



Date: February 20, 2015

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

Centers for Medicare & Medicaid Services (CMS)

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

The Centers for Medicare & Medicaid Services (CMS) is releasing this final 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 Health Insurance Marketplace-related topics are set out in 45 C.F.R. Subtitle A, Subchapter B. Additional requirements were included in a final rule titled, “Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016” (2016 Payment Notice Final Rule), CMS-9944-F, which went on public display on February 20, 2015.² 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 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

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; CMS-9944-F.

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.).

CONTENTS

Chapter 1: Certification Process for Qualified Health Plans	5
Section 1. QHP Application and Certification Process	6
i. Registration and QHP Application.....	9
ii. Issuer Data Collection and Coordination with States	10
iii. FFM Review of QHP Applications	10
iv. Data Changes	11
v. QHP/SADP Certification and Privacy and Security Agreement and Senior Officer Acknowledgements.	14
vi. Sale of Ancillary Products on the FFMs	15
Section 2. QHP Certification Process in a State Performing Plan Management Functions in the FFMs	15
i. QHP Application and State Review Process.....	17
ii. Data Changes	18
Section 3. Recertification for 2016.....	19
i. Policy and Process for Recertification	19
ii. Plan ID Crosswalk.....	19
Section 4. OPM Certification of Multi-State Plan (MSP) Options.....	20
Chapter 2: Qualified Health Plan and Stand-Alone Dental Plan Certification Standards.....	21
Section 1. Licensure and Good Standing	21
Section 2. Service Area	22
Section 3. Network Adequacy	22
i. Network Adequacy Standard	22
ii. Provider Directory Links.....	24
Section 4. Essential Community Providers	24
i. Evaluation of Network Adequacy with respect to all ECPs	25
ii. Evaluation of Network Adequacy with respect to dental ECPs	30
Section 5. Accreditation	31
Section 6. Patient Safety Standards for QHP Issuers	32
Section 7. Quality Reporting	33
i. QHP Issuer Data Collection and Reporting Requirements	33
ii. Marketplace Oversight & Display Requirements.....	34
Section 8. Review of Rates	35
Section 9. Discriminatory Benefit Design.....	36
i. EHB Discriminatory Benefit Design.....	36
ii. QHP Discriminatory Benefit Design.....	37
Section 10. Prescription Drugs	38

i.	Formulary Outlier Review	40
ii.	Review of Prescription Drugs	41
	Section 11. Supporting Informed Consumer Choice/Meaningful Difference	41
	Section 12. Third Party Payment of Premiums and Cost-sharing	41
	Section 13. Cost-Sharing Reductions	42
	Section 14. Data Integrity Tool	43
	Chapter 3: Stand-alone Dental Plans: 2016 Approach.....	44
	Section 1. Stand-alone Dental Plan Rates	45
	Section 2. Intent to Apply	45
	Chapter 4: Qualified Health Plan Performance and Oversight	45
	Section 1. Account Management: 2016 Issues	45
	Section 2. QHP Issuer Compliance Monitoring Program	46
	Section 3. QHP Issuer Compliance Reviews.....	47
	Section 4. FFM Oversight of Agents and Brokers	48
i.	QHP Issuer Responsibilities.....	48
ii.	Agent and Broker Agreements	49
iii.	Monitoring and Oversight	50
iv.	Web-brokers.....	51
v.	Compensation.....	52
vi.	Registration Requirement for Re-enrollment Transactions.....	54
vii.	HHS-Approved Vendors of FFM Training and Information Verification.....	54
	Section 5. Oversight of Marketing Activities.....	54
	Chapter 5: FF-SHOPS.....	56
	Section 1. Dental Changes	56
	Section 2. Premiums Based on Average Enrollee Premium Amounts	57
	Section 3. Online Renewals	59
	Section 4. Employee Choice	60
	Section 5. Employer Group Size in the FF-SHOPS.....	61
	Chapter 6: Consumer Support and Related Issues	62
	Section 1. Consumer Case Tracking and Resolution	62
	Section 2. Coverage Appeals.....	63
	Section 3. Meaningful Access	63
	Section 4. Summary of Benefits and Coverage	65
	Section 5. Transparency in Coverage Reporting	66
	Chapter 7: Tribal Relations and Support.....	67

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 was the case for the 2015 benefit year, 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 ensuring 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 are conditions of offering health insurance in the State provided that the applicable laws are in accordance with Federal law. 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 along the timeline specified by CMS 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

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 this guidance references the "State."

beginning in 2016 maintains many aspects of the QHP certification process that CMS carried out in calendar year 2014 for plans effective beginning in 2015, including close coordination and collaboration with States. CMS is also incorporating 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 for evaluating QHPs against a certification standard when CMS is performing plan management functions for plan years beginning in 2016. States performing QHP certification reviews may exercise flexibility in their application of CMS's 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 calendar year that an issuer intends to continue to offer them on an FFM; or in the case of an FF-SHOP certification of a QHP, the QHP retains its certification

through the end of the employer’s plan year, which may extend beyond the calendar year for which the FF-SHOP certified the QHP.

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 plan years 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.

Activity		Dates (Approximate)
QHP Application Submission and Review Process	Initial FFM QHP Application Submission Window ⁴	4/15/2015 – 5/15/2015 ⁵
	FFM Review of Initial QHP Application Submissions Received as of May 15	5/18/2015 – 6/26/2015
	First Correction Notice Sent	6/29/2015 – 6/30/2015

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. This submission deadline applies to URRT and Form Filing submissions for QHPs and non-QHPs.

⁵ The deadline for a health insurance issuer to submit all QHP and non-QHP URR rate filing justifications to CMS and the applicable State is May 15th. The deadline for a State with an Effective Rate Review Program to post on the State’s website at least the information contained in Parts I, II, and III of the Rate Filing Justification that CMS makes available on its website for proposed rate increases subject to review (or post a link to the information on the CMS website) is the 10th business day after receipt of all rate filings in the relevant market segment.

Activity		Dates (Approximate)
	Deadline for Submission of Revised QHP Data for Re-review	7/10/2015
	FFM Review of Corrected QHP Application Submissions Received as of July 10	7/13/2015 – 8/12/2015
	Second Correction Notice Sent	8/13/2015 – 8/14/2015
	Final Deadline for Submission of QHP Data; Final Deadline for State Plan Approval; Deadline for All Risk Pools with QHPs to be in “final” status in the URR System; ⁶ Data Locked Down	8/25/2015
	Final FFM Review of Corrected QHP Application Submissions Received as of August 25	8/26/2015 – 9/16/2015
QHP Agreement/Final Certification	Certification Notices and QHP Agreements Sent to Issuers	9/17/2015 – 9/18/2015 ⁷
	Agreements Signed by Issuers and Returned to CMS with Final Plan List	9/21/2015 – 9/25/2015
	Validation Notice Confirming Final Plan List and Countersigned Agreements Sent to Issuers	10/8/2015 – 10/9/2015
Open Enrollment		11/1/2015 – 1/31/2016

⁶ There are three final submission statuses in HIOS. All submissions in the single risk pool with QHPs that do not have any rate increases subject to review (rate increase less than 10%) must be in a status of “Rate Filing Accepted.” For submissions with rate increases that are subject to review (rate increase of 10% or greater), the submission must be in a status of “Review Complete” if the rate increase received a determination of “not unreasonable,” or in a status of “Final Justification Submitted” if the rate increase received a determination of “unreasonable” and the issuer has submitted the final justification.

⁷ All risk pools with no QHPs must be in final status in the URR system by September 18, 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 register in the CMS Enterprise Identity Management System (EIDM) to gain access to HIOS where they request user roles (such as QHP Issuer Submitter and QHP Issuer Validator) and obtain HIOS user IDs. Issuers must obtain HIOS product and plan IDs. Once issuers have registered in the EIDM and HIOS systems, they are required to obtain a Health Plan Identifier (HPID) in the Health Plan and Other Entity System (HPOES) if they meet the definition of a controlling health plan at 45 C.F.R. § 162.103. In addition, each health plan that an issuer intends to offer on the Marketplace is required to obtain an HPID if it is a controlling health plan.⁸

CMS expects that between April 15, 2015 and May 15, 2015 issuers will access the QHP Application in HIOS to submit all information necessary for certification of health plans and SADPs as QHPs. CMS will use the QHP Application to 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 cover the adherence of the vendors and contractors of the issuer 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 referenced in Table 1.1 above. In the 2016 Payment Notice Final Rule, CMS requires issuers not seeking to offer QHPs to submit the URRT on this same timeline.