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From: Center for Consumer Information and Insurance Oversight (CCIIO)

Centers for Medicare & Medicaid Services (CMS)

Title: DRAFT 2016 Letter to Issuers in the Federally-facilitated Marketplaces

The Centers for Medicare & Medicaid Services (CMS) is releasing this draft 2016 Letter to Issuers in the Federally-facilitated Marketplaces (Letter). This Letter provides issuers seeking to offer qualified health plans (QHPs), including stand-alone dental plans (SADPs), in the Federally-facilitated Marketplaces (FFMs) or the Federally-facilitated Small Business Health Options Programs (FF-SHOPs) with operational and technical guidance to help them successfully participate in those Marketplaces in 2016. Unless otherwise specified, references to the FFMs include the FF-SHOPs.

Throughout this Letter, CMS identifies the areas in which states performing plan management functions in the FFMs have flexibility to follow an approach different from that articulated in this guidance. CMS notes that the policies articulated in this Letter apply to the certification process for plan years beginning in 2016.¹

Previously published rules concerning market-wide and QHP certification standards, eligibility and enrollment procedures, and other Marketplace-related topics are set out in 45 C.F.R. Subtitle A, Subchapter B. Additional proposed requirements are included in a proposed rule titled, "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016" (2016 Payment Notice proposed rule), CMS-9944-P, published on November 26, 2014.²

CMS expects issuers to consult all applicable regulations, in conjunction with the final version of this Letter, to ensure full compliance with the requirements of the Affordable Care Act. Throughout the plan year, QHPs may be required to correct deficiencies identified in CMS's

¹ Plan years in the FF-SHOPs will not always align with calendar year 2016.

² Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016; 79 Federal Register 70674 (November 26, 2014).

post-certification activities, as a result of the investigation of consumer complaints or oversight by state regulators or by CMS, or as a result of an issuer's own industry-standard internal compliance and risk management program. QHP issuers in the FFMs may also be subject to other requirements for plan years beginning in 2016, as indicated in future rulemaking.

Unless otherwise indicated, regulatory references in this Letter are to Title 45 of the Code of Federal Regulations (C.F.R.).

Comments

CMS welcomes comments on this proposed guidance. To the extent that this guidance summarizes policies proposed through other rulemaking processes that have not yet been finalized, such as the rulemaking process for the 2016 Payment Notice proposed rule, stakeholders should comment on those underlying policies through the ongoing rulemaking processes, and not through the comment process for this Letter. Please send comments on other aspects of this Letter to FFEcomments@cms.hhs.gov by January 12, 2015. Comments will be most helpful if organized by subsections of this Letter.

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CHAPTER 1: CERTIFICATION PROCESS FOR QUALIFIED HEALTH PLANS

The Affordable Care Act and the applicable regulations establish that health plans must meet a number of standards in order to be certified or recertified as QHPs. Several of these are market-wide standards that apply to plans offered in the individual and small group markets inside as well as outside of the Marketplaces. The remaining standards are specific to QHPs seeking certification or recertification from the Marketplaces.

As in 2015, CMS expects to rely on states' reviews of policy forms and rate filings for market-wide standards as part of its QHP certification process, provided that such states review for compliance with standards that are consistent with federal laws and regulations and complete such reviews in a manner consistent with operational timelines.³ In addition to assuring compliance with ACA requirements, all QHP and SADP issuers must be licensed and in good standing to offer health insurance coverage in each state in which the issuer offers health insurance coverage, and in compliance with all applicable state laws that the state imposes as conditions of participation or certification as QHPs. CMS further interprets this requirement to mean that, in order to have plans certified as QHPs in the FFMs, in addition to receiving final approval from CMS for their QHP Application submissions, issuers must receive any applicable form and rate filing approval from the appropriate state regulatory authority. Issuers should follow state guidance regarding compliance with the processes, criteria, and timeline for reviews conducted by states. States must provide CMS with state recommendations for QHP certification by the final data lockdown date in order for CMS to consider the recommendations and certify, or deny certification to, QHPs, including SADPs. CMS will provide states with more detailed guidance regarding the process for submitting final plan approval recommendations to CMS as the final data lockdown date nears.

This Chapter provides an overview of the QHP certification process in the FFMs, both when a state is performing plan management functions and making QHP certification recommendations to CMS, as well as when CMS is performing plan management functions and certifying QHPs. The QHP certification process that will take place in calendar year 2015 for plans effective beginning in 2016 maintains many aspects of the QHP certification process that CMS carried out

³ 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 Marketplaces. Under sections 2723 and 2761 of the PHS Act and existing regulations, codified at 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 the 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. In direct enforcement states (currently, direct enforcement states are Alabama, Missouri, Oklahoma, Texas, and Wyoming), CMS enforces the market-wide provisions. Issuers in these states should work with CMS in instances in which it refers to the “state” in this guidance.

in calendar year 2014 for plans effective beginning in 2015, including close coordination and collaboration with states. CMS also proposes to incorporate some modified review standards as well as operational changes for the QHP certification process for plans effective beginning in 2016, as noted in this Letter.

Each section describes CMS's planned approach to evaluating QHPs against a certification standard when CMS is performing plan management functions for plan years beginning in 2016. States that are performing QHP certification reviews have flexibility in their application of QHP certification standards, provided that the state's application of each standard is consistent with CMS regulations and guidance. Issuers seeking QHP certification in states that are performing plan management functions should continue to refer to state direction in addition to this guidance.

Similar to the QHP certification process for plan years beginning in 2015, states that choose to conduct reviews of QHP Applications and provide QHP certification recommendations to CMS for plan years beginning in 2016 will evaluate health plans against QHP certification standards. CMS will review the state's recommendations or findings to confirm that they are consistent with federal regulatory standards and will communicate any concerns to the state. CMS is responsible for the final QHP certification decisions in each FFM, including FFMs in which CMS is not performing plan management functions.

In states not conducting reviews or making recommendations to CMS, CMS will continue to integrate state regulatory activities into its decision-making for QHP certification, provided that states make these determinations and provide information to CMS consistent with federal standards and FFM timelines. These principles underlie the discussion in this Letter about the QHP certification process.

Section 1. QHP Application and Certification Process

This section describes how CMS, as administrator of the FFMs, will conduct QHP certification when CMS is performing the review and certification of QHPs, including SADPs.

In accordance with 45 C.F.R. part 155 subpart K, CMS will review, and approve or deny, QHP Applications from issuers that are applying to offer QHPs in the FFMs. Table 1.1 presents a high-level overview of key dates in the QHP certification process. Each major component of the process is described in greater detail in the subsections that follow.

For certification of a plan as a QHP effective beginning in 2016, issuers must submit a complete QHP Application for all plans they intend to offer on an FFM. Plans previously certified as QHPs must be recertified each year that an issuer intends to continue to offer them on an FFM. CMS will review QHP Applications against all QHP certification standards for issuers that are currently offering QHPs in an FFM, as well as issuers applying for QHP certification in an FFM for the first time. CMS expects states performing plan management functions in an FFM to

review QHP Applications from all issuers applying for certification of a QHP for a plan year beginning in 2016.

CMS intends to provide more specific guidance regarding the QHP certification timeline noted below before the beginning of the application submission window. Issuers are expected to adhere to the QHP certification timeline. Issuers that fail to meet deadlines or do not follow the process outlined below may have their QHP Application denied.

Issuers of SADPs will follow the same QHP Application timeline as that of medical plans. Issuers that wish to have SADPs certified by CMS for sale off the FFMs must also follow the same application timeline and requirements, with the exception of agreement signing.

Table 1.1. Key Dates for QHP Certification in the FFMs

Note: All dates are subject to change. The given dates are dependent on whether the dates in the 2016 Payment Notice proposed rule are finalized.

Activity		Dates (Approximate)
QHP Application Submission and Review Process	Initial FFM QHP Application Submission Window ⁴	3/16/2015 – 4/15/2015
	FFM Review of QHP Application Submissions as of Initial Submission Deadline of April 15	4/16/2015 – 5/26/2015
	First Correction Notice Sent	5/27/2015 – 5/28/2015
	Deadline for Submission of Revised QHP Data for Re-review	6/9/2015
	FFM Review of Corrected QHP Application Submissions Received as of June 9	6/10/2015 – 7/14/2015
	Second Correction Notice Sent	7/15/2015 - 7/16/2015
	Final Deadline for Submission of QHP Data; Final Deadline for State Plan Approval; Deadline	7/24/2015

⁴ URRT and Form Filing submissions to CMS in states in which CMS is either the Effective Rate Reviewer or direct enforcer of federal law follow the same Initial Submission Window and Deadline as the QHP Initial FFM QHP Application Submission Window.

Activity		Dates (Approximate)
	for All Risk Pools with QHPs to be in “Final” Status in the URR System; Data Locked Down	
	Final FFM Review of Corrected QHP Application Submissions Received as of July 24	7/27/2015 - 8/14/2015
QHP Agreement/Final Certification	Certification Notices and QHP Agreements Sent to Issuers, Agreements Signed by Issuers, Agreements Countersigned by CMS, QHP Data Finalized	8/17/2015 – 9/15/2015 ⁵
Open Enrollment		10/1/2015

i. Registration and QHP Application

To offer QHPs in the FFMs for plan years beginning in 2016 in states where CMS is performing both the primary review and certification of QHPs, health insurance issuers will complete QHP Applications electronically through the Health Insurance Oversight System (HIOS). Before submitting an application, issuers must gain access to HIOS and request user roles (such as QHP Issuer Submitter and QHP Issuer Validator) and obtain HIOS user IDs.

CMS expects that between March 16, 2015 and April 15, 2015 issuers will access the QHP Application in HIOS to submit all information necessary for certification of health plans and SADPs as QHPs. The QHP Application will collect both issuer-level information and plan-level benefit and rate data, 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 provide requested supporting documentation. Based on the requirement set forth in 45 C.F.R. 156.340 that QHP issuers maintain responsibility for the compliance of their delegated and downstream entities, these attestations will also reflect that vendors and contractors of the issuer will adhere to applicable requirements.

Issuers seeking to offer QHPs must also submit the Unified Rate Review Template (URRT) to CMS via HIOS according to the same timeline. In the proposed 2016 Payment Notice, CMS proposes to require issuers not seeking to offer QHPs to submit the URRT on the same timeline. Consistent with the approach for plan years beginning in 2015, issuers do not need to submit URRTs for SADPs.

⁵ All risk pools with no QHPs must be in “final” status in the URR system by September 15, 2015.

ii. Issuer Data Collection and Coordination with States

CMS expects states to review potential QHPs for compliance with all requirements under state law, as well as market-wide standards established by the Affordable Care Act. Specifically, CMS expects states to review potential QHPs for compliance with essential health benefits (EHB) and actuarial value (AV) standards, among others.⁶ State regulators may request access to QHP data templates to facilitate review of potential QHPs.

Issuers in direct enforcement states (Alabama, Missouri, Oklahoma, Texas, and Wyoming) will also be required to comply with any CMS requirements relating to form filing, in addition to any applicable state requirements. Issuers may contact the CMS Form Filing Team at formfiling@cms.hhs.gov for details. Additionally, issuers in direct enforcement states will be required to submit rate filings for federal rate compliance review. Issuers may contact the CMS Rate Review team at ratereview@cms.hhs.gov for details.

CMS expects that states will establish the timeline, communication process, and resubmission window for any reviews conducted under state authority. As noted previously, issuers should comply with any state-specific guidelines for review and resubmission related to state-reviewed standards. CMS notes that issuers may be required to submit data to state regulators in addition to that required for QHP certification through the FFMs, 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. In addition, CMS will work with all state regulators near the end of the QHP certification cycle to confirm that all potential QHPs meet applicable state and federal standards, and are approved for sale in the FFMs.

iii. FFM Review of QHP Applications

Issuers applying for QHP certification in the FFMs will submit complete and accurate QHP Applications through HIOS by April 15, 2015. Plans for which QHP Applications are received after this date and plans for which significant changes to the initial submission are submitted after this date without prior approval of CMS may not be considered for certification. CMS will not review for certification QHPs that are submitted for offering only outside of the FFMs or that at any point in the application cycle change to being offered only outside of the FFMs. CMS reviews all prospective SADPs, whether offered on or off an FFM.

⁶ CMS notes that, because SADP issuers are only required under federal law to adhere to pediatric dental EHB requirements for SADPs offered through a Marketplace, CMS does not have the same expectation of state review for SADPs offered through the Marketplace if such standards are otherwise not applicable under state law. Accordingly, CMS plans to review SADPs for compliance with applicable Affordable Care Act standards.

CMS expects to review FFM QHP Applications in two rounds: one between April 16 and May 26, 2015 and a second between June 10 and July 14, 2015. Following each review period, CMS will send applicants notices summarizing any need for corrections identified during CMS’s review. Issuers will be able to upload revised QHP data templates and make other necessary changes to QHP Applications in response to CMS’s feedback until July 24, 2015. Issuers must submit all final QHP data by July 24, 2015.

Issuers may withdraw plans prior to July 24, 2015 by removing the plan from their QHP Application and submitting a plan withdrawal notification form. Issuers will be given a final opportunity to withdraw plans during the agreement signing process.

After July 24, 2015, CMS will conduct a final round of review and make final certification decisions. CMS will notify issuers of its certification decisions between August 17 and September 15, 2015. Issuers will not have an opportunity to make any further corrections to their QHP Application data after receiving CMS certification notices and prior to agreement signing.

iv. Data Changes

Issuers applying for QHP certification will be able to view plan data in the Plan Preview environment in order to identify and correct data submission errors before the QHP Application data submission deadline.

During the certification process for plan years beginning in 2016, CMS will allow issuers to make changes to their QHP application based on the guidelines discussed below. These changes are in addition to any corrections CMS has identified during its review of QHP Applications. Table 1.2 presents a high level overview of key dates during the FFMs’ QHP data change process. Each phase of the process is described in greater detail in the subsections that follow.

Table 1.2. Key Dates for QHP Data Changes in the FFMs

Note: All dates are subject to change.

