be created by the issuer and sent to the Exchange. The identifiers, their sources, and definitions will be included in the CMS Companion Guide to include information about the qualifiers that will be used with each identifier, where they will be found in the transaction, and how they will be defined. The key identifiers for the enrollment transaction are the subscriber identifier, which is the identifier for the person with the primary coverage, and the member identifier, which is associated with the other individuals who are insured with the subscriber.

iv. Unique Identifiers for the Subscriber

Issuers use unique numbers to identify subscribers and members, and these numbers are often associated with the individual for as long as such individual maintains coverage through a group or health plan with that issuer. The ASC X12 834 standard requires the use of an individual identifier in each transaction to ensure the accuracy of an exchange of data between two trading partners, and the consistency of that information over time.

CMS will assign a unique identifier to each individual enrolled in a QHP. The unique identifier will be associated with the specific issuer and will not “travel” with the qualified individual if the individual changes QHPs. If the qualified individual changes to a QHP with another issuer, he or she will receive a new identifier. However, if the qualified individual returns to a QHP issuer

from whom he or she previously held coverage through the Exchange, the same identifier will be reassigned to that person.

Because CMS will be redirecting qualified individuals to QHP issuers to make initial premium payments rather than aggregating premiums in the FFEs serving the individual market, there will be a unique application ID to aid issuers in matching initial premium payments made by qualified individuals to the ASC X12 834 transactions sent by the Exchange. Qualified individuals will be able to refer to the unique application ID in communications with issuers if there are issues with the premium payment process.

SECTION 5. TERMINATION OF COVERAGE AND CANCELLATION OPTIONS

The FFE will initiate all enrollee terminations of coverage and enrollment, except that the QHP issuer may initiate terminations in cases of non-payment of premium to the issuer by the enrollee and situations covered by 45 C.F.R. § 147.128 (e.g., fraudulent activity by the enrollee). When enrollees wish to terminate coverage, they should provide reasonable notice. Issuers will receive termination information from the Exchange through an ASC X12 834 transaction, and guidance on the data elements to be used in the transaction will be provided in the Companion Guide.

SECTION 6. GRACE PERIODS FOR NON-PAYMENT OF PREMIUMS

In accordance with the Exchange Final Rule, issuers will be permitted to terminate coverage for enrollees who fail to pay premiums. However, 45 C.F.R. § 156.270(d) requires issuers to observe a three month grace period before terminating coverage for those enrollees who are receiving APTCs. The grace period only applies to enrollees who have already paid their share of one month's premium in full; for enrollees who meet this initial requirement, the grace period is triggered once the enrollee subsequently misses a premium payment. The final rule outlines a process for addressing such instances of non-payment, including issuer responsibilities with respect to provider notification and claims payment.

If an enrollee makes all outstanding premium payments before the end of the grace period, the enrollee's enrollment with the same QHP remains intact. However, if an enrollee exhausts the grace period without making all outstanding premium payments, the issuer must terminate coverage with notice to the enrollee. An enrollee may not extend the grace period by paying only a portion of the outstanding premium (e.g., by paying the first outstanding month's premium). Only complete payment of all outstanding premiums will bring the qualified individuals into good standing. If coverage is terminated for non-payment of premiums, the last day of coverage may be the last day of the first month of the grace period; thus, coverage may be terminated retroactively. If an enrollee exhausts the grace period, the issuer must return APTCs

for the second and third months to the Treasury Department. CMS will provide information about this process in the future.

If an enrollee's coverage in a QHP is terminated for non-payment of premiums, as indicated on the 834 transaction via the disenrollment code, he or she may not enroll in another QHP with any issuer through a special enrollment period. 45 C.F.R. § 155.420(d)(1) and (e). We anticipate that all Exchanges will have access to this information as part of the enrollment information sent by QHP issuers in the ASC X12 834 standard. If a QHP issuer terminates the enrollee's coverage for non-payment, all individuals on the policy also lose coverage. Applicable state law will govern grace periods for enrollees not receiving APTCs within the Exchange.

SECTION 7 NOTICE REQUIREMENTS

i. Notice of Premium Non-payment— to Enrollees

Issuers must notify enrollees who are receiving APTCs and who have failed to make a premium payment that they are delinquent in such payment, as described in 45 C.F.R. § 156.270(f). The notice should be written in plain language and comply with the standards provided herein under Chapter 6, Section 6 with regard to the provision of notice to people with limited English proficiency or to people with disabilities. Issuers should include the following information:

- Purpose of the notice;
- An identification/reference number unique to the notice;
- The name of the QHP and affiliated issuer;
- Primary subscriber and relevant contact information;
- Names of all enrollees affected by the unpaid premium;
- Explanation about the three-month grace period, including applicable dates;
- The telephone number for the QHP customer service; and
- Consequences of losing coverage, including:
 - Repayment of premium tax credits provided for months of coverage that is retroactively terminated,
 - Inability to participate in a special enrollment period, and
 - Individual responsibility for paying any medical claims incurred during the period of the retroactively terminated coverage.

ii. Notice of Pending Claims—to Providers

In accordance with 45 C.F.R. § 156.270(d)(3), issuers must notify providers that may be affected (meaning at least providers that submit claims for services rendered during the grace period) that an enrollee has lapsed in his or her payment of premiums. Issuers may utilize automated electronic processes to convey such notices. The notice must indicate there is a

possibility that the issuer may deny payment of claims incurred during the second and third months of the grace period if the enrollee exhausts the grace period without paying the premiums in full. Issuers should notify all potentially affected providers as soon as is practicable when an enrollee enters the grace period, since the risk and burden are greatest on the provider. Issuers should include the following information in the provider notification:

- Purpose of the notice;
- A notice-unique identification number;
- The name of the QHP and affiliated issuer;
- Names of all individuals affected under the policy and possibly under the care of this provider;
- An explanation of the three month grace period, including applicable dates, including:
 - Whether the enrollee is in the second or third month of the grace period,
 - Consequences of grace period exhaustion for the enrollee and provider, and
 - Options for the provider; and
- The QHP customer service telephone number specifically for use by providers, if available.

SECTION 8. ENROLLMENT RECONCILIATION

On at least a monthly basis, as determined by CMS, the Exchange and issuers will exchange full enrollment files to identify and resolve discrepancies between the enrollment records and to ensure information in each system (Exchange and issuer) is consistent.

i. Reconciliation Process

To operationalize the requirements in 45 C.F.R. § 1 55.400(d) and 45 C.F.R. § 1 56.265(f), in an FFE, including a State Partnership Exchange, CMS will conduct a reconciliation process electronically and in a bi-directional flow between the Exchange and the issuer, meaning that each party will send the other a full file of data for comparison. At a scheduled time each month, each issuer will compile an ASC X12 834 audit file comprised of all enrollments for a specified period of time (e.g., one quarter), and will transmit this through the Data Services Hub (Hub). CMS will compare the issuer records with the internal enrollment records for the Exchange for that same period of time. The files will be transmitted through the Hub and will be processed based on evaluation criteria to be established for the reconciliation processes. At the same time CMS is comparing its files to those of the issuers, CMS will compile and send an ASC X12 834 audit file to each issuer for the same time period, comprised of all individuals enrolled in that issuer's QHPs. Each QHP issuer will use this file for its own comparison and analysis.

The data exchange will allow the issuers and the Exchange to identify discrepancies using key data elements including name, date of birth, issuer ID numbers, plan/level, effective and

termination dates, cancellations, and APTC and CSR amounts. CMS will create a discrepancy report for each issuer, and each QHP issuer will create a similar discrepancy report for the Exchange. CMS will publish information regarding the content and format for the discrepancy report in future guidance, and will include it in future versions of the Companion Guide.

CMS will analyze the discrepancy reports and conduct appropriate research to understand and resolve discrepancies so that ultimately the issuer and CMS will have the same enrollment data. This may involve some manual effort and discussions on the part of both CMS and/or QHP issuers to obtain correct information from the enrollee.

ii. Enrollment and Mid-year Changes

Issuers will receive from the Exchange electronic transactions containing enrollment changes and updates due to enrollees reporting changes in circumstances throughout the benefit year and as part of the eligibility redetermination process. The Exchange will send transactions in sequential order and should be applied sequentially in order to ensure that issuers have the most up-to-date mid-year change data. Issuers will also periodically receive an update from the Exchange with retroactive changes. The most common instances in which this will occur include birth, death, errors, QHP material provision violations, and exceptional circumstances. The process for how APTC and CSR will be handled is outlined in the Final Payment Notice.

SECTION 9. DIRECT ENROLLMENT WITH THE QHP ISSUER

As provided in 45 C.F.R. § 156.265(b), a QHP issuer may treat an enrollee as enrolled in the QHP through the Exchange if certain conditions are met and procedures followed. In order to facilitate enrollment of qualified individuals in a QHP through the Exchange when such individuals approach an issuer directly, the issuer must ensure the individuals receive an eligibility determination for coverage through the Exchange. CMS will provide additional guidance as to how individuals that approach the issuer are referred to the State Partnership Exchange or FFE website to complete the eligibility determination process shortly.

SECTION 10. AGENTS AND BROKERS

Section 1312(e) of the Affordable Care Act and 45 C.F.R. § 155.220 permit states to allow agents and brokers to enroll qualified individuals, employers, and employees in QHPs through an Exchange. Where permitted by the state, agents and brokers (including web-brokers) may assist with the eligibility application and enrollment processes, including plan selection, as well as in applying for insurance affordability programs, including APTCs and CSRs, subject to the standards outlined in 45 C.F.R. § 155.220.

All agents and brokers, including web-brokers, seeking to enroll individuals through an FFE or FF-SHOP must be licensed as producers by the state and adhere to all applicable state laws. States will maintain their current roles of overseeing agents and brokers in their insurance markets, including licensure requirements, appointments with issuers, and any compensation standards.³²

CMS will work with agents and brokers, including web-brokers, to facilitate enrollment in an FFE or FF-SHOP, including a State Partnership Exchange, to the extent permitted by state law. As described in the Exchange Final Rule, CMS will enter into agreements with registered agents and brokers to ensure compliance with federal regulation and Exchange privacy and security requirements.

This Exchange-specific Agent/Broker Agreement will govern agents' and brokers' access to the Exchange. CMS will monitor and oversee agents and brokers to confirm ongoing compliance with the terms of the Agent/Broker Agreement. CMS anticipates that this monitoring and oversight will be limited to the terms of the Agent/Broker Agreement not covered by state law, such as the Exchange's privacy and security requirements and standards for obtaining consumer consent. If an agent or broker violates the terms of the Agent/Broker Agreement with the FFE, CMS may suspend or terminate agent or broker access to the Exchange. We plan to release additional information on this process in the future.

CMS intends to notify the state when an agent's or broker's Exchange access has been suspended or terminated. CMS also intends to refer any identified market conduct issues (for example, failure to act in the best interest of the consumer) to states for follow-up and remediation.

Issuers must ensure that marketing actions taken on their behalf by agents and brokers, including web-brokers, participating in FFEs and FF-SHOPs comply with applicable federal and state requirements. Any marketing materials related to an issuer's QHPs and used by an agent or broker must conform to requirements in the QHP issuer's Agreement with the Exchange.

³² However, a QHP issuer participating in an FFE or FF-SHOP must pay the same commission for a QHP sold inside and outside of an Exchange.

Chapter 6: Consumer Support

SECTION 1. CALL CENTER AND WEBSITE

Issuers should have their own call centers and websites to support consumers' customer service needs. CMS will also provide customer support and is responsible for the operation of the FFE Call Center, to support consumers in states that do not have a State-based Exchange, including states where a State Partnership Exchange is operating. The Call Center will provide an unbiased central point of contact for consumers and employees.

Where possible, the customer service representatives at the Call Center will be able to provide referrals to the appropriate state or federal agencies or assistance programs (such as Navigators and other in-person assisters), or issuers.

The Call Center will be established so that all customer service representatives are able to address requests for general information, consumer eligibility, plan comparisons, and enrollment.

CMS will also operate a website to support consumers in states that do not have a State-based Exchange. The website supporting FFEs and State Partnership Exchanges will be compliant with section 508 of the Rehabilitation Act of 1973, designed to accommodate people with disabilities according to federal requirements, and will support the following key program topics in both English and Spanish:

- Consumer education,
- Customer self-service,
- Exchange, Medicaid and CHIP program support (e.g., eligibility determinations, enabling successful plan selection, and enrollments), and
- Information about available consumer support (such as customer service representatives, assisters, Navigators, agents, etc.).

Additionally, the website will be designed to support seamless handoffs (or redirections) to more appropriate websites. For example, if a consumer indicates he or she resides in a state with a State Based Exchange where a website for that State Based Exchange is available, the consumer will be re-directed to the appropriate website.

Mobile support is also a strong focus for the Exchange. At a minimum, the website will be provided in a mobile-friendly format using responsive design techniques.

CMS is also funding Navigators in each FFE and State Partnership Exchange that will provide assistance to consumers as directed in 45 C.F.R. § 155.210. The duties of Navigators include maintaining expertise in eligibility, enrollment, and program specifications; conducting public outreach; providing information in a fair, impartial and accurate manner; facilitating selection of

a QHP; making referrals to consumer assistance entities when appropriate; and providing information in a manner that is culturally and linguistically appropriate and that is accessible by individuals with disabilities.

SECTION 2. CONSUMER EDUCATION

CMS encourages QHPs to engage in consumer education efforts. Educational, marketing, and plan materials should comply with the requirements for meaningful access for limited English proficient individuals and for people with disabilities, as required by 45 C.F.R. §§ 155.230(b) and 156.250. In addition, CMS notes that QHPs are required to provide a Summary of Benefits and Coverage (SBC) and uniform glossary to current enrollees as well as to individuals and small employers seeking insurance in accordance with the rules set forth at 45 C.F.R. § 147.200.

SECTION 3. PROVIDER DIRECTORY

Pursuant to 45 C.F.R. § 156.230, CMS will require QHPs to make their provider directories available to the Exchange for publication online by providing the URL link to their network directory. CMS expects the directory to include location, contact information, specialty and medical group, and any institutional affiliations for each provider. CMS encourages issuers to include information such as whether the provider is accepting new patients, languages spoken, provider credentials, and whether the provider is an Indian provider.

SECTION 4. COMPLAINTS TRACKING AND RESOLUTION

CMS expects QHP issuers to investigate and resolve consumer complaints received directly from members or forwarded to the issuer by the state and/or CMS. Complaints may be forwarded within a CMS complaint tracking system developed by CMS or by other means as determined by CMS and states. CMS expects issuers to resolve complaints in a timely and accurate manner to ensure consumers receive the highest level of service and to meet QHP issuer participation standards as outlined in 45 C.F.R. § 156.200.

In addition, issuers are expected to comply with all applicable state and federal laws related to consumer complaints, including advising consumers of their appeal rights. CMS intends to track complaints and use aggregated complaints information as a tool for directing oversight activities in FFEs and State Partnership Exchanges. To the greatest degree possible, CMS will collaborate with states in tracking complaints and sharing information suggestive of issuer performance problems. We intend to provide further information on issuer standards for consumer complaints in the future.

SECTION 5. COVERAGE APPEALS

QHPs are required to meet the standards for internal claims and appeals and external review established in 45 C.F.R. § 147.136, which codifies section 2719 of the PHS Act, as added by the Affordable Care Act. Section 2719 of the PHS Act requires that all non-grandfathered group health plans and health insurance issuers offering group or individual health insurance coverage implement an effective process for internal claims and appeals and external review. QHPs must fully comply with the requirements of 45 C.F.R. § 147.136 and any applicable guidance documents.

SECTION 6. MEANINGFUL ACCESS

In order to ensure meaningful access by limited-English proficient speakers and by people with disabilities, the Exchange Final Rule requires that QHP issuers provide all applications, forms, and notices to enrollees in plain language and in a manner that is accessible and timely to individuals living with disabilities and individuals with limited English proficiency. *See* 45 C.F.R. §§ 155.205(c), 155.230(b), and 156.250. Additionally, 45 C.F.R. § 156.200(e) prohibits QHP issuers, with respect to QHPs, from discriminating on the basis of race, color, national origin, or disability, among other bases.

QHPs are reminded that these meaningful access requirements are independent of other obligations QHPs may have. In accordance with 45 C.F.R. §§ 155.205(c), 155.230(b), and 156.250, providing meaningful access includes but is not limited to the following. For people with disabilities, providing meaningful access includes the use of accessible websites and the provision of auxiliary aids and services in accordance with the Americans with Disabilities Act and section 504 of the Rehabilitation Act. For limited-English proficient speakers, providing meaningful access includes providing oral interpretation, written translations, and taglines in non-English languages indicating the availability of language services. Furthermore, QHP issuers must inform individuals of the availability of the services described above, instruct consumers how to access those same services, and indicate to applicants and enrollees that said services will be provided at no cost to them.

CMS remains open to proposals for how issuers plan to meet the regulatory meaningful access requirements.

CMS expects that QHP issuers will ensure meaningful access to at least the following essential documents:

- Applications (including the single streamlined application);
- Consent, grievance, and complaint forms, and any documents requiring a signature;
- Correspondence containing information about eligibility and participation criteria;

- Notices pertaining to the denial, reduction, modification, or termination of services, benefits, non-payment, and/or coverage;
- A plan's explanation of benefits or similar claim processing information;
- QHP ratings information, as applicable;
- Rebate notices; and
- Any other document that contains information that is critical for obtaining health insurance coverage or access to care through the QHP.

Documents related to appeals and SBC are not included in this list because they have their own regulatory standards with which issuers must comply.

We intend to further address and clarify the standards for ensuring meaningful access by limited-English-proficient speakers and by people with disabilities in the future. QHP issuers will be held to whatever standards will ultimately apply as a result of that guidance.

Chapter 7: Tribal Relations and Support

SECTION 1. MODEL CONTRACT ADDENDUM FOR TRIBAL ISSUERS WORKING WITH INDIAN PROVIDERS

The federal government has a historic and unique relationship with Indian tribes. In adhering to QHP certification standards, CMS encourages QHPs to engage with Indian health care providers, through which a significant portion of American Indians and Alaska Natives (AI/AN) access care. To promote contracting between issuers and Indian health care providers, CMS developed a Model QHP Addendum (Addendum) to facilitate the inclusion of Indian Health Service, Tribal Organization, and Urban Indian Organization providers (Indian health care providers) in QHP provider networks. The Addendum is a model standardized document for QHP issuers to use in contracting with Indian health care providers; the Addendum is also intended to help QHP issuers comply with the QHP certification standards set forth in part 156 of the Exchange Final Rule.

Although the Addendum is voluntary, it can assist QHP issuers in including Indian health care providers in their networks and provides an efficient way to establish contract relationships with such providers, while also helping to ensure that AI/ANs can continue to be served by their Indian provider of choice. The Model QHP Addendum will be available soon on our website, along with a database of Indian health care providers compiled by the Indian Health Service.

SECTION 2. TRIBAL SPONSORSHIP OF PREMIUMS

45 C.F.R. § 155.240(b) provides Exchanges with flexibility to permit Indian Tribes, Tribal organizations, and urban Indian organizations to pay QHP premiums—including aggregated payment—on behalf of members who are qualified individuals, subject to terms and conditions determined by the Exchange. Feedback provided during consultation with Tribal governments indicates that AI/ANs may be reluctant to enroll in QHPs if Tribes are not able to pay premiums on their behalf. As a result, CMS is considering options for supporting the payment of QHP premiums by Tribes on behalf of their members in FFEs. There are a number of logistical challenges that must be addressed to support an effective Tribal premium payment program for 2014 or future plan years, and CMS intends to issue further guidance on this issue. CMS also expects that Tribes and issuers will work together to explore possibilities for Tribal payment of premiums.

Appendix A: Authorities Cited

Patient Protection and Affordable Care Act of 2010, Pub. L. 111-148, 124 Stat. 119 (2010)
(codified as amended in scattered sections of 26, 29 & 42 U.S.C.)

Health Care and Education Reconciliation Act of 2010, Pub. L. 111-152, 124 Stat. 1029 (2010)
(codified as amended in scattered sections of 26, 29 & 42 U.S.C.)

Internal Revenue Code, 26 U.S.C. §1, *et seq.*

Public Health Service Act, 42 U.S.C. §201, *et seq.*

Rehabilitation Act of 1973, 29 U.S.C. §701 *et seq.*

Social Security Act, 42 U.S.C. §301, *et seq.*

Patient Protection and Affordable Care Act; Establishment of Consumer Operated and Oriented
Plan Program, 76 Fed. Reg. 77392 (Dec. 13, 2011) (to be codified at 45 C.F.R. part 156)

Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health
Plans; Exchange Standards for Employers, 77 Fed. Reg. 18310 (Mar. 27, 2012) (to be codified at
45 C.F.R. parts 155, 156, & 157)

Patient Protection and Affordable Care Act; Data Collection to Support Standards Related to
Essential Health Benefits; Recognition of Entities for the Accreditation of Qualified Health
Plans, 77 Fed. Reg. 42658 (Jul. 20, 2012) (to be codified at 45 C.F.R. part 156)

Patient Protection and Affordable Care Act; Establishment of the Multi-State Plan Program for
the Affordable Insurance Exchanges, RIN 3206-AM47 (displayed Mar. 1, 2012) (to be codified
at 45 C.F.R. part 800)

Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits,
Actuarial Value, and Accreditation, 78 Fed. Reg. 12834 (Feb. 25, 2013) (to be codified at 45
C.F.R. parts 147, 155, & 156)

Patient Protection and Affordable Care Act; Health Insurance Market Rules; Rate Review, 78
Fed. Reg. 13406 (Feb. 27, 2013) (to be codified at 45 C.F.R. parts 144, 147, 150, 154, & 156)

Patient Protection and Affordable Care Act; CMS Notice of Benefit and Payment Parameters for 2014, RIN 0938-AR51 (displayed Mar. 1, 2013) (to be codified at 45 C.F.R. parts 153, 155, 156, 157, & 158.).

Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Small Business Health Options Program, RIN 0938-AR76 (displayed Mar. 1, 2013) (to be codified at 45 C.F.R. parts 155 & 156)

Internal Revenue Serv., Health Insurance Premium Tax Credit, 77 Fed. Reg. 30377 (May 23, 2012) (to be codified at 26 C.F.R. parts 1 & 602).

Ctr. Consumer Info. & Ins. Oversight, Ctrs. for Medicare & Medicaid Serv., General Guidance on Federally-facilitated Exchanges (May 16, 2012), *available at* <http://cciio.cms.gov/resources/files/ffe-guidance-05-16-2012.pdf>.

Ctr. Consumer Info. & Ins. Oversight, Ctrs. for Medicare & Medicaid Serv., Guidance on State Partnership Exchange Options in the Federally-facilitated Exchange (January 3, 2013), *available at* <http://cciio.cms.gov/resources/files/partnership-guidance-01-03-2013.pdf>.

Ctr. Consumer Info. & Ins. Oversight, Ctrs. For Medicare & Medicaid Serv., Issuers of Stand-alone Dental Plans: Intent to Offer in FFE States (January 28, 2013), *available at*: <http://cciio.cms.gov/resources/files/voluntary-dental-reporting-list-1-28-13.pdf>.

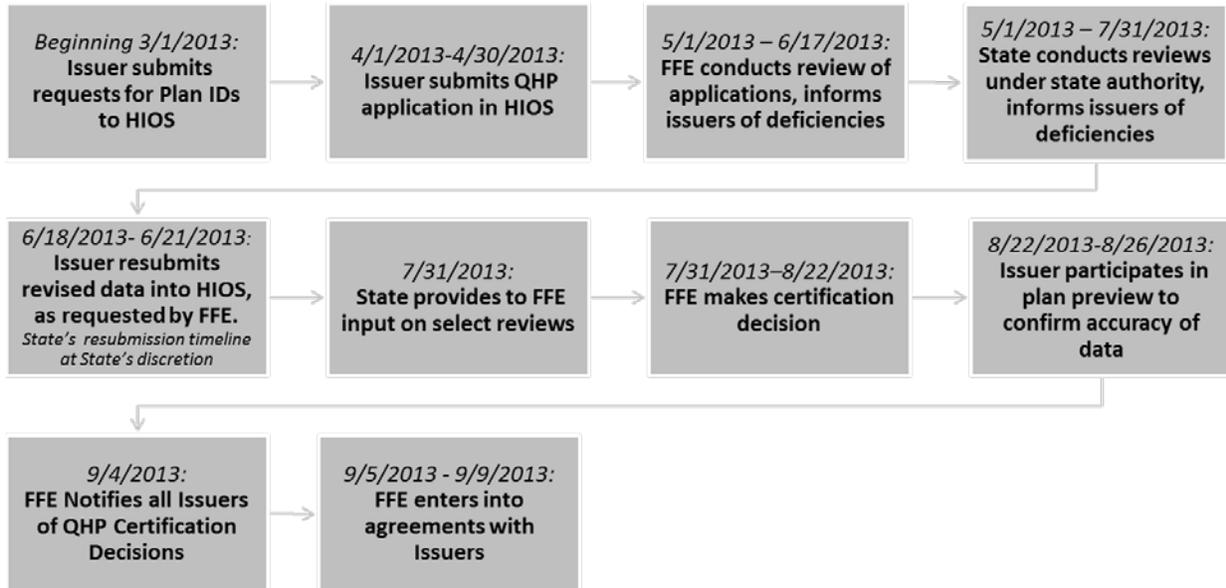
Ctr. Consumer Info. & Ins. Oversight, Ctrs. for Medicare & Medicaid Serv., Instructions related to the ASC X12 Benefit Enrollment and Maintenance (834) transaction, based on the 005010X220 Implementation Guide and its associated 005010X220A1 addenda for the Federally facilitated Exchange (FFE) (January 31, 2013), *available at*: <http://cciio.cms.gov/resources/files/companion-guide-for-ffe-enrollment-transaction-v1.pdf>.

Internal Revenue Serv., Rev. Proc. 2012-26, 26 C.F.R. §601.602, *available at* <http://www.irs.gov/pub/irs-drop/rp-12-26.pdf>.

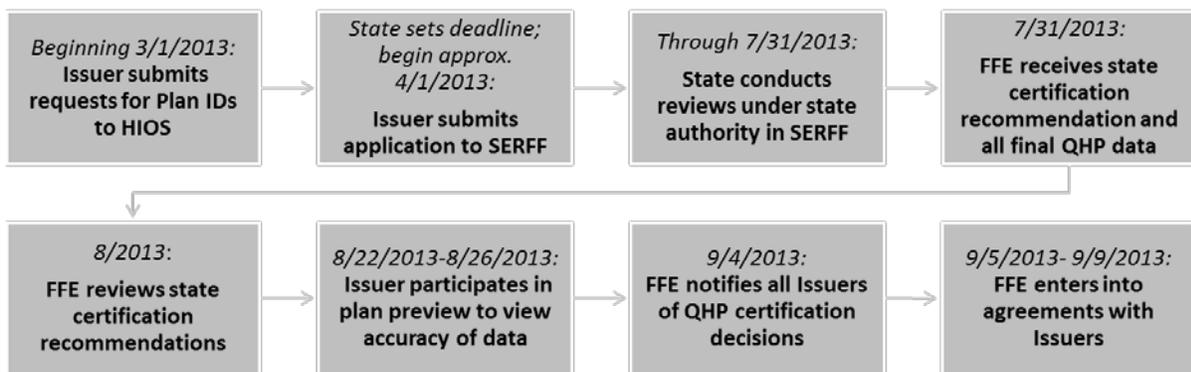
Appendix B: High-level Process Flows for QHP Certification

Note: all dates are subject to minor changes.

Non-Partnership FFE



State Partnership Exchange



Appendix C: Additional Guidance on EHB Prescription Drug Coverage, Actuarial Value, and Cost Sharing

This appendix provides additional guidance and clarification on 45 CFR §§ 156.122, 156.130, and 156.135. Specifically, it address the drug count service CMS developed to compute the number of drugs per category and class offered by an EHB-compliant formulary, the prescription drug exceptions process, calculating AV for health plans that are not compatible with the AV Calculator, and AV standards for the annual limitation on deductibles for health plans offered in the small group market.

EHB Prescription Drug Coverage

i. Drug Count Service

45 C.F.R. § 156.122 requires a health plan providing essential health benefits to cover at least the greater of 1) one drug in every United States Pharmacopeial Convention (USP) Model category and class, or 2) the same number of prescription drugs in each category and class as the EHB-benchmark plan. A drug is considered covered regardless of tiers and cost sharing. The specific drugs covered on each health plan’s formulary may vary as long as the minimum number in each category and class is met. For example, if a benchmark plan covers Clarinex (desloratadine) but not Patanase (olopatadine), a plan providing EHB could cover Patanase (olopatadine) but not Clarinex (desloratadine) because both of those drugs are in the same category. Similarly, if a benchmark plan covers five drugs in the antihistamines class and a plan providing EHB covers five different drugs in the antihistamines class, this plan would also meet the standard.

CMS computed the number of chemically distinct drugs covered by each EHB benchmark by category and class by cross-walking NDC codes to categories and classes using the USP Model Guidelines version 5.0. Different dosages of the same drug, different concentrations of the same active ingredient, brands and their generic equivalents, extended release and non-extended release formulations, and different delivery methods of the same drug were counted as one drug.

Table 1.1 Examples of Chemically Distinct and Not Chemically Distinct Drugs

Chemically Distinct (counted as two drugs)	Not Chemically Distinct (counted as one drug)
<ul style="list-style-type: none"> • Ibuprofen oral tablet and naproxen oral tablet • Epivir (lamivudine) oral tablet and Epzicom (abacavir and lamivudine) oral tablet 	<ul style="list-style-type: none"> • Brand name Aricept (donepezil hydrochloride) and generic donepezil hydrochloride • Ritalin LA (methylphenidate hydrochloride) 20 mg extended release capsule and Ritalin 20 mg oral tablet • Penicillin oral solution, Penicillin oral

	tablet
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CMS has developed a count service that computes the number of drugs per category and class offered by an EHB-compliant formulary. States may elect to use CMS’s drug count service to review plan formularies, if desired. CMS notes that formularies that include more than the minimum number of required drugs would not be considered to provide benefits in excess of EHB, because this scenario is similar to offering more generous coverage of the same benefit or a more robust provider network.

ii. Prescription Drug Exceptions Process

45 C.F.R. § 156.122(c) establishes that a health plan providing EHB must have procedures in place that allow an enrollee to request and access clinically appropriate drugs not covered by the health plan. The exceptions process outlined below is distinct from the exceptions process described in PHS Act section 2719.

CMS recognizes that most commercial health plans already have an exceptions process in place. Those plans may continue to use their current processes, so long as the existing processes allow an enrollee to request both an internal and an independent review of the exception request. Otherwise, CMS encourages issuers to utilize the following process:

- **Step 1 – Internal review:** The issuer would consider an exception request (made verbally or in writing within 60 calendar days following notification of the denial, by an enrollee, enrollee’s representative, or prescriber on behalf of an enrollee) and provide verbal notification of its determination as expeditiously as an enrollee’s health condition requires. CMS encourages issuers to provide a decision no later than 72 hours after the request is received. When an enrollee is suffering from a serious health condition, CMS encourages issuers to provide a decision no later than 24 hours after receiving the request. The issuer would provide its decision in writing no later than 48 hours after verbal notice has been given. The issuer would also advise the consumer about his or her ability to request an independent review.
- **Step 2 – Independent review:** If the issuer denies the exception request in Step 1, the enrollee (or enrollee’s representative or prescriber) may request, orally or in writing, a second review, within 60 calendar days of the internal review decision. The independent review entity (IRE) contracted by the issuer to review the exception request denial would make a decision within the same timeframes described in Step 1. The IRE’s decision would be provided in writing no later than 48 hours after verbal notice has been given.

Consistent with the Medicare Part D program, CMS suggests that a drug is clinically appropriate, and should be covered, if an oral or written supporting statement is submitted from a prescriber,

and establishes that the requested prescription drug is clinically appropriate to treat the enrollee's disease or medical condition, based on one or more of the following criteria:

- i. All of the covered drugs on any tier of the plan's covered drug list for treatment for the same condition would not be as effective for the enrollee as the requested drug, and/or would have adverse effects for the enrollee, or
- ii. The number of doses available under a dose restriction for the prescription drug:
 - a. Has been ineffective in the treatment of the enrollee's disease or medical condition or,
 - b. Based on both sound clinical evidence and medical and scientific evidence, the known relevant physical or mental characteristics of the enrollee, and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance; or
- iii. The prescription drug alternative(s) listed on the covered drug list or required to be used in accordance with step therapy requirements:
 - a. Has been ineffective in the treatment of the enrollee's disease or medical condition or, based on both sound clinical evidence and medical and scientific evidence, the known relevant physical or mental characteristics of the enrollee, and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance; or
 - b. Has caused or, based on sound clinical evidence and medical and scientific evidence, is likely to cause an adverse reaction or other harm to the enrollee.

As part of the required exceptions process, CMS strongly encourages plans offering EHB to allow the enrollee to have the medication in dispute during the entire review process and, if the exception request is granted, to allow the enrollee to have access to the non-covered drug in subsequent plan/policy years should enrollment continue without interruption.

Calculating the Actuarial Value of Health Plans that Are Not Compatible with the AV Calculator

Although the AV Calculator has been designed to accommodate the vast majority of plan designs, there is the possibility that the Calculator will not be able to accommodate a small percentage of plan designs. Under 45 C.F.R. § 156.135(b), issuers with plan designs that are not compatible with the AV Calculator will need to use an alternate method to calculate AV, as described below.

For example, the following types of plan designs would not be compatible with the AV Calculator:

Example 1: A plan with coinsurance rates that increase with out-of-pocket spending, such as a plan design with 10 percent coinsurance for the first \$1,000 in consumer spending after the deductible, 20 percent coinsurance for the next \$1,000 in consumer spending, and 40 percent coinsurance up to a \$6,400 out-of-pocket maximum. This plan design would not be compatible because the current AV Calculator can accommodate only a single coinsurance rate for each benefit.

Example 2: A plan with a multi-tiered provider or hospital network with substantial amounts of utilization expected in tiers other than the two lowest-priced tiers. This plan design would not be compatible because the current AV Calculator does not take into account utilization beyond the second network tier when computing AV.

Generally, a plan design that includes different cost sharing for services not included in the AV Calculator would be considered compatible with the AV Calculator. For example, advanced imaging is a single cost-sharing input in the Calculator; a plan design would not be considered incompatible because it assigns different copayment amounts to different types of imaging (e.g., MRI versus CT). Similarly, because the AV Calculator does not consider quantitative or qualitative limits for any benefit, the application of limits to a particular benefit would generally not necessitate one of the alternative methods for AV calculation.

To account for plan designs that are incompatible and ensure that requiring the use of the AV Calculator allows for plan innovation, 45 C.F.R. § 156.135(b) provides two alternative methods of calculating AV for plans that cannot meaningfully fit within the parameters of the AV Calculator. Issuers of such plans must:

- Make adjustments to certain key plan design features to input a modified plan design that fits into the parameters of the AV Calculator, and have an actuary certify that the plan design was appropriately fit into the parameters of the AV Calculator; or
- Use the AV Calculator to determine the AV for plan provisions that do fit within its parameters, and then have an actuary calculate appropriate adjustments to the Calculator-generated AV to account for remaining plan features. For example, a plan with reference pricing for prescription drugs could use the Calculator to determine the AV for the medical benefits in its plan and then make adjustments to reflect its prescription drug benefits.

Both of the AV calculation methods for evaluating incompatible plans designs must be certified by a member of the American Academy of Actuaries, in accordance with generally accepted actuarial principles and methodologies. If an issuer uses either of the two alternate methods for calculating AV just described, the issuer must submit an actuarial certification.

ii. Family Plan Design

The AV Calculator standard population and claims data were developed using claims data that did not include any family cost-sharing information. Issuers of plans with deductibles and/or out of pocket maximum costs that accumulate at the family rather than the individual level have several options depending on the specifics of the family plan.

In the case of a plan with a deductible and/or out-of-pocket maximum that accumulates first at the individual level and in addition at the family level, the plan enters the individual deductible and out-of-pocket maximum into the AV Calculator to determine AV. If deductible and out-of-pocket maximum accrues only at the family level and not at the individual level, the issuer may either include the family deductible and out-of-pocket maximum into that actuarial value calculator or, if the issuer believes that the family plan cost-sharing features of the plan's cost-sharing features will make a material difference in the AV produced by the calculator, the issuer may use one of the §156.135(b) exceptions described above to calculate AV and include plan-specific data on how the family-specific cost sharing is adjusted.

Annual Limitations on Deductibles for Employer-sponsored Health Plans in the Small Group Market

Section 1302(c)(2) of the Affordable Care Act places limits on the deductibles for health plans offered in the small group market as part of the EHB package that must be offered by issuers in the individual and small group markets and qualified health plans. As provided in 45 C.F.R. § 156.130(b)(3), a health plan may exceed the annual deductible limit if it cannot reasonably reach a given level of coverage (i.e. metal level) without doing so. For example, if the only way that an issuer can offer a bronze plan and a \$2,000 deductible is by offering all other services at a 90 percent cost-sharing rate, the plan may exceed the deductible because this would be considered an 'unreasonable' plan design. The health plan could instead be offered at the bronze level of coverage with a \$3,000 deductible and a 40 percent cost-sharing rate, which is consistent with what is commonly offered in the small group market today. When designing a bronze level plan with a deductible that exceeds the maximum, an issuer should increase the deductible by the smallest amount that achieves a reasonable plan design. CMS recommends that states collect general compliance information through market-wide targeted audits or an alternative state-based enforcement of this provision.