Activity	Allowed Changes	Dates (Approximate)
Initial Application Submission	Issuers will submit QHP applications including recertification for 2015 plans and new 2016 plans. All changes allowed.	3/16/2015 – 4/15/2015
QHP Review and Modification	No new plans may be submitted. Petition to CMS required for changes to	4/16/2015 – 7/24/2015

	<p>service area, plan type (e.g. HMO, PPO), and for other significant changes. Petitions must be submitted by 7/10/2015.</p> <p>All other changes allowed with state authorization.</p>	
After Final Data Submission	<p>No data changes will be allowed prior to Certification.</p> <p>CMS may offer limited data correction windows after agreement signing. For a data correction window, issuers must have approval from CMS and their state for all changes. Allowed changes are only changes defined by CMS or necessary to correct data display errors or align QHPs with products and plans as approved by the state.</p>	7/25/2015 – onward

Initial Application Submission

As described in Section 1 of Chapter 1, issuers will submit their initial QHP Applications between March 16 and April 15, 2015, including applications for SADPs to be offered on and off the FFM⁷. Issuers that intend to include new QHPs must submit their 2016 QHP Application data during this submission window. Issuers that are requesting recertification of 2015 QHPs must follow the guidelines in Chapter 1, Section 3 for recertification for 2016.

QHP Review and Modification

After the close of the initial QHP Application submission window, issuers will be able to upload revised data templates on an as-needed basis until the final data submission deadline of July 24, 2015. CMS reviews will occur at pre-defined times during this window and will be based on the QHP data in the system on certain dates as listed in Table 1.1. Issuers will be able to upload revised QHP data templates and make other necessary changes to QHP Applications in response to CMS feedback until the final data submission deadline. Issuers will also be able to make

⁷ URRT and Form Filing submissions to CMS in states in which CMS is either the Effective Rate Reviewer or direct enforcer of federal law follow the same Initial Submission Window and Deadline as the QHP Initial FFM QHP Application Submission Window.

changes based on state feedback, and make other minor corrections to their applications on the same timeline.

Issuers cannot add new plans during this time or change the initial offering of an off-FFM plan to offer the plan both on and off an FFM.

CMS intends to implement a petition process to receive and review requests for changes that are particularly significant during this time. An example of a significant change is a change to the issuer's service area or to a plan type (e.g. HMP, PPO). These must be reviewed and approved by CMS and the state prior to submission of an update to the QHP Application. Requests must be submitted at least two weeks prior to the final data submission deadline, to allow CMS sufficient time for review. Issuers will be required to provide a justification for any requested significant changes, as well as submit a signed data change request form and evidence of state approval. Issuers must make all significant changes to QHP applications prior to the final data submission deadline. During past years' certification cycles, the vast majority of requests from issuers to make significant changes after the data submission deadline were related to data inaccuracies and/or the incompleteness of an application. Because an issuer's failure to meet this required deadline calls into question an issuer's ability to submit a valid QHP application, the issuer may be at risk for non-certification or compliance action. CMS intends to release further instructions on this process and retains the ability to determine which changes are significant and therefore subject to this process.

All other changes must be authorized by the issuer's state, or for QHP or Dual Issuers (issuers that offer both QHPs and SADPs, but not issuers that offer embedded dental in their QHPs) in direct enforcement states, CMS Form Filing within CCIIO must approve the changes. The issuer is not required to submit evidence of state approval to CMS, but should confirm with its state that all changes made meet any state requirements for changes to QHP data.

Data changes to plans that are being recertified must follow the uniform modification guidelines, as outlined in Chapter 1, section 3, "Recertification for 2016."

Post Final Data Submission

On July 25, 2015, HIOS will be closed and no additional QHP data changes will be allowed until CMS completes its certification decisions and issuers sign the QHP Privacy and Security Agreement and Senior Official Acknowledgement. After this occurs, CMS may offer a limited data correction window, during which issuers will not be allowed to make further changes to QHP data unless changes are pre-approved by CMS and the state. Issuers may request to make changes necessary to correct data display errors or align QHPs with products and plans as approved by the state, or from a limited list of changes that do not impact certification, such as URLs and plan marketing names. During a data correction window, issuers will be required to provide a justification for any requested changes and submit a signed data change request form and evidence of state approval. Issuers are responsible for ensuring that requested changes are in

compliance with federal QHP certification standards as laid out in the Affordable Care Act, federal regulations, and all other guidelines discussed in this letter. Discrepancies between the issuer's QHP filings and approved state filings may result in compliance action. Additional requirements may apply, and CMS intends to release further instructions on this process.

v. QHP/SADP Certification and Privacy and Security Agreement and Senior Officer Acknowledgements

As with the certification process for plan years beginning in 2015, issuers intending to offer QHPs or SADPs in the FFMs, including issuers in states performing plan management functions, will be required to sign and submit to CMS a QHP Privacy and Security Agreement and a Senior Officer Acknowledgement. Issuers will submit these signed agreements along with a final list of QHPs and SADPs they intend to offer on the FFMs. Among other things, the QHP Privacy and Security Agreement will include provisions for safeguarding the privacy of plan applicant and participant data in the FFMs and standards for issuer testing prior to the beginning of open enrollment. An officer of the legal entity who has legal authority to contractually bind the issuer must sign the agreement. The Senior Officer Acknowledgment includes provisions confirming that a senior officer of the issuer has knowledge of the content of the issuer's plans, as well as the content of the completed attestations and this Letter.

CMS will review these submissions and, if they are accurate and complete, sign and return the QHP Privacy and Security Agreement to issuers. The receipt of a signed QHP Privacy and Security Agreement completes the certification process for the following plan year. CMS will not sign the Senior Officer Acknowledgement.

The documents will apply to all of the QHPs offered by a single issuer in the FFMs at the HIOS Issuer ID level or designee company.

Of note, issuers should ensure that the legal entity information listed in HIOS under the Issuer General Information section is identical to the legal entity information that will be used when executing the documents.

vi. Sale of Ancillary Products on the FFMs

Ancillary insurance products and health plans that are not QHPs (e.g., stand-alone vision plans, disability, or life insurance products) will not be offered on the FFMs. The FFMs will only offer QHPs and SADPs.

Section 2. QHP Certification Process in a State Performing Plan Management Functions in the FFM

This section describes how states performing plan management functions in the FFM will conduct QHP Application reviews. Issuers applying in states where CMS is performing all QHP Application review and QHP certification should refer to Section 1 of Chapter 1.

In FFM where the state is performing plan management functions, issuers will work directly with the state to submit all QHP issuer application data in accordance with state guidance.⁸ States performing review of QHP Applications will generally utilize the System for Electronic Rate and Form Filing (SERFF) to collect QHP Applications from issuers. The state will review QHP Applications for compliance with the standards described in this guidance and will provide a certification recommendation for each proposed plan to CMS. CMS will review and confirm the state’s QHP certification recommendations, make final QHP certification decisions, and load certified QHP plans on the Marketplace website. CMS will work closely with states that are performing plan management functions to coordinate this process.

As indicated in Table 1.3, the QHP certification process in states where the state is performing plan management functions will align with the process for issuers for which CMS is performing the review. Each phase of the process is described in greater detail in the subsections that follow. CMS also intends to provide more specific information regarding the QHP certification timeline as the application submission period for plan years beginning in 2016 approaches.

Table 1.3 Key Dates for QHP Certification in FFM States Where the State is Performing Plan Management Functions

Note: All dates are subject to change.

Activity		Dates (Approximate)
QHP Application Submission and Review Process	Issuers Submit Plan Data to States and States Review	Varied ⁹
	First SERFF Data Transfer Deadline for States	4/15/2015

⁸ CMS will work with states performing plan management functions in the FFM to ensure that such guidance is consistent with federal regulatory standards and operational timelines.

⁹ Date varies as determined by each respective state application submission deadline.

Activity		Dates (Approximate)
QHP Application Submission and Review Process	FFMs Review Plan Data	4/16/2015 – 5/26/2015
	FFMs Notify States of any Needed Corrections to QHP Data	5/27/2015 – 5/28/2015
	Issuers Resubmit Plan Data into SERFF	Varied ¹⁰
	Second SERFF Data Transfer Deadline for States	6/9/2015
	FFMs Conduct Re-review of Plan Data	6/10/2015 – 7/14/2015
	FFMs Notify States of any Needed Corrections to QHP Data	7/15/2015 - 7/16/2015
	Issuers Resubmit Plan Data into SERFF	Varied ¹¹
	Final Deadline for Submission of QHP Data and Certification Recommendations; Deadline for All Risk Pools with QHPs to Be in “Final” Status in the URR System; Data Locked Down	7/24/2015
	FFMs Conduct Final Review of QHP Application Data	7/27/2015 - 8/14/2015
QHP Agreement/Final Certification	Certification Notices and QHP Agreements Sent to Issuers, Agreements Signed by Issuers, Agreements Countersigned by CCIIO, QHP Data Finalized	8/17/2015 – 9/15/2015
Open Enrollment		10/1/2015

¹⁰ Date varies as determined by each respective state application submission deadline.

¹¹ Date varies as determined by each respective state application submission deadline.

i. QHP Application and State Review Process

An issuer's HIOS issuer ID will be used to link the state and federal records for a given issuer or QHP. Therefore, like an issuer applying in HIOS, an issuer applying to a state via SERFF must access HIOS and obtain the necessary identification numbers and user roles.

Issuers in states performing plan management functions in the FFMs are to submit QHP Applications, typically in SERFF, according to the timeline set by each state. Each state will define the relevant submission window as well as dates and processes for corrections and resubmissions. Issuers seeking to offer QHPs must submit the URRT to the state, and to CMS via HIOS, on the same timeline as the submission of the QHP Application. In the 2016 Payment Notice proposed rule, CMS proposes to require issuers not seeking to offer QHPs to submit the URRT on the same timeline. Issuers that are applying for QHP certification in states performing plan management functions in the FFMs should not submit QHP Applications into HIOS.

CMS will provide three defined SERFF data transfer windows in order to better coordinate the flow of QHP data from states performing plan management functions in the FFMs. The first SERFF data transfer will take place by April 15, 2015 and will constitute an initial transfer by each state. This transfer should include all plans submitted to the state for certification including SADPs for off-Marketplace sale. CMS will treat all data transferred by April 15, 2015 as draft data. QHP data in this transfer do not need to be final, and the plans included in the transfer do not need to be in final, approved status. CMS will review the plan data in the initial transfer, and will notify states of any needed corrections. States will work with issuers to revise their submissions according to CMS and state feedback.

The second SERFF transfer deadline is June 9, 2015. CMS will review the data transferred by June 9, 2015 and will notify states of any needed corrections. States will again be able to work with issuers to revise their submissions according to CMS and state feedback.

All final plan data must be transferred from SERFF to HIOS by July 24, 2015 and CMS will use the data transferred by July 24, 2015 to make final QHP certification decisions based on state recommendations.

ii. Data Changes

For issuers in states performing plan management functions in the FFMs, Plan Preview capability will begin after the state transfers QHP data from SERFF. Issuers in these states will be able to review plan data and make any necessary corrections in SERFF according to the timeline established by the state. Changes will be reflected once the state retransfers plan data from SERFF to HIOS.

On July 25, 2015 SERFF data submissions will be closed, and no additional changes will be allowed until after CMS makes certification decisions and issuers sign the QHP Agreement.

Issuers should work with their state to determine state specific data change deadlines prior to July 25, 2015. After Agreement signing, CMS may offer the opportunity for a limited data correction window.

Any changes to QHP data transferred to HIOS must follow the data changes process described in Section 1, subsection iv of Chapter 1.

Section 3. Recertification for 2016

i. Policy and Process for Recertification

For plan years beginning in 2016, CMS's process for recertifying a QHP or SADP that was certified for the 2015 benefit year will largely mirror the 2015 process for certification of a plan. Issuers seeking recertification will submit all information required under the 2016 QHP Application for plans that were QHPs or SADPs in 2015. CMS anticipates moving to a more streamlined recertification process for future plan years.

To be eligible for recertification for plan years beginning in 2016, a QHP or SADP certified by an FFM must be the same "plan," as defined in 45 C.F.R. 144.103, as the plan that was certified for plan years beginning in 2015. CMS anticipates using the amended definition of "plan" from §144.103 of the 2016 Payment Notice proposed rule, if it is finalized as proposed. The same definition of "plan" also will apply to reenrollment of current enrollees into the same plan, pursuant to §155.335(j). CMS intends to use this standard (45 C.F.R. 144.104) to determine whether an SADP is eligible for recertification. A QHP or SADP recertified for plan years beginning in 2016 must use the same HIOS plan identification numbers that it used for its certification for plan years beginning in 2015.

If an issuer chooses to not recertify a plan in the Marketplace, it is subject to the standards outlined in 45 C.F.R. 156.290.

ii. Plan ID Crosswalk

Last year, CMS developed and released a Plan ID Crosswalk Template for issuers to complete and submit to CMS. For the FFMs, this template cross-walked 2014 QHP plan ID and service area combinations (e.g., Plan ID and County combinations) to a 2015 QHP plan ID. This data will facilitate enrollment transactions from CMS to the issuer in mid-December 2014 for those individual market enrollees who had not actively selected a different QHP during open enrollment at that time.

CMS expects to implement a similar approach for automatic re-enrollment from 2015 to 2016 QHPs in the FFMs. In addition, CMS expects that the FF-SHOPs will support automatic re-enrollment for plan years beginning in 2016. As a result, issuers that offered plans on the

individual market FFMs as well as the FF-SHOPs in plan years beginning in 2015, including QHPs and SADPs, will submit Plan ID Crosswalk data.

To note, SADPs, as excepted benefits, are not subject to the guaranteed renewability standards specified at 45 C.F.R. 147.106. However, as CMS has indicated in previous guidance, it again aims to apply the hierarchy set forth at 45 C.F.R. 155.335(j) and the business rules established for the 2016 Plan ID Crosswalk Template to SADPs in order to support automatic re-enrollment for re-enrollment plan years beginning in 2016.

For a submission process, CMS expects that issuers will submit the template to a CMS email address, which is the same method that was used for plan years beginning in 2015.

CMS will conduct an overall data integrity review of submitted Plan ID Crosswalk data. This will include, but not be limited to, an evaluation for compliance with 45 C.F.R. 155.335(j) and with the final rule on Annual Eligibility Redeterminations for Marketplace Participation and Insurance Affordability Programs.¹² This will also include a review for consistency with submitted Service Area and Plans and Benefits Template data for both 2015 and 2016.

Section 4. OPM Certification of Multi-State Plan (MSP) Options

This section provides additional guidance for health insurance issuers seeking to offer Multi-State Plan (MSP) options in FFMs and State-based Marketplaces (SBMs).

The U.S. Office of Personnel Management (OPM) is responsible for implementing the MSP Program as required under section 1334 of the Affordable Care Act. In accordance with section 1334(d) of the Affordable Care Act, MSP options offered by MSP issuers under contract with OPM are deemed to be certified by a Marketplace.

OPM anticipates that the process for MSP issuers to participate in a Marketplace for the 2016 benefit year will largely mirror that used for 2015, subject to finalization of a proposed rule for the program published on November 24, 2014.¹³ Issuers seeking to offer MSP coverage must apply to participate via OPM's online application portal. OPM will evaluate issuer applications and determine which issuers are qualified to become MSP issuers. OPM works closely with

¹² Patient Protection and Affordable Care Act; Annual Eligibility Redeterminations for Exchange Participation and Insurance Affordability Programs; Final Rule, 79 Federal Register 52994; September 5, 2014; Codified at 45 C.F.R. parts 146, 147, 148, 155, and 156.

¹³ Patient Protection and Affordable Care Act; Establishment of the Multi-State Plan Program for the Affordable Insurance Exchanges; Propose rule; 79 FR 69802; November 24, 2014.

states in reviewing benefits and rates to achieve its goals of offering more choice for consumers and maintaining a level playing field for all issuers within a state.

OPM's contract with each MSP issuer identifies each MSP option that the issuer will offer and in what state it will be offered. Each MSP option so identified is deemed to be certified by OPM to be offered through the Marketplace(s) operating in those states. In addition, the MSP Program contract sets forth performance requirements for MSP issuers.

For more information on requirements for MSP issuers, issuers should visit <http://www.opm.gov/healthcare-insurance/multi-state-plan-program/issuer/>. OPM will post specific instructions regarding the 2016 application timeline and process when available.

CHAPTER 2: QUALIFIED HEALTH PLAN AND STAND-ALONE DENTAL PLAN CERTIFICATION STANDARDS

Section 1. Licensure and Good Standing

This section describes issuer requirements for licensure and good standing and how CMS will review prospective QHPs and SADPs for compliance with these standards in the FFMs. States performing plan management functions may use a similar approach. This approach is largely the same approach used in 2015. However, the 2015 Letter to Issuers described a State Certification Form. CMS does not intend to use such a form for 2016 certification.

The following is a summary of key points:

- Each QHP issuer must be licensed and in good standing in each state in which it applies to offer QHPs for the applicable market, product type, and service area (see 45 C.F.R. 156.200(b)(4)).
- CMS interprets the good standing requirement to mean that the issuer is licensed to offer health insurance or health plans in the state, of the type the issuer is proposing to offer as QHPs, is in compliance with all applicable state solvency requirements, and is in compliance with all other applicable state laws and regulations.
- Issuers must provide one of the following supporting documents as part of the QHP Application: state license, certificate of authority, certificate of compliance, or an equivalent form or document for the product(s) in the service area(s) in which the issuer intends to offer a QHP.
- Issuers applying for QHP certification must be able to demonstrate state licensure by no later than 90 days prior to open enrollment.

Section 2. Service Area

This section describes issuer requirements for service area and how CMS will conduct its review for compliance with this standard in the FFMs. States performing plan management functions may use a similar approach. This approach is the same approach used in 2015 and applies to both QHPs and SADPs.

The Marketplace must ensure that each service area of a QHP covers a minimum geographic area that is at least the entire geographic area of a county, or a group of counties defined by the Marketplace, unless the Marketplace determines that serving a smaller geographic area is necessary, nondiscriminatory, and in the best interest of the qualified individuals and employers (see 45 C.F.R. 155.1055(a)). The Marketplace must also ensure that the service area of a QHP has been established without regard to racial, ethnic, language, or health status-related factors as specified under section 2705(a) of the Public Health Service (PHS) Act, or other factors that exclude specific high utilizing, high cost or medically-underserved populations (see 45 C.F.R. 155.1055(b)). CMS considers the service area of a plan to be the county or set of counties (or partial counties) that is covered by that particular plan. CMS will review requests for service areas that serve a geographic area smaller than a county (i.e., a partial county request) to ensure that each service area meets the above regulatory standards.

Any change to the list of counties associated with a particular plan is considered a change in the service area, even if the issuer offers other plans or products in the counties (or partial counties) in question.

QHP issuers will not be allowed to change their plans' service area after their initial data submission except via petition to CMS. Petitions for service area changes must follow a CMS-prescribed format that will be detailed in future guidance and will only be allowed with state approval. Changes to service areas will only be approved under very limited circumstances. CMS will not allow changes to service area after the final data submission date. For additional information on the data change process, please see Chapter 1, Section IV.

Section 3. Network Adequacy

This section includes information on network adequacy evaluation and network provider directory requirements. This section applies to QHPs and SADPs.

i. Network Adequacy Standard

This section describes how CMS will conduct its network adequacy review during 2016 QHP certification and recertification. States performing plan management functions may use a similar approach.

Pursuant to 45 C.F.R. 156.230(a)(2), an issuer of a QHP that uses a provider network must “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 to enrollees without unreasonable delay.” All issuers applying for QHP certification will need to attest that they meet this standard as part of the certification/recertification process.

As was done during the 2015 certification process, for 2016 certification CMS will assess provider networks using a “reasonable access” standard in order to identify networks that fail to provide access without unreasonable delay, consistent with requirements specified at 45 C.F.R. 156.230(a)(2). In order to determine whether an issuer meets the “reasonable access” standard, each issuer will submit detailed network provider data as part of its QHP certification application, including information on its physicians, facilities, and pharmacies as part of the certification process. CMS will analyze each issuer's network data and will focus most closely on those areas which have historically raised network adequacy concerns. CMS expects that these areas will include the following:

- Hospital systems,
- Mental health providers,
- Oncology providers,
- Primary care providers, and
- Dental providers, if applicable.

If CMS determines that an issuer’s network may be inadequate under the reasonable access review standard, CMS will notify the issuer of the identified problem area(s) during the certification review process and will request that the issuer address the concern by adding providers to its network or submitting a justification explaining how it will provide reasonable access to enrollees in the area(s) identified. CMS will use the issuer’s updated provider data, and any written justifications submitted as part of the certification process, in assessing whether the issuer has met the regulatory requirement prior to making the certification or recertification determination. CMS will share information about its analysis and coordinate with states that are conducting network adequacy reviews. CMS intends to provide additional technical detail regarding the collection method for the network data, and instructions explaining what should be included in any justification, as part of the 2016 certification/recertification instructions. CMS also reminds issuers that they must meet network adequacy standards throughout the year, as providers enter and leave the network, and not just at certification. CMS will continue to monitor network adequacy, for example, via complaint tracking, to determine whether the QHP’s network(s) continues to meet the current network adequacy standards.

CMS also intends to use information learned during the QHP certification process to assist in its articulation of future network adequacy standards in future rulemaking. Additionally, the National Association of Insurance Commissioners has formed a workgroup that is considering

revisions to its *Managed Care Network Adequacy Model Act*. CMS intends to evaluate the results of this workgroup for future rulemaking.

ii. Provider Directory Links

The content of this section applies to all QHP issuers in the FFMs, including in states performing plan management functions in the FFM.

Pursuant to the 45 C.F.R. 156.230(b), CMS, as administrator of the FFMs, will require QHPs to make their provider directories available to the FFMs for publication online by providing the URL link to their network directory. As noted in the 2016 Payment Notice proposed rule, CMS intends to strengthen the provider directory requirement. Specifically, CMS proposed that a QHP issuer must publish a current, accurate, and complete provider directory, including information regarding which providers are accepting new patients, in a manner that is easily accessible to plan enrollees, prospective enrollees, the state, the FFM, HHS, and OPM. As part of this requirement, CMS proposed that a provider directory will be considered current if it is updated at least monthly and easily accessible when the general public is able to view all of the current providers for a plan on the plan's public website through a clearly identifiable link or tab without having to create or access an account or enter a policy number. The general public should be able to easily discern which providers participate in which plan(s) and provider network(s). Further, if the health plan issuer maintains multiple provider networks, the plan(s) and provider network(s) associated with each provider should be clearly identified on the website. CMS also proposed requiring issuers to make this information publicly available on their websites in a machine-readable file and format specified by HHS, to allow the creation of user-friendly aggregated information sources, and is considering whether the provider information should be submitted to HHS through an HHS-designated standardized template. CMS proposed these requirements to enhance the transparency of QHP provider directories and to help consumers make more informed decisions about their health care coverage.

Section 4. Essential Community Providers

This section describes how CMS plans to conduct reviews of the essential community provider (ECP) standard for QHP and SADP certification and recertification in 2016. States performing plan management functions in the FFMs may use a similar approach.

ECPs include providers that serve predominantly low-income and medically underserved individuals, and specifically include providers described in section 340B of the PHS Act and section 1927(c)(1)(D)(i)(IV) of the Social Security Act. At 45 C.F.R. 156.235, CMS established requirements for inclusion of ECPs in QHP provider networks and provided an alternate standard for issuers that provide a majority of covered services through physicians employed by the issuer or a single contracted medical group. Indian health providers are included among other ECPs, as reflected in table 2.1.

i. Evaluation of Network Adequacy with respect to all ECPs

Because the number and types of ECPs available vary significantly by location, and consistent with the approach in prior years, CMS intends to evaluate QHP Applications for sufficient inclusion of ECPs for plan years beginning in 2016 against the ECP inclusion standard described below.

General ECP Standard

Similar to 2015, for plan years beginning in 2016, CMS will utilize a general ECP enforcement standard whereby it will consider the issuer to have satisfied the regulatory standard if an application demonstrates satisfaction of the following criteria:

- Contracts with at least 30 percent of available ECPs in each plan's service area to participate in the plan's provider network;
- Offers contracts in good faith to all available Indian health providers in the service area, to include the Indian Health Service, Indian Tribes, Tribal organizations, and urban Indian organizations, applying the special terms and conditions necessitated by federal law and regulations as referenced in the recommended model QHP Addendum¹⁴ for Indian health providers developed by CMS; and
- Offers contracts in good faith to 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 and provides medical or dental services that are covered by the issuer plan type.

To be offered in good faith, a contract should offer terms that a willing, similarly-situated, non-ECP provider would accept or has accepted. CMS will expect issuers to be able to provide verification of such offers if CMS chooses to review the offers for compliance with the policy.

As in previous years, 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 application materials with detailed instructions to support issuers in completing the template.

To assist issuers in identifying these providers, CMS has published a non-exhaustive list of available ECPs based on data maintained by CMS and other federal agencies, which issuers may use to assess their satisfaction of the ECP standard. This non-exhaustive list is updated annually near the beginning of the calendar year and is available at:

<http://cciio.cms.gov/programs/exchanges/qhp.html>.

¹⁴ The model QHP Addendum for Indian health providers is available at <http://www.cms.gov/cciio/programs-and-initiatives/health-insurance-marketplaces/qhp.html>.

Issuers will be permitted to write in ECPs not on the HHS non-exhaustive ECP list for consideration as part of CMS’s certification review, conditioned on the issuer satisfying the ECP write-in criteria provided below. Examples of allowable write-ins include any providers that are currently eligible to participate in the 340B program but that are not included on the HHS non-exhaustive ECP list, or not-for-profit or state-owned providers that would be entities described in section 340B, 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. Other providers that provide health care to populations residing in low-income zip codes or Health Professional Shortage Areas (HPSAs) could also be considered ECPs, on the condition that they do not limit their practice on the basis of a particular source of coverage (i.e., Marketplace plan, Medicare, Medicaid, etc.). CMS may conduct targeted audits of issuers that satisfy the ECP standard by virtue of writing in a significant number of their ECPs.

To write in a provider not on the HHS non-exhaustive ECP list, an issuer must include the following information:

- The provider’s zip code reflecting provider location within a low-income zip code or HPSA included on the “Low-Income and Health Professional Shortage Area Zip Code Listing”;¹⁵
- The provider’s street address (P.O. Box not sufficient, and only one ECP will be counted per address); and
- The National Provider Identifier (NPI) number, if the provider has an NPI number.

CMS will determine issuer satisfaction of the 30 percent ECP standard using the following calculation methodology:

- The denominator of available ECPs consists of any ECPs on the non-exhaustive HHS list of ECPs that are located within the plan’s service area and any allowable ECP write-ins that are located within the plan’s service area that the issuer has chosen to list on its template.
- The numerator of the issuer’s contracted ECPs consists of any ECPs that the issuer has listed from the non-exhaustive HHS list of ECPs that are located within the plan’s service area and any allowable ECP write-ins that are located within the plan’s service area that the issuer has chosen to list on its template.

¹⁵ “Low-Income and Health Professional Shortage Area (HPSA) Zip Code Listing,” available at: <http://www.cms.gov/ccio/programs-and-initiatives/health-insurance-marketplaces/qhp.html>

- Applicable to both the numerator and denominator, multiple providers at a single street location will count as one ECP toward the available ECPs in the plan’s service area and toward the issuer’s satisfaction of the proposed ECP participation standard to ensure a sufficient number and geographic distribution of ECPs as required under 45 C.F.R. 156.235(a).

If an issuer’s application does not satisfy the 30 percent ECP standard as well as the requirement to offer contracts in good faith to all available Indian health providers in the service area, and at least one ECP in each ECP category in each county in the service area, as described above, the issuer will be required to include as part of its application a satisfactory narrative justification describing how the issuer’s provider network(s), as presently constituted, provides an adequate level of service for low-income and medically underserved individuals and how the issuer plans to increase ECP participation in the issuer’s provider network(s) in future years. Issuers that submit a narrative justification will do so as part of the issuer application for QHP certification.

At a minimum, such narrative justification would include the following:

- The number of contracts offered to ECPs for plan years beginning in 2016;
- The number of additional contracts an issuer expects to offer for plan years beginning in 2016 and the timeframe of those planned negotiations;
- The names of the ECP hospitals, FQHCs, Indian health providers, Ryan White providers, family planning providers, and providers in the other ECP categories listed in Table 2.1 to which the issuer has offered contracts in good faith, but an agreement with the providers has not yet been reached; and
- Contingency plans for how the issuer’s provider network, as currently designed, will provide adequate care to enrollees who might otherwise be cared for by relevant ECPs. For example, if available Hemophilia Treatment Centers, Ryan White HIV/AIDS Program providers, or Indian health providers are missing from the network(s), the Application must explain how its target populations will be served.

Table 2.1: ECP Categories and Provider Types in the FFM

Major ECP Category	ECP Provider Types
Federally Qualified Health Centers (FQHC)	FQHC and FQHC “Look-Alike” Clinics, Outpatient health programs/facilities operated by Indian tribes, tribal organizations, programs operated by Urban Indian Organizations
Ryan White Providers	Ryan White HIV/AIDS Program Providers

Major ECP Category	ECP Provider Types
Family Planning Providers	Title X Family Planning Clinics and Title X “Look-Alike” Family Planning Clinics
Indian Health Providers	Indian Health Service (IHS providers), Indian Tribes, Tribal organizations, and urban Indian Organizations
Hospitals	Disproportionate Share Hospital (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, Community Mental Health Centers, Rural Health Clinics, and other entities that serve predominantly low-income, medically underserved individuals.

Alternate ECP Standard

Issuers that qualify for the alternate ECP standard articulated in 45 C.F.R. 156.235(a)(2) and (b)¹⁶ must demonstrate 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 plan’s service area, in accordance with the Marketplace’s network adequacy standards. CMS interprets this standard as being met if the issuer complies with the ECP standard described above, based on employed or contracted providers located in HPSAs or 5-digit low-income zip codes in which 30 percent or more of the population falls below 200 percent of the federal poverty level (FPL). Issuers that qualify for the alternate ECP standard are not reviewed for compliance with the two additional general ECP standard requirements of offering contracts in good faith to all available Indian health providers and at least one ECP per ECP category in each county in the service area, because these additional requirements are not applicable when the issuer provides a majority of covered professional services through physicians employed by the issuer or through a single contracted medical group. Instead, alternate ECP standard issuers must

¹⁶ 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.

indicate the ECP provider type when listing each contracted or employed provider in the issuer's template.

As with the general ECP standard, an application that does not demonstrate compliance with the 30 percent ECP standard must include a narrative justification describing how the issuer's provider network(s) complies with the regulatory standard. In the context of issuers that qualify for the alternate ECP standard, an issuer's explanation in the ECP Supplemental Response Form would address how the issuer intends to ensure coverage to low-income populations residing in HPSAs or low-income zip codes in the service area(s). 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:

- Individuals with HIV/AIDS (including those with co-morbid behavioral health conditions);
- American Indians and Alaska Natives (AI/AN);
- Low-income and underserved individuals seeking women's health and reproductive health services; and
- Other specific populations served by ECPs in the service area.

CMS is providing issuers with a database of zip codes listed as HPSAs or low-income areas where 30 percent or more of the population falls below 200 percent of the FPL. The database is available at <http://www.cms.gov/ccio/programs-and-initiatives/health-insurance-marketplaces/qhp.html>. Issuers that qualify for the general or alternate ECP standard would use this same HPSA and low-income zip code database as well as the same template to complete the ECP section of the application. As with the general ECP standard, issuers that qualify for the alternate ECP standard may write in additional providers not on the HHS non-exhaustive ECP list toward satisfaction of the 30 percent ECP standard only if such providers are located within a low-income zip code or HPSA included on the "Low-Income and Health Professional Shortage Area Zip Code Listing" referenced above.

CMS will continue to assess QHP provider networks, including ECPs, and may revise its approach to reviewing for compliance with network adequacy and ECP standards in later years.

ii. Evaluation of Network Adequacy with respect to dental ECPs

SADPs will be reviewed for satisfaction of the ECP standard described in subsection (i) of this same section, with the exception of the requirement to offer contracts in good faith to at least one ECP in each ECP category (see Table 2.1 above) in each county in the service area, where an ECP in that category is available. Providers in several of the ECP categories listed in Table 2.1

do not generally provide dental services; therefore, CMS considers this ECP category requirement not applicable to SADPs.

CMS will consider issuers of SADPs to be compliant with the ECP standard if they demonstrate in their application satisfaction of the 30 percent ECP standard (described in more detail above) and the requirement to offer contracts in good faith to all available Indian health providers in the plan's service area. Otherwise, an SADP issuer's application that does not satisfy the 30 percent ECP standard as well as the requirement to offer contracts in good faith to all available Indian health providers in the service area will be required to include as part of its application a satisfactory narrative justification describing how the issuer's provider network(s), as currently designed, provides an adequate level of service for low-income and medically underserved individuals and how the issuer plans to increase ECP participation in the issuer's provider network(s) in future years, as necessary. An SADP issuer that submits a narrative justification would do so as part of the issuer application for QHP certification. See discussion in subsection (i) for additional guidance on the minimum level of detail expected to be included in a satisfactory narrative justification.

Section 5. Accreditation

This section describes how CMS will conduct a review of the accreditation standards necessary for QHP certification and recertification. States performing plan management functions in the FFM may use a similar approach. This section does not apply to SADPs.

Requirements at 45 C.F.R. 155.1045(b) establish the timeline by which QHP issuers offering coverage in the FFM must be accredited. In 2016, CMS is continuing its phased approach to accreditation for QHP issuers in the FFM. The accreditation requirements for QHP issuers entering their third year are the same as for QHP issuers entering their second year, as previously stated in the 2015 Letter to Issuers. Prior to a QHP issuer's third year of QHP certification, the QHP issuer must be accredited by a recognized accrediting entity based on the policies and procedures that are applicable to its Marketplace products, or a QHP issuer must have commercial or Medicaid health plan accreditation granted by a recognized accrediting entity for the same state in which the issuer is offering Marketplace coverage, and the administrative policies and procedures underlying that accreditation must be the same or similar to the administrative policies and procedures used in connection with the QHP. SADP issuers will not be reviewed for accreditation status.

As CMS required in 2015, QHP issuers entering their third year of Marketplace participation will be required to attest that the administrative policies and procedures applicable to their Marketplace products have been reviewed and approved by a recognized accrediting entity in compliance with 45 C.F.R. 155.1045(b)(2). The timeline in 45 C.F.R. 155.1045(b) will be applied by looking at the issuer's accreditation status 90 days prior to open enrollment. An issuer will not be considered accredited if the accreditation review is scheduled or in process.

Issuers entering their initial year of QHP certification for plan years beginning in 2016 (i.e., issuers that did not offer a QHP the previous year) must meet the requirement at 45 C.F.R. 155.1045(b)(1). New QHP issuers may submit accreditation information for display if they have existing accreditation.

In addition to the attestation noted above related to the review and approval of administrative policies and procedures, issuers will be asked to provide some information about their accreditation status to determine if the standard in 45 C.F.R. 155.1045(b) is met, including information on their accrediting entity and status. This information will be verified with the indicated accrediting entity. The National Committee for Quality Assurance (NCQA), URAC, and the Accreditation Association for Ambulatory Health Care (AAAHC) have been recognized by CMS as accrediting entities for the purpose of QHP certification. The issuer will be asked for information related to accreditation of their commercial, Medicaid, or Marketplace products.

Issuers will be considered accredited if the QHP issuer is accredited with the following status: by AAAHC with “Accredited,” status; by NCQA with “Excellent,” “Commendable,” “Accredited,” and /or “Interim” status; or by URAC with “Full,” “Provisional,” and/ or “Conditional,” status.

Section 6. Patient Safety Standards for QHP Issuers

This section describes how CMS will review issuer compliance with the patient safety standards for purposes of QHP certification and recertification. States performing plan management functions may use a similar approach. SADP issuers will not be reviewed for patient safety standards compliance in 2016.

Regulations at 45 C.F.R. 156.1110 outline how QHP issuers can demonstrate compliance with the patient safety standards. Specifically, the regulation requires QHP issuers that contract with a hospital with greater than 50 beds to verify that the hospital, as defined in section 1861(e) of the SSA, is Medicare-certified or has been issued a Medicaid-only CMS Certification Number (CCN) and is subject to the Medicare Hospital Condition of Participation requirements for:

- (1) A quality assessment and performance improvement program as specified in 42 C.F.R. 482.21; and
- (2) Discharge planning as specified in 42 C.F.R. 482.43.

In addition, QHP issuers are required to collect and maintain documentation of the CCNs from their applicable network hospitals.

As part of the certification for plan years beginning in 2016, QHP issuers will be required to demonstrate compliance with these patient safety standards as part of the QHP Application with an attestation that they have collected and are maintaining the required documentation from their network hospitals.

Section 7. Quality Reporting

This section describes how CMS will review issuer compliance with the quality reporting standards related to the Quality Rating System (QRS) and the Enrollee Satisfaction Survey (QHP Enrollee Survey) for purposes of QHP certification and recertification. States performing plan management functions in an FFM may use a similar approach. Child-only plans and SADPs are not subject to the quality reporting standards at this time.

i. QHP Issuer Data Collection and Reporting Requirements

As established in the final rule, “Patient Protection and Affordable Care Act; Exchange and Insurance Market Standards for 2015 and Beyond,”¹⁷ QHP issuers are required to comply with standards and requirements related to data collection of quality rating information through implementation of the QRS pursuant to 45 C.F.R. 156.1120, and the QHP Enrollee Survey pursuant to 45 C.F.R. 156.1125. QHP issuers offering coverage through the Marketplaces must annually collect and report validated data, on a timeline and in a standardized form and manner specified by HHS, to support the calculation of the QRS scores and ratings for each QHP that has been offered in a Marketplace for at least one year.¹⁸ QHP issuers are also required to contract with and authorize an HHS-approved vendor to annually collect and submit QHP Enrollee Survey data on their behalf for each QHP. QHPs required to submit are those with more than 500 enrollees in the previous year that have been offered in an FFM for at least one year.¹⁹ The specific requirements related to data collection, validation and submission, as well as minimum enrollment criteria, for the QRS and QHP Enrollee Survey are detailed in technical guidance that CMS anticipates will be issued on an annual basis.

Using the QHP issuer’s validated data submissions, CMS will calculate QRS scores and ratings and QHP Enrollee Survey results for each QHP product using a standard methodology and will assign each QHP a quality performance rating on a 1- to 5-star rating scale. QHP issuers may reference their respective QRS scores and ratings, as well as QHP Enrollee Survey results, in its marketing materials in a manner specified by HHS.²⁰ An issuer that elects to include QRS and QHP Enrollee Survey information in its marketing materials must do so in a manner that does not mislead consumers. Guidance related to the use of QRS scores and ratings and QHP Enrollee Survey results in QHP issuer marketing materials is forthcoming.

¹⁷ See Patient Protection and Affordable Care Act; Exchange and Insurance Market Standards for 2015 and Beyond, 79 Federal Register 30240; May 27, 2014. Codified at 45 C.F.R. Parts 144, 146, 147, et al.

¹⁸ 45 C.F.R. 156.1120.

¹⁹ 45 C.F.R. 156.1125.

²⁰ 45 C.F.R. 156.1120(c) and 156.1125(c).

CMS is continuing its phased approach to implementation of the Marketplace quality reporting standards. The QRS scores and ratings and QHP Enrollee Survey results calculated by CMS in 2016 will be publicly displayed on Marketplace websites in time for open enrollment for the 2017 coverage year. In preparation, CMS requires QHP issuers offering coverage through the Marketplace in 2014 to report data for the QRS and QHP Enrollee Survey 2015 beta test. CMS published QRS and QHP Enrollee Survey technical guidance, specifying requirements for the 2015 beta test, in addition to accompanying QRS measure technical specifications, on the CMS Marketplace Quality Initiatives website in September 2014.²¹ The beta test is a critical step for both CMS and QHP issuers to prepare for 2016 public reporting. Outcomes of the beta test will be used to refine QRS and QHP Enrollee Survey requirements for 2016. CMS anticipates that it will refine the technical guidance based on the beta test and will publish any updates by the fall of 2015.

QHP issuers offering products that do not meet minimum enrollment criteria are not required to comply with QRS and QHP Enrollee Survey requirements, but are encouraged to submit survey and clinical quality measure data for products offered through the Marketplace at the discretion of the QHP issuer. Specific requirements related to data collection, validation, and submissions are detailed in the technical guidance.

Consistent with 45 C.F.R. 156.200(b)(5), in order to demonstrate compliance with the quality reporting standards as part of the certification process for the 2016 coverage year, QHP issuers will be required to attest that they comply with the specific quality reporting and implementation requirements related to the QRS and QHP Enrollee Survey.

ii. Marketplace Oversight & Display Requirements

Consistent with 45 C.F.R. 155.200(d), Marketplaces are required to oversee implementation of the QRS and QHP Enrollee Survey (among other QHP Issuer Marketplace quality initiatives). In addition, beginning in 2016, Marketplaces must prominently display on their respective websites quality rating information assigned to each QHP under the QRS and QHP Enrollee Survey, as calculated by HHS and in a form and manner specified by HHS.²² Guidance related to the Marketplace display requirements is forthcoming.

The FFMs will publicly display the QRS scores and ratings and QHP Enrollee Survey results on its website to help consumers compare QHPs beginning in 2016 to align with the start of open

²¹ 2015 Beta Test of the Quality Rating System and Qualified Health Plan Enrollee Experience Survey:

Technical Guidance for 2015, September 2014, available at: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Health-Insurance-Marketplace-Quality-Initiatives.html> .

²² 45 C.F.R. 155.1400 and 155.1405.

enrollment for the 2017 coverage year. State-based Marketplaces are also required to display the QRS scores and ratings and QHP Enrollee Survey results calculated by HHS on their respective websites in the 2016 calendar year to facilitate consumer shopping during open enrollment for the 2017 coverage year.

Section 8. Review of Rates

This section addresses how CMS will work with states to review rate increases for QHPs when certifying plans as QHPs for participation in the FFM. States performing plan management functions in an FFM may use a similar approach. The approach for SADPs is discussed in Chapter 3, Section 1: Stand-alone Dental Plan Rates.

Regulations at 45 C.F.R. 155.1020 require a Marketplace to consider all rate increases when certifying plans as QHPs. For the 2016 benefit year, CMS plans to complete the same reviews noted in Section 4 of the 2015 Letter to Issuers when considering rate increases for purposes of QHP certification in the FFM, including in states performing plan management functions in the FFM.

When considering rate increases, CMS will consider:

- Issuers' data and actuarial justification provided in the Unified Rate Review Template (URRT);
- Other information submitted as part of a filing under an Effective Rate Review program;
- Recommendations by applicable state regulators about patterns or practices of excessive or unjustified rate increases and whether or not particular issuers should be excluded from participation in the Marketplace;
- Any excess of premium rate growth outside the Marketplace as compared to growth inside the Marketplace.

CMS does not plan to duplicate reviews by states to enforce state law, and will integrate state and other CMS rate reviews into its QHP certification process, provided that states provide information to CMS consistent with federal standards and agreed-upon timelines. For rate increases not being reviewed by a state under an Effective Rate Review program or CMS on behalf of a state (for those states that do not have Effective Rate Review programs), the issuer will enter justifications in Part I of the rate filing justification (URRT).

CMS plans to continue review for rate outliers in order to identify possible market disruptions, as described in Section 4 of the 2015 Letter to Issuers. CMS recognizes that the 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 identification process and will

consider the state's assessment of the plan's rates when determining whether, based on its rates, certifying the QHP to be offered on the FFMs would be in the interest of consumers.

Section 9. Discriminatory Benefit Design

This section addresses how CMS will review health plans applying to be QHPs or SADPs in the FFMs for compliance with nondiscrimination standards. States performing plan management functions may use a similar approach.

i. EHB Discriminatory Benefit Design

Non-discrimination in benefit design with respect to EHB is a market-wide consumer protection that applies inside and outside of Marketplaces. As stated in 45 CFR 156.125(a), an issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions. The enforcement of this standard is largely conducted by states. CMS encourages states that are enforcing the Affordable Care Act to consider a number of strategies for assessing compliance with this standard including, but not limited to analysis of information entered in the "explanations" and "exclusions" sections of the QHP Plans and Benefits Template.

As previously stated in guidance, EHB-benchmark plans may not reflect all requirements effective for plan years starting on or after January 1, 2014. Therefore, when designing plans that are substantially equal to the EHB-benchmark plan, issuers should design plan benefits, including coverage and limitations, to comply with requirements and limitations that apply to plans beginning in 2014. CMS cautions both issuers and states that age limits are discriminatory when applied to services that have been found clinically effective at all ages. For example, it would be arbitrary to limit a hearing aid to enrollees who are 6 years of age and younger since there may be some older enrollees for whom a hearing aid is medically necessary. Although CMS does not enumerate which benefits fall into each statutory EHB category, issuers should not attempt to circumvent coverage of medically necessary benefits by labeling the benefit as a "pediatric service," thereby excluding adults. CMS also cautions issuers to avoid discouraging enrollment of individuals with chronic health needs. For example, if an issuer refuses to cover a single-tablet drug regimen or extended-release product that is customarily prescribed and is just as effective as a multi-tablet regimen, absent an appropriate reason for such refusal, such a plan design effectively discriminates against, or discourages enrollment by, individuals who would benefit from such innovative therapeutic options. As another example, if an issuer places most or all drugs that treat a specific condition on the highest cost tiers, that plan design effectively discriminates against, or discourages enrollment by, individuals who have those chronic conditions.

ii. QHP Discriminatory Benefit Design

For purposes of QHP certification, CMS will assess compliance with this standard by collecting an attestation 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). CMS will continue to assess compliance through issuer monitoring and compliance reviews, including analysis of appeals and complaints.

In addition to complying with EHB non-discrimination standards, QHPs must not employ market practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs pursuant to 45 C.F.R. 156.225. As in prior QHP certification review cycles, CMS will perform an outlier analysis on QHP cost sharing (e.g., co-payments and co-insurance). CMS's outlier analysis will compare benefit packages with comparable cost-sharing structures to identify cost-sharing outliers with respect to specific benefits.

Additionally, CMS is considering conducting a review of each QHP to identify outliers based upon estimated out-of-pocket costs associated with standard treatment protocols for specific medical conditions using nationally-recognized clinical guidelines. The conditions under consideration include: bipolar disorder, diabetes, HIV, rheumatoid arthritis, and schizophrenia.

Also in reviewing a plan's cost-sharing structure, CMS will analyze information contained in the Plans and Benefits Template, including, but not limited to the "explanations" and "exclusions" sections, with the objective of identifying discriminatory features or wording. Discriminatory cost sharing language would typically involve reduction in the generosity of a benefit in some manner for subsets of individuals for reasons not clearly based on common medical management practices.

CMS will notify an issuer when it sees an indication of 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. CMS conducts this examination whenever a plan required to cover EHB reduces those benefits for a particular group. Issuers are expected to impose limitations and exclusions, if any, based on clinical guidelines and medical evidence, and are expected to use reasonable medical management. Issuers may be asked to submit justification with supporting document to CMS explaining how the plan design is not discriminatory.

Section 10. Prescription Drugs

CMS seeks to ensure that all Marketplace consumers, regardless of medical condition, have appropriate access to prescription drugs. CMS will not review SADPs for adherence to prescription drug standards as part of the QHP certification process.

In 2015 for the FFM, CMS applied standards described in the 2015 Letter to Issuers to the formulary drug list URL that it collected during QHP Application. Similar to 2015, CMS will

collect QHPs' formulary drug list URLs as part of QHP application and will make formulary drug list URL links provided by issuers available to consumers on HealthCare.gov. This formulary drug list URL link should be the same direct formulary drug list URL link for obtaining information on prescription drug coverage in the Summary of Benefits and Coverage, in accordance with § 147.200(a)(2)(i)(K).

CMS has proposed a number of changes to the EHB prescription drug benefit in the 2016 Payment Notice proposed rule. While some of these changes are being proposed for 2017, some of these changes are also being proposed for 2016. The proposed changes include a requirement that issuers' formulary drug list URL be up-to-date, accurate, and include a complete list of all covered drugs. The formulary drug list URL would be required to include any tiering structure that the plan has adopted and any restrictions on the manner in which a drug can be obtained. Also, CMS proposed that the formulary drug list URL would need to be available in a manner that is easily accessible to plan enrollees, prospective enrollees, the state, the Marketplace, HHS, OPM, and the general public. A formulary drug list URL would be easily accessible when it can be viewed on the plan's public web site through a clearly identifiable link or tab without requiring an individual to create or access an account or enter a policy number; and if an issuer offers more than one plan, when an individual can easily discern which formulary drug list applies to which plan. CMS is also considering requiring issuers to make this information publicly available on their web sites in a machine readable file and format specified by HHS. The purpose of establishing machine-readable files with the formulary drug list data would be to provide the opportunity for third parties to create resources that aggregate information on different plans. CMS believes this option would increase transparency by allowing software developers to access this information and create innovative and informative tools to help enrollees better understand plans' formulary drug lists. As an alternative, CMS is also considering whether the formulary drug list information could be submitted to HHS through an HHS-designed standardized template for the same purposes.

The 2016 Payment Notice proposed rule also includes proposed requirements for the prescription drug exception process (under which an enrollee can request and gain access to a drug not on the plan's formulary). These proposed provisions would require that an issuer notify the enrollee or the enrollee's designee and the prescribing physician (or other prescriber, as appropriate) of its coverage decision no more than 72 hours following the receipt of a standard exception request, as well as a requirement that the issuer have an external review process conducted by an independent review organization if the issuer denies a standard or expedited exception request. If our proposals on the exception process are finalized, QHPs would need to update their policies and procedures to reflect the new requirements for plan years beginning in 2016.

Lastly, CMS continues to encourage issuers to temporarily cover nonformulary drugs (including drugs that are on an issuer's formulary but require prior authorization or step therapy) as if they were on formulary (or without imposing prior authorization or step therapy requirements) during the first 30 days of coverage when an enrollee is transitioning to a new plan.

To help ensure that QHPs are in compliance with applicable regulations, CMS will conduct the following reviews as part of the 2016 QHP certification process. If CMS identifies a potential QHP for follow-up based on this review, CMS may offer the issuer the opportunity to resolve the identified issue and proceed in the certification process. CMS anticipates that it may offer the issuer the opportunity to submit a justification with supporting documentation explaining how the plan is not discriminatory or to make a change to its application to address the concern.

i. Formulary Outlier Review

Consistent with 45 C.F.R. 156.225 and 45 C.F.R. 156.125, CMS will review each QHP's formulary drug list to ensure non-discrimination in QHP prescription benefit design. CMS will perform an outlier analysis to identify QHPs that are outliers based on an unusually large number of drugs subject to prior authorization and/or step therapy requirements in a particular USP category and class. CMS encourages states performing plan management functions in the FFM to implement this type of review.

ii. Review of Prescription Drugs Based Upon Clinical Appropriateness

CMS will review each QHP's prescription drug coverage for clinical appropriateness. Based on data submitted by issuers in the prescription drug template, the clinical appropriateness review will analyze the availability of covered drugs recommended by nationally-recognized clinical guidelines used in the treatment of the following four medical conditions: bipolar disorder, diabetes, rheumatoid arthritis, and schizophrenia. The purpose of the analysis is to ensure that issuers are offering a sufficient number and type of drugs needed to effectively treat these conditions, and on some first line drugs, are not restricting access through lack of coverage and inappropriate use of utilization management techniques.

Section 11. Supporting Informed Consumer Choice/Meaningful Difference

The content of this section applies to QHP issuers in the FFM, including issuers participating in states that are performing plan management functions. This section does not apply to SADPs.

For 2016, CMS intends to use a similar approach as in previous years to assess whether all plans proposed to be offered by potential QHP issuers are meaningfully different from other plans the issuer has submitted for certification, in accordance with the requirements of 45 C.F.R.156.298.

CMS will organize an issuer's proposed QHPs from a given state into subgroups based on plan type, metal level, and overlapping counties/service areas. Second, CMS will review each subgroup to determine whether the potential QHPs in that subgroup differ from each other as detailed in the 2015 Letter to Issuers. If CMS finds that two or more plans within a subgroup do not differ based on at least one of the criteria, then those QHPs would be flagged for additional review and follow-up.

If CMS flags a potential QHP for follow-up, it anticipates that the issuer would be given the opportunity to amend its submission for one or more of the identified health plans. Alternatively, the issuer would be able to submit a justification 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.

CMS will not review SADPs for meaningful difference as part of the certification process.

Section 12. Third Party Payment of Premiums and Cost-sharing

Issuers of individual market QHPs, including SADPs, are required under 45 C.F.R. 156.1250 to accept third party premium and cost-sharing payments made on behalf of enrollees by the Ryan White HIV/AIDS Program; Indian tribes, tribal organizations, and urban Indian organizations; and other federal and state government programs.²³

HHS may impose civil money penalties against QHP issuers in the FFMs for violations of 45 C.F.R. 156.1250, as set forth in 45 C.F.R. 156.805(a)(1) and 156.805(a)(4). Under 45 C.F.R. 156.805(c), an issuer offering a QHP or SADP through the FFMs may be subject to a maximum penalty of \$100 per day, per each individual who is adversely affected by the QHP or SADP issuer's non-compliance.

Section 13. Cost-Sharing Reductions

QHP issuers are required under 45 C.F.R. 156.420 to submit three plan variations for each silver level QHP an issuer offers through the Marketplace, as well as zero and limited cost-sharing plan variations for all QHPs an issuer offers through the Marketplace. This section does not apply to SADPs, as cost-sharing reductions do not apply to SADPs. In the 2016 certification cycle, CMS will continue to review QHP Applications for compliance with Part 156, subpart E.

The certification review will include a review of each submitted Plans and Benefits Template to ensure that Silver plan variations:

- Meet 2016 AV requirements.
- Do not have an annual limitation on cost-sharing that exceeds the permissible threshold for the specified plan variation, as finalized in the 2016 Payment Notice proposed rule.

²³ This standard was effective on March 14, 2014; see Patient Protection and Affordable Care Act; Third Party Payment of Qualified Health Plan Premiums; Interim Final Rule; 79 Federal Register 15240 (March 19, 2014); codified at 45 C.F.R. part 156. The standard applies to all individual market QHPs and SADPs, regardless of whether they are offered through the FFM, an SBM, or outside of the Marketplace.

- Are designed such that the cost-sharing for enrollees under any silver plan variation for an EHB (or non-EHB, under the non-EHB out-of-pocket policy at 45 C.F.R. 156.420(d)²⁴) does not exceed the corresponding cost-sharing in the standard silver plan or any other silver plan variation of the standard silver plan with a lower AV. For example, if an enrollee in a 87 percent plan variation pays a \$40 co-pay for a specialist visit, the specialist visit co-payment for an enrollee in the associated 94 percent plan variation must be less than or equal to \$40.
- Are designed such that zero cost-sharing plan variations may not have positive cost-sharing for any EHB, either in or out-of-network. This includes any copayment, coinsurance, deductible, or application of an annual limitation on cost-sharing.²⁵
- Are designed such that, for limited cost-sharing plan variations and zero cost-sharing plan variations, the cost-sharing values (for example, copayment and/or coinsurance) for a non-EHB are the same or less than the values for the non-EHB under the associated standard plan.

Section 14. Data Integrity Tool

This section describes the Data Integrity Tool and the data integrity reviews that CMS will conduct for 2016 QHP applications.

The Data Integrity Tool is a publicly available Excel-based tool that allows issuers to check that the data contained in their QHP templates is in the correct format and conforms to validity checks that CMS will conduct upon submission. Running the QHP templates through the Data Integrity Tool provides issuers immediate feedback regarding the quality of their templates before uploading the final versions into HIOS or SERFF, potentially reducing the need for rework and resubmission. It should be noted that the tool does not replicate all HIOS and SERFF validations and that the tool contains many checks necessary for correct template submissions that are not performed by either HIOS or SERFF.

Based on a successful experience in 2014 for plan years beginning in 2015, CMS expects issuers to use the Data Integrity Tool in 2015 for plan years beginning in 2016 because it is in the best

²⁴ To simplify benefit design, issuers may reduce out-of-pocket spending for non-EHB benefits for enrollees in plan variations, so that they no longer equal non-EHB out-of-pocket in the associated standard plan. However, such non-EHB cost-sharing reductions are not eligible for HHS reimbursement.

²⁵ If the QHP is a closed-panel HMO that does not cover services furnished by a provider outside of the network (i.e., cost-sharing for services provided by an out-of-network provider is at 100 percent), the cost-sharing, for these non-covered services would not need to be eliminated for the zero cost-sharing plan variation, and should be entered as it would be for non-covered out-of-network services under the corresponding standard plan.

interest of both the issuers and CMS. Issuers that choose not to use the Data Integrity Tool should contact their CMS Account Manager in advance of the QHP submission and discuss why they are not using it. Issuers that do not use the Data Integrity Tool incur the risk that their plan information will not display properly on Plan Compare, including the risk that their plans will not be displayed at all due to display errors.

The Data Integrity Tool can be used by QHP and SADP issuers, and runs checks specific to individual and SHOP market plans. CMS will be releasing an updated version of the Data Integrity Tool that will incorporate validations specific to the 2016 QHP Application templates.

CMS will conduct data integrity reviews on all QHP and SADP applications for plan years beginning in 2016. During each review round, CMS will send issuers notices of data integrity errors that would result in either improper display of plan information to consumers or other irregularities. CMS will send summary data integrity review results to states during each review round. Data integrity notices are different from correction notices, which are generated during the separate process of QHP certification reviews.

CHAPTER 3: STAND-ALONE DENTAL PLANS: 2016 APPROACH

Issuers submitting applications for certification of SADPs will have several unique standards due to their excepted benefit status, as described in the 2014 Letter to Issuers on the Federally-facilitated and State Partnership Marketplaces (2014 Letter to Issuers),²⁶ and their limited scope of benefits. The chart below (Table 3.1) is intended to assist issuers in understanding those standards that are applicable to SADPs seeking certification in the FFEs for plan years beginning in 2016, and is consistent with the approach in prior years. CMS notes that in addition to the certification standards outlined below, SADP issuers will need to comply with operational processes and standards. The application of QHP standards is addressed throughout the sections of this Letter. Therefore, this section only addresses those standards or evaluations that are unique to SADPs.

Table 3.1: Standards and Tools Applicable to Stand-alone Dental Plans

Standard or Tool Applies (* denotes modified standard)		Standard or Tool Does Not Apply
Essential Health Benefits*	Actuarial Value*	Accreditation

²⁶ Letter to Issuers on Federally-facilitated and State Partnership Exchanges; April 5, 2013; available at: http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2014_letter_to_issuers_04052013.pdf.

Annual Limits on Cost-sharing*	Licensure	Cost-sharing Reduction Plan Variations
Network Adequacy	Inclusion of ECPs	Unified Rate Review Template
Marketing	Service Area	Meaningful Difference
Non-discrimination	Acceptance of Third Party Premium and Cost-sharing Payments	Patient Safety
Data Integrity Tool		Quality Reporting
		Prescription Drugs
		Cost Sharing Reductions

Section 1. Stand-alone Dental Plan Rates

In the 2014 Letter to Issuers, CMS outlined a process for SADPs to complete the rating template portion of the QHP Application. As in previous years, for 2016 certification SADP issuers will complete the rating templates in accordance with the associated rating and business rules and indicate in the 2016 Plan and Benefits Template whether they were committing to charging that rate (“guaranteed” rates) or retaining flexibility to change the rate (“estimated” rates).

Section 2. Intent to Apply

As described in the 2014 Letter to Issuers, QHP issuers are permitted to offer QHPs that omit coverage of the pediatric dental EHB if a SADP exists in the same service area in which they intend to offer coverage on the Marketplace. For the 2014 and 2015 plan years, CMS conducted a voluntary reporting process for SADP issuers to communicate their intent to apply. CMS intends to follow a similar approach for 2016. Additional guidance advising SADP issuers of this reporting process will be released separately.

CHAPTER 4: QUALIFIED HEALTH PLAN PERFORMANCE AND OVERSIGHT

Section 1. Account Management: 2016 Issues

All issuers participating in the FFM, including issuers in states that are performing plan management functions, will continue to have an assigned Account Manager. In addition, CMS will assign an Account Manager to issuers participating in states that use CMS’s eligibility system and platform (i.e., HealthCare.gov and the FFMs Call Center). For issuers offering QHPs

through the Marketplace for the first time in September 2015, CMS will assign an Account Manager prior to the start of plan years beginning in 2016. The Account Managers will serve as issuers' primary point of contact with the FFMs for non-technical QHP and SADP issues and will provide QHP issuers with clarification and other assistance related to issuers' responsibilities and requirements for participating in the FFM. Additionally, the Account Manager will communicate updates to issuers, direct issuers to other resources as appropriate, and coordinate resolution of cross-cutting issues. CMS expects that states, regardless of Marketplace type, will continue to take the lead in addressing market-wide issues, such as complaints related to market conduct.

CMS has also assigned a CO-OP Program Account Manager to each CO-OP in addition to the federal Account Manager. The CO-OP Program Account Manager serves as the CO-OP's primary point of contact with the CO-OP Program Division for questions and issues regarding CO-OP responsibilities and requirements pursuant to section 1322 of the Affordable Care Act, 45 C.F.R. part 156, subpart F, and the CO-OP Program Funding Opportunity Announcement.

Section 2. QHP Issuer Compliance Monitoring Program

This section describes how CMS, in its role as operator of the FFM, will monitor issuer compliance with all applicable Marketplace standards on an ongoing basis throughout plan years beginning in 2016. CMS anticipates adopting the same approach in states that are performing plan management functions.

Pursuant to 45 C.F.R. 155.1010(a)(2), CMS will be monitoring QHP issuers participating in the FFMs for demonstration of ongoing compliance with the certification requirements of 45 C.F.R. 155.1000(c). CMS will evaluate an issuer's performance to determine if making the issuer's health plan(s) available is in the best interest of qualified individuals and employers enrolling in coverage through the Marketplace. Compliance monitoring will be based on several data sources, at the state and national level, including, but not limited to: complaints data; issuer self-reporting of problems; issuer policies, procedures, and operations; network adequacy analysis; and indicators of customer service and satisfaction.

The Program Integrity: Marketplace, SHOP and Eligibility Appeals Final Rule²⁷ established the good faith compliance policy at 45 C.F.R. 156.800(c) in acknowledgement of the operational and systemic changes that took place during the 2014 calendar year. In the 2016 Payment Notice proposed rule, CMS is proposing to extend that policy through the 2015 calendar year. Under that policy, if finalized for the 2015 calendar year, CMS will not impose civil money penalties on issuers or decertify QHPs that are not in compliance with applicable Marketplace requirements

²⁷ Patient Protection and Affordable Care Act: Program Integrity: Exchange, SHOP and Eligibility Appeals; Final Rule, 78 Federal Register 54070 (Aug. 30, 2013) (codified at 45 C.F.R. Parts 147, 153, 155, and 156).

when the QHP issuer has made good faith efforts to comply with applicable requirements. Consistent with this good faith compliance policy, CMS expects issuers to develop effective internal monitoring programs to identify, report, and correct compliance violations in their operations. Furthermore, where compliance violations are identified by CMS, issuers are expected to have internal policies and procedures for coordinating with CMS to correct those violations when notified. When an issuer fails to develop a work plan to correct a compliance violation or fails to act on that work plan, CMS will consider such failure to be inconsistent with good faith compliance, as it did in 2014. Regardless of the good faith compliance policy, issuers are expected to be in compliance with all applicable Marketplace standards at all times.

If finalized as proposed in the 2016 Payment Notice proposed rule, the good faith compliance policy will end in the 2015 calendar year. By plan years beginning in 2016, issuers will have gained more experience operating in the FFMs environment and will be more familiar with the Marketplace requirements. As a general principle, CMS intends to continue providing technical assistance to issuers to assist with understanding applicable Marketplace standards and guidance. As in prior years, CMS will continue to work with states on oversight activities to prevent unnecessary duplication of effort and/or enforcement actions.

Section 3. QHP Issuer Compliance Reviews

This section describes how CMS, as administrator of the FFM, will assess QHP and SADP issuer compliance with applicable FFM standards and operational performance by performing a limited number of compliance reviews. States performing plan management functions in the FFMs may wish to take a similar approach to assessing issuer compliance with applicable FFM standards by choosing to perform selected compliance reviews on issuers in their respective states.

Consistent with CMS's authority under 45 C.F.R. 156.715, CMS will perform these compliance reviews to monitor issuer compliance with applicable FFM-specific requirements and operational standards. CMS will conduct compliance reviews throughout the year and issuer notification of selection for a review may occur at any time during the year.

CMS will generally use a risk-based process, based in part on compliance monitoring (e.g., complaint data) and available performance data, to select issuers for standard²⁸ compliance reviews. CMS may also select a QHP/SADP or issuer for a compliance review based on a specific issue of potential non-compliance. If CMS selects a QHP/SADP or issuer due to a specific issue of potential non-compliance, CMS may perform a targeted²⁹ review specific to the area(s) of potential non-compliance and/or conduct the compliance review on an expedited

²⁸ Standard reviews include all review areas.

²⁹ Targeted reviews can include all review areas or just select review areas.

basis.³⁰ In some cases, due to the potential magnitude of harm to consumers, CMS may conduct limited, expedited compliance reviews of issuers to ensure that potential operational problems can be identified and addressed early on.

CMS may conduct either a desk review or an on-site review³¹ and the type and location of the review will be included in the issuer selection notification. CMS will review data at both the issuer and the QHP/SADP level. CMS may request, as part of the compliance review process, policies, procedures, and any other applicable documentation³² reasonably necessary to evaluate and verify compliance with the applicable FFM requirements.

CMS intends to coordinate with the state regulatory entities, when appropriate, in conducting the compliance reviews. At the conclusion of all compliance reviews for the year, CMS will share the results of the reviews conducted by the Agency with states and the lessons learned with issuers.

Section 4. FFM Oversight of Agents and Brokers

This section describes how CMS will approach oversight of agents and brokers participating in the FFM. It also provides an overview of accompanying QHP issuer responsibilities regarding their relationships with and oversight obligations for their affiliated agents and brokers who will be assisting with enrollment in QHPs offered through the FFM. Unless noted otherwise, references to agents and brokers include web-brokers.³³

i. QHP Issuer Responsibilities

Pursuant to 45 C.F.R. 156.340, a QHP issuer participating in the FFMs maintains responsibility for ensuring that its delegated and downstream entities, including affiliated agents and brokers, comply with applicable laws and regulations. Accordingly, CMS expects QHP issuers to confirm all affiliated agents' and brokers' licensure statuses, verify that they fulfilled the applicable FFM registration and training requirements, executed the applicable FFM Privacy/Security Agreement(s), and if applicable, signed the General FFM Marketplace Agreement before allowing access to the QHP issuer's tools to assist with enrollment through the FFMs and/or providing compensation for Marketplace transactions. QHP issuers may verify agents and

³⁰ Issuers selected for expedited compliance reviews will be required to submit documentation with a shorter turnaround time.

³¹ On-site reviews will take place at the issuer's place of business.

³² Additional documentation could include sample sets of applicable data (i.e., notices, claims, complaints, etc.).

³³ CMS uses the term "web-broker" to refer to agents or brokers who use their own website, or that of another agent or broker, to facilitate enrollment in a QHP through the FFM in accordance with 45 C.F.R. 155.220(c)(3).

brokers' FFM registration and training status according to the registration completion list on the CMS agent and broker resources page³⁴ or by requesting a copy of the FFMs User ID and training completion certificate (if applicable) from each affiliated agent or broker. In addition, QHP issuers are responsible for ensuring that all activities conducted on their behalf by affiliated agents and brokers comply with applicable federal and state standards, including those related to privacy and security, conflict(s) of interest, marketing, and continuing education.

ii. Agent and Broker Agreements

Agents and brokers must comply with all applicable privacy and security requirements, including but not limited to the standards established by HHS pursuant to 45 C.F.R. 155.260, related to the use of handling of personally identifiable information (PII) by non-Marketplace entities. Before assisting consumers in the FFM, agents and brokers must execute the Individual Market and/or FF-SHOP Privacy/Security Agreement (depending on whether the agent or broker is participating in the FFMs for the Individual Market, the FF-SHOP, or both), which includes further details on the Marketplace privacy and security standards related to the use and disclosure of PII.

Every agent and broker must execute an Agreement with CMS as part of the registration process with the FFM. These Agreements include:

- Agent Broker General Agreement for the FFMs Individual Market (General Agreement) — all agents and brokers who wish to assist consumers in the FFMs for the Individual Market must electronically execute this General Agreement.
- Agreement Between Agent or Broker and CMS for the FFMs Individual Market (IM Privacy and Security Agreement) — all agents and brokers who wish to assist individual market consumers in the FFMs must electronically execute this Privacy and Security Agreement.
- Agreement Between Agents and Brokers and CMS for the FF-SHOP (SHOP Privacy and Security Agreement) — all agents and brokers who wish to assist FF-SHOP consumers must electronically execute this Privacy and Security Agreement.
- Agreement Between Web-Broker Entity and CMS for the FFMs for the Individual Market (Web-Broker Agreement) — all web-brokers who wish to assist individual market consumers in the FFMs must electronically execute this Web-Broker Agreement.

By signing the applicable Agreements, agents and brokers attest that they will:

³⁴ This page is available at: <http://www.cms.gov/CCIIO/programs-and-initiatives/health-insurance-marketplaces/a-b-resources.html> .

- Comply with Marketplace privacy and security requirements, such as standards for use and disclosure of PII;
- Comply with all applicable state and federal laws and regulations;
- Maintain valid licensure in all states where they wish to enroll qualified individuals and employers/employees into QHPs through the FFM; and
- Complete the full FFM registration process in advance of assisting consumers, including taking all applicable training.

Pursuant to 45 C.F.R. 155.285, HHS may impose a civil money penalty of up to \$25,000 for each application for failure to provide correct information to the Marketplace, or for improper use or disclosure of consumer PII, where such failure is attributable to negligence or disregard of any HHS rules or regulations. HHS may impose a civil money penalty of up to \$250,000 for knowingly and willfully providing false or fraudulent information to the Marketplace.

iii. Monitoring and Oversight

CMS works with states to coordinate oversight activities related to agents and brokers. CMS may investigate complaints pertaining to agents and brokers in the FFM, and will monitor QHP issuer activities to confirm they are meeting their responsibilities for oversight of affiliated agents and brokers.

HHS may terminate an agent's or broker's Agreement(s) with the FFMs for cause if it determines that a specific finding of noncompliance or a pattern of noncompliance is sufficiently severe, or if the agent or broker materially breaches any term of the General Agreement, IM Privacy and Security Agreement, SHOP Privacy and Security Agreement, and/or the Web-Broker Agreement, as applicable.³⁵ In addition, HHS will inform the applicable state or states (in which an agent or broker is licensed) of any such terminations. A termination would effectively bar the agent or broker from assisting with enrollment through the FFM. Termination can be temporary (e.g., subject to reinstatement upon correction of the noncompliance) or permanent. If an agent or broker's Agreement(s) with the FFMs is terminated (either by the agent or broker or by the FFM), the agent or broker must continue to protect any PII that was accessed during the term of his or her relationship with the FFMs in accordance with the IM and/or SHOP Privacy/Security Agreement and the applicable requirements under 45 C.F.R. 155.260.

³⁵ 45 C.F.R. 155.220(g).

iv. Web-brokers

CMS regulations establish additional requirements that apply when an agent or broker uses their own website, or that of another agent or broker, to facilitate enrollment in a QHP through the FFM.³⁶ CMS uses the term “web-broker” to refer to such agents or brokers who use a non-FFM website to assist consumers in the QHP selection and enrollment process as described in 45 C.F.R. 155.220(c)(3). Web-brokers provide another option for consumers seeking to enroll in QHPs through the FFM, alongside traditional agents and brokers who assist consumers with enrollment through the Marketplace. Pursuant to 45 C.F.R. 155.220(i), beginning January 1, 2015, SHOPS may permit agents and brokers, in states that permit such activity under state law, to use a QHP issuer or web-broker website to provide assistance to employers and facilitate enrollment of employees in SHOP QHPs, subject to the requirements of 45 C.F.R. 155.220(c)(3).³⁷ The FF-SHOPS may elect to implement this functionality for plan years beginning in 2016.

To the extent permitted by a state, CMS works with web-brokers that meet all applicable requirements to provide an alternate option to help consumers select and enroll in QHPs through the FFMs online. Web-brokers provide an additional channel for the FFMs to reach consumers and to help them enroll in individual market QHPs. CMS has developed the capability to support Direct Enrollment integration between the web-broker’s website and HealthCare.gov using secure redirect and application programming interface (API) mechanisms. The Direct Enrollment pathway enables a consumer to initiate his or her shopping experience on the web-broker’s website, connect securely to HealthCare.gov to complete the eligibility application and determination process, and return securely to the web-broker’s site to compare plans and enroll in a QHP.

v. Compensation

Agents and brokers are compensated directly by QHP issuers as per the terms of their QHP issuer contracts for assisting consumers to enroll in QHPs through the FFM. Compensation includes commissions, fees, or other incentives as established in the relevant contract between a QHP issuer and the agent or broker. An agent or broker must be affiliated or have a contractual relationship with the respective issuer, in accordance with applicable state law, and must complete the applicable FFM registration requirements in order to be paid by an issuer for a Marketplace transaction. The FFMs does not set compensation levels or pay commissions to agents or brokers. CMS does not require QHP issuers to offer contracts to agents and brokers,

³⁶ 45 C.F.R. 155.220(c)(3),(4).

³⁷ Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2015; Final Rule, 79 Federal Register 13744, 13792 (March 11, 2014) (45 C.F.R. parts 144, 147, 153, et al.).

including offering compensation for enrollment in QHPs through the FFM. QHP issuers should compensate only affiliated agents and brokers that are compliant with applicable federal and state requirements, including those for registration with the FFM.³⁸

The FFMs transmits the identifying information of agents and brokers (e.g., national producer number (NPN)) to QHP issuers on the 834s, but the FFMs does not play a role in setting compensation levels or ensuring that compensation is paid to agents and brokers because the FFMs is not a party to the contract between the QHP issuer and the agent or broker. However, federal regulations require QHP issuers to provide the same compensation to agents and brokers for QHPs offered through the FFMs as they do for similar health plans offered in the state outside the Marketplace.³⁹ This compensation approach is a required participation standard for QHP issuers offering coverage in the FFMs, including both the Individual Market and SHOP.

Agents and brokers who are acting as Navigators, certified application counselors, and/or (in FFMs and SPMs) non-Navigator assistance personnel may not receive any direct or indirect compensation from health insurance or stop loss insurance issuers in connection with the enrollment of any individuals or employees in a QHP or non-QHP.

The specific location where the NPN can be captured is dependent on the Marketplace (i.e., Individual or SHOP Marketplace), re-enrollment type (i.e., passive or active), enrollment pathway (i.e., direct enrollment or Marketplace/Side-by-Side pathway), application form (i.e., new streamlined application or classic FFM application), and the timing of the NPN entry (i.e., during the eligibility application process or during the plan selection process). Please refer to the guidance document, “Operational Tips for Agents/Brokers Assisting Consumers with Plan years beginning in 2015 Enrollments in the FFM” for more details.⁴⁰

vi. Registration Requirement for Re-enrollment Transactions

Agents or brokers who are assisting consumers with enrollment in QHPs offered through the FFMs must have a current FFM registration at the time they are providing assistance. Because passive re-enrollments assume that agents or brokers are not providing assistance to consumers to facilitate their re-enrollments, agents or brokers would not need to have a current registration to be listed on the 2015 re-enrollment transaction. In contrast, for active re-enrollments that

³⁸ See “i. QHP Issuer Responsibilities” under this section, and 45 C.F.R. 156.340

³⁹ 45 C.F.R. 156.200(f).

⁴⁰ Operational Tips for Agents/Brokers Assisting Consumers with Plan Year 2015 Enrollments in the FFM, November 12, 2014. Available at: <http://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/Operational-Tips-Enrollment-11-12-2014-508.pdf> .

involve agent or broker assistance, agents or brokers must have a current registration with the FFMs at the time they are assisting consumers.

Section 5. Oversight of Marketing Activities

This section describes how CMS will monitor QHP marketing during plan years beginning in 2016 in the FFMs and provides information that supplements what was discussed in the 2015 Letter to Issuers. States performing plan management functions in the FFMs are encouraged to take a similar approach.

Regulations at 45 C.F.R. 156.200(e) provide that QHP issuers must not, with respect to their QHPs, discriminate on the basis of race, color, national origin, disability, age, sex, gender identity, or sexual orientation. 45 C.F.R. 156.225(a) requires that in order to have a plan certified as a QHP, a QHP issuer must comply with all applicable state laws on health plan marketing by health insurance issuers. In addition, 45 C.F.R. 156.225(b) states that a QHP issuer must not employ marketing practices that will have the effect of discouraging the enrollment of individuals with significant health needs in QHPs.

As noted in the 2015 Letter to Issuers, states generally regulate health plan marketing practices and materials and related documents under state law, and CMS does not intend to review QHP marketing materials for compliance with state standards as described at 45 C.F.R. 156.225(a). In FFM states, CMS may review QHP marketing materials for compliance with 45 C.F.R. 156.200(e) and 45 C.F.R. 156.225(b). CMS will work with states to determine where additional monitoring and review of marketing activities may be needed. For all QHP issuers in the FFM, CMS recommends that agreements with agents and brokers, as well as marketing materials distributed to enrollees and to prospective enrollees, contain a clause such as the following: “[Insert plan’s legal or marketing name] does not discriminate on the basis of race, color, national origin, disability, age, sex, gender identity, sexual orientation, or health status in the administration of the plan, including enrollment and benefit determinations.” If CMS receives a consumer complaint about an issuer’s marketing activities or about an agent’s, broker’s, or web-broker’s conduct which is generally overseen by the state, CMS will send the complaint to the state regulators, as appropriate, for investigation. Following the state’s investigation, CMS may take the necessary enforcement action against the issuer or agent, broker, or web-broker.

All marketing, whether paper, electronic, or other media, must reflect accurate information that complies with both Marketplace and market-wide standards. In addition, marketing materials that solicit PII must comply with the privacy and security standards described at 45 C.F.R. 155.260. CMS will refer cases of false advertising/false information, as well as privacy and/or security violations, to the appropriate state and federal entities. Following the state’s or other entities’ investigation, CMS may take the necessary enforcement action against the QHP issuer or agent, broker, or web-broker.

CMS strongly suggests that QHP issuers, agents, brokers, and web-brokers not use “Marketplace” or “Exchange” in the name of their businesses or websites. If an agent or broker assists a consumer with individual market FFM or FF-SHOP QHP selection through the agent’s, broker’s, or web-broker’s non-FFM website, a standardized disclaimer must be prominently displayed to indicate that the site is not the Health Insurance Marketplace website, and a link to the FFMs website must also be provided.⁴¹

CHAPTER 5: FF-SHOPS

Section 1. Dental Changes

For plan years beginning as early as 2016, employers offering coverage through the FF-SHOPS will be able to offer dental coverage without also having to offer medical coverage. When only dental coverage is offered by an employer and dependent dental coverage is also made available by the employer, an employee would have to enroll in dental coverage before dependents of that employee will be able to enroll in dental coverage, just as is the case for medical coverage.

In addition, if an employer offers both medical and dental coverage to employees and their dependents through an FF-SHOP, and an employee enrolls in both medical and dental coverage, the employee’s dependents will be able to enroll in either the medical or dental coverage selected by the employee, or in both. CMS notes that dependents of an employee will be able to enroll only in the medical and dental plans in which the employee has enrolled.

For example, the following situations might be possible:

- An employee and all dependents are enrolled in the same medical and dental coverage.
- An employee and one dependent are enrolled in the same medical and dental coverage, but another dependent is enrolled only in the dental coverage in which the employee is enrolled.
- An employee and one dependent are enrolled in the same medical and dental coverage, while another dependent is enrolled only in the medical coverage in which the employee is enrolled.

⁴¹ See 45 C.F.R. 155.220(c)(3)(vii). Also see 45 C.F.R. 155.220(i), which allows SHOPS to permit agents and brokers, in states that permit such activity under state law, to use an Internet website to provide assistance to qualified employers and facilitate enrollment of qualified employees in SHOP QHPs, subject to the requirements of 45 C.F.R. 155.220(c)(3).

- An employee is enrolled in both medical and dental coverage, and one dependent is enrolled only in the medical coverage in which the employee is enrolled, while another dependent is enrolled only in the dental coverage in which the employee is enrolled.

Section 2. Premiums Based on Average Enrollee Premium Amounts

45 C.F.R. 147.102(c)(3)(iii) and 156.285(a)(4)(ii) establish parameters for premiums based on average enrollee premium amounts in the FF-SHOPs. CMS anticipates that the capacity to calculate and display premiums based on an average enrollee premium amount will be available in the FF-SHOPs for plan years beginning in 2016.

45 C.F.R. 147.102(c)(3)(iii) does not require medical and dental issuers participating in the FF-SHOPs to make available premiums based on average enrollee premium amounts to small employers. 45 C.F.R. §156.285(a)(4)(ii) precludes a QHP issuer participating in the FF-SHOPs from offering a qualified employer premiums based on average enrollee premium amounts if the employer elects to offer employees a choice of plans at a specified level of coverage as described in 155.705(b)(3)(iv)(A) and 155.705(b)(3)(v)(B). Thus, in the FF-SHOPs, premiums based on average enrollee premium amounts will be available only to qualified employers that choose to offer their employees a single plan instead of employee choice. When employers choose the single plan option, they will also be able to decide whether to pay premiums using a per-member methodology or one based on average enrollee premium amounts. Employers will be able to search issuers by an indicator showing whether the issuer makes available premiums based on average enrollee premium amounts. If an employer selects the option to select issuers that make available premiums based on average enrollee amounts, then only those issuers that have made this option available will be displayed.⁴²

To determine the total premium charged for a given family composition under a methodology based on average enrollee premium amounts, the FF-SHOPs will sum the average enrollee premium amount for each covered family member age 21 and older and the average enrollee premium amount for each covered family member under age 21, as applicable, taking into account no more than three covered children under age 21. Applicable tobacco rating factors will be excluded from these premium calculations and will be added separately to enrollee charges on monthly invoices.

For example, suppose the average enrollee premium for a group health plan is \$200 for each covered individual age 21 and older and \$100 for each covered individual under age 21. Also suppose that none of the enrollees use tobacco. In this example, the premium charged for a single employee (over age 21) would be \$200; the premium charged for an employee and spouse (both

⁴² As part of the 2016 QHP Application process, medical and dental issuers will document their decision to accept or not accept premiums based on average enrollee premium amounts.

over age 21) would be \$400 ($\$200 + \200); and the premium charged for a family consisting of an employee and spouse (both over age 21) and four children (all under age 21) would be \$700 ($\$200 + \$200 + \$100 + \$100 + \$100 + \0).

If an issuer offering premiums based on average enrollee premium amounts wishes to rate for tobacco use, consistent with applicable federal and state law, the FF-SHOPs will calculate the tobacco rating factor based on the applicable enrollee's per-member premium, not the average enrollee premium amount. The resulting tobacco rating factor is added to the average enrollee premium amount for the enrollee who uses tobacco to create a premium specific to each tobacco user.

For example, an employer chooses a plan offering premiums based on average enrollee premium amounts. The issuer imposes a 1.5:1 tobacco rating factor. Assume that the average enrollee premium for a group health plan is \$100 for each covered individual age 21 and older, that the premium for a 45-year old is \$100, and the premium for a 35-year old is \$80. In this example, the premium charged for the 45-year old who uses tobacco would be \$150 ($\$100 + (0.5 \times 100)$), and the premium charged for the 35-year old who uses tobacco would be \$120 ($\$80 + (0.5 \times 80)$), subject to the non-discrimination and wellness provisions under section 2705 of the PHS Act. A tobacco indicator and a wellness program indicator are present on member-level 834 transactions, which will inform FF-SHOP issuers whether a tobacco rating factor has been applied.

After an employer completes the enrollment process, the average enrollee premium amounts calculated will be locked in for the plan year and recalculated only at the time of renewal. Thus, regardless of how a group's composition changes during its plan year, premiums charged for children and adults will remain the same until the time of renewal. Any new hires or dependents added as a result of a special enrollment period will be charged the same average enrollee premium amount charged to initial enrollees.

The Group XML file transmitted to the issuer during initial enrollment will contain an indicator (either yes or no) indicating whether premiums based on average enrollee premium amounts apply to a group for the plan year as well as two average enrollee premium amounts--- one for dependents under age 21 and one for enrollees 21 and older. 834 enrollment transactions will also contain the average enrollee premium amount charged for each enrollee.

Issuers will communicate to CMS whether they will make available plans with premiums based on average enrollee premium amounts at the time of initial enrollment through the Plans and Benefits template.

Section 3. Online Renewals

For plan years beginning on or after January 1, 2016, CMS anticipates that all renewals of FF-SHOP participation and all renewals of health and dental coverage offered through the FF-

SHOPs will be handled by employers and employees online at HealthCare.gov. Employers and employees working with an agent or broker will also need to handle renewals and changes to FF-SHOP participation and coverage at HealthCare.gov. An employer may decide to renew its FF-SHOP participation as well as the coverage it offered through the FF-SHOPs in the previous year. The employer may also decide that it will renew its FF-SHOP participation, but not renew the coverage it offered through the FF-SHOPs in the previous year. Both of these circumstances are considered renewals of FF-SHOP participation and must follow the FF-SHOP renewal process, even where they do not result in an issuer's renewing coverage under the product offered through the SHOPs, as defined for purposes of guaranteed renewability.

The FF-SHOP renewal process applies to employer groups that were determined eligible to buy coverage through the FF-SHOPs and had employees enroll in the FF-SHOP in the previous plan year. The employer renewing participation will have an annual election period during which he or she can renew or change his or her FF-SHOP coverage offer to employees. This election period will begin when rate and plan information becomes available for the quarter in which coverage would end, but not more than two months before the date an enrollment must be submitted to avoid a gap in coverage. Employers must provide their employees with an annual open enrollment period of at least one week to decide whether to accept the coverage offer. All enrollments must be submitted by the 15th day of the month for coverage to start the first day of the next month. The employer's election period will therefore end at least one week prior to the deadline for completing an enrollment that would take effect at the end of the employer's prior plan year.

Pursuant to 45 C.F.R. 155.710(d), the FF-SHOPs must allow an employer to continue participating in an FF-SHOP for plan years beginning in 2016 if the following conditions are met: (1) the employer received a determination of eligibility from an FF-SHOP in a prior year and has continued participating in that FF-SHOP since that time, (2) the employer had 100 or fewer full-time-equivalent employees when the group began participating in FF-SHOPs, but added employees after the group began participating and now has more than 100 full-time-equivalent employees, and (3) the employer continues to meet all other requirements for participating in an FF-SHOP. For plan years beginning in 2016, the FF-SHOPs will be sending notices to employer groups and employees regarding the annual employer election period and the annual employee open enrollment period. Issuers are not responsible for distributing these notices, but are still subject to market-wide requirements regarding notices under 147.106.

Section 4. Employee Choice

Pursuant to 45 C.F.R. 155.705(b)(3)(vi), for plan years beginning in 2015, states could request that the FF-SHOPs provide employers only with the option to offer a single plan, rather than providing employers with the option to offer employee choice. This was a transitional policy that applied only to plan years beginning in 2015. For plan years beginning on or after January 1, 2016, employee choice will be available to all qualified employers in all states. Thus, in all FF-

SHOPs for plan years beginning in 2016, employers will have a choice of two methods to make QHPs available to qualified employees: (1) they can offer employees a choice of all QHPs at a single level of coverage -- bronze, silver, gold, or platinum, or (2) they can offer a single QHP. Employers will also have the option to make available either (1) all SADPs at a single level of coverage – high or low, or (2) a single SADP.

Section 5. Employer Group Size in the FF-SHOPs

Pursuant to 45 C.F.R. 155.20, small employer means, in connection with a group health plan, an employer who employed an average of at least 1 but not more than 100 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year. In the case of plan years beginning before January 1, 2016, a State may elect to define small employer by substituting “50 employees” for “100 employees.” For plan years beginning on or after January 1, 2016, this policy no longer applies, and a small employer is defined as an employer who employed an average of at least one but not more than 100 full-time-equivalent employees on business days during the preceding calendar year and who employ at least 1 employee on the first day of the plan year. Thus, for plan years beginning on or after January 1, 2016, QHPs and SADPs will be available through the FF-SHOPs to employers with one to 100 full-time-equivalent employees. Coverage through the FF-SHOPs will also be available to employers that were determined eligible to participate in the FF-SHOPs for plan years prior to 2016, that have participated in the SHOPs continuously since first becoming eligible, and that grew to larger than 100 full-time-equivalent employees since first becoming eligible, so long as these employers continue to meet all other conditions of participation.

Under guidance CMS issued on March 5, 2014, CMS announced transition relief that would apply to employers with between 51 and 100 employees, if permitted by the state and the issuer of the group coverage. CMS seeks comment on how the transition relief should affect the operation of the FF-SHOPs in 2016.

CHAPTER 6: CONSUMER SUPPORT AND RELATED ISSUES

Section 1. Consumer Case Tracking and Resolution

The content of this section applies to QHP and SADP issuers in the FFM, including in states performing plan management functions.

CMS expects QHP issuers to thoroughly investigate and resolve consumer issues received directly from members or forwarded to the QHP issuer by the state through the issuer’s internal customer service process and as required by state law. Additionally, QHP issuers operating in the FFMs must investigate and resolve consumer cases, including complaints, forwarded by CMS in accordance with the requirements at 45 C.F.R. 156.1010. Cases are forwarded through the Health Insurance Casework System (HICS). CMS expects issuers to resolve all cases in a timely and

accurate manner to ensure consumers receive the highest level of service and to meet QHP issuer participation standards as outlined at 45 C.F.R. 156.200. Timeframes for resolving cases forwarded by CMS are specified in 45 C.F.R. 156.1010(d).

Cases that CMS may forward include, but are not limited to, issues related to cancellations/terminations, proper application of the advance payments of the premium tax credit, and adjustments of effective dates based on special enrollment periods (SEPs) or enrollment errors. In all cases, CMS expects QHP issuers operating in the FFM to conduct appropriate research using all of the tools and systems available to them, including but not limited to 834 transactions and pre-audit files. Additionally, CMS expects QHP issuers operating in the FFM to contact consumers as appropriate to conduct their investigations and research in order to ensure that issuers are using the most recent information available from the consumer. Issuers may often need to contact a consumer prior to the resolution of a case as a critical part of the investigation and research process. CMS expects that issuers will carry out the needed research for their cases in a comprehensive manner that assures consumers that issuers' case resolutions are based on all of the available and most current information. CMS Regional Office staff is available to assist QHP issuers by providing technical assistance on casework matters beyond QHP issuers' control to resolve.

QHP issuers operating in the FFM, including in states performing plan management functions, are expected to comply with all applicable state and federal laws related to consumer complaints, including any applicable requirement to advise consumers of their appeal rights. CMS tracks cases and uses this information as a tool for directing oversight activities in the FFM. To the greatest degree possible, CMS collaborates with states, sharing information suggestive of issuer performance problems.

Section 2. Coverage Appeals

The content of this section applies to all QHP issuers in the FFM, including in states performing plan management functions.

As in plan years beginning in 2015, in 2016 QHPs are required to meet the same standards for internal claims and appeals and external review established at 45 C.F.R. 147.136, which implements 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 non-grandfathered 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.

Section 3. Meaningful Access

This section summarizes the existing requirements and guidance that apply to QHP issuers (including SADP issuers) to ensure meaningful access by limited-English proficient (LEP) speakers and by individuals with disabilities and proposed changes to certain issuer obligations.

In the 2016 Payment Notice proposed rule, CMS proposed to specify that a QHP issuer's existing obligation to provide oral interpretation services includes making available telephonic interpretation services in at least 150 languages. CMS also proposed amending 45 C.F.R. 156.250 to require QHP issuers to provide all information that is critical for obtaining health insurance coverage or access to health care services through the QHP to qualified individuals, applicants, qualified employers, qualified employees, and enrollees in a manner consistent with 45 C.F.R. 155.205(c). All such requirements would apply to QHP issuers operating in the FFMs.

Under these proposed amendments to 45 C.F.R. 156.250, QHP issuers would be required to ensure meaningful access to at least the following essential documents:

- Applications;
- 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;
- Rebate notices;
- Any document the issuer is required by state or federal law to provide to a qualified individual, applicant, qualified employer, qualified employee, or enrollee (for example, the summary of benefits and coverage required under 45 C.F.R. 147.200); and
- Any other document that contains information that is critical for obtaining health insurance coverage or access to care through the QHP.

In order to achieve greater consistency among certain programs within HHS, CMS is working with other HHS components to further specify standards for ensuring meaningful access by LEP speakers and by people with disabilities.

Finally, QHP issuers operating in the FFMs are reminded that the meaningful access requirements at 45 C.F.R. 155.205(c), 155.230(b), and 156.250, as well as non-discrimination prohibitions at 45 C.F.R. 156.200(e), are independent of other obligations QHP issuers may have. For example, QHP issuers that receive federal financial assistance are subject to Title VI of

the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973,⁴³ and section 1557 of the Affordable Care Act, and as a result, have separate responsibilities under the law not to discriminate on the basis of race, color, national origin, sex, age and disability, in providing access to their services.

Section 4. Summary of Benefits and Coverage

The content of this section applies to all QHP issuers in the FFM, including states performing plan management functions. This does not apply to SADPs.

As discussed in the 2015 Letter to Issuers, QHPs are required to provide the Summary of Benefits and Coverage (SBC) in a manner compliant with the standards set forth in 45 C.F.R. 147.200, which implements section 2715 of the PHS Act, as added by the Affordable Care Act. Specifically, issuers must fully comply with the requirements of 45 C.F.R. 147.200(a)(3), which requires issuers to “provide an SBC in the form, and in accordance with the instructions for completing the SBC, that are specified by the Secretary in guidance.” CMS expects that all URL links included on the SBC be easily accessible to consumers, including shoppers, and link directly to the information referenced on the SBC. For example, in accordance with 45 C.F.R. 147.200(a)(2)(i)(K), the link for obtaining information on prescription drug coverage in the SBC should directly link to the formulary for the benefit package reflected on the SBC, as noted previously.

In the 2016 Payment Notice proposed rule, CMS proposed to amend 45 C.F.R. 156.420 and 156.425 to require QHP issuers to provide SBCs that accurately represent plan variations in a manner consistent with the requirements set forth at 45 C.F.R. 147.200 to ensure that consumers have access to SBCs that accurately represent cost-sharing responsibilities for all coverage options, including plan variations, and are provided adequate notice of the plan variations. If this amendment is finalized as proposed, QHP issuers will be required to create separate SBCs for each plan variation and therefore may not combine information about multiple plan variations in one SBC.

⁴³ Consistent with Section 504 of the Rehabilitation Act and HHS implementing regulations at 45 C.F.R. 84, covered entities, which include all recipients of federal financial assistance, are required to “provide auxiliary aids to persons with disabilities, at no additional cost, where necessary to afford an equal opportunity to participate in or benefit from a program or activity” (<http://www.hhs.gov/ocr/civilrights/understanding/disability/>). CMS encourages QHP issuers seeking to understand their legal obligations to provide auxiliary aids and services to people with disabilities to reference the U.S. Department of Justice’s Effective Communications guidance at <http://www.ada.gov/effective-comm.htm>.

Section 5. Transparency in Coverage Reporting

The content of this section outlines transparency reporting requirements for all QHP including SADP issuers in the FFM, including the FFMs in states that are performing plan management functions. This section further outlines CMS's intent to implement the requirement for QHP issuers participating in the FFMs to comply with transparency requirements in 2016.

Under section 1311(e)(3) of the Affordable Care Act, as implemented by regulations at 45 C.F.R. 156.220, issuers seeking certification of a health plan as a QHP must make accurate and timely disclosures of certain information to the appropriate Marketplace, the Secretary of HHS, and the state insurance commissioner, and make it available to the public. As noted in the 2016 Payment Notice proposed rule, because a full year of claims data will be available, CMS anticipates the collection and public display of the required information listed in 45 C.F.R. 156.220 from QHP issuers offering coverage through Marketplaces beginning in 2016. In the 2016 Payment Notice proposed rule, CMS is soliciting comments to inform future technical guidance that will provide details on the implementation of the transparency in coverage reporting requirements, including what information must be provided and the timing of submissions. Via that proposed rulemaking, CMS is also seeking comments on the manner in which the Marketplaces and QHP issuers should publicly display the collected information pursuant to 45 C.F.R. 155.1040(a) and 156.220(b), respectively.

CMS will release additional guidance when the transparency in coverage data submission and public display requirements have been finalized.

CHAPTER 7: TRIBAL RELATIONS AND SUPPORT

CMS has a historic and unique relationship with federally-recognized Indian tribes and Indian health care providers: health programs operated by the Indian Health Service (IHS), Tribes and Tribal organizations, and urban Indian organizations. In adhering to QHP certification standards, CMS encourages QHPs to contract with Indian health care providers, through which a significant number of American Indians and Alaska Natives (AI/AN) access health care. To promote contracting between issuers and Indian health care providers, CMS is continuing to require QHPs to offer contracts in good faith to all available Indian health providers in the QHP's service area, applying the special terms and conditions necessitated by federal law and regulations as referenced in the Model QHP Addendum⁴⁴ (Addendum), as described in the 2014 Letter to Issuers. Issuers should refer to that document and the addendum itself, both of which are available on the CCIIO website, for further details. A list of Indian health care providers and address/contact information may be found on the CCIIO website.

⁴⁴ The model QHP Addendum for Indian health providers is available at <http://www.cms.gov/ccio/programs-and-initiatives/health-insurance-marketplaces/qhp.html>.

Section 206 of the Indian Health Care Improvement Act (IHCIA) (25 USC § 1621e) provides for a right of recovery from an insurance company and other third party entities, including QHP issuers, for reasonable charges billed by an Indian health care provider when providing services, or, if higher, the highest amount the third party would pay for services furnished by other providers. This right of recovery applies whether the Indian health care provider is in a plan network or not. Further details can be found at <http://www.ihs.gov/ihcia/>.

Even though Indian health care providers have a right of recovery under section 206 of the IHCIA, CMS encourages issuers and Indian health care providers to develop mutually beneficial business relationships that promote effective care for medically underserved and vulnerable populations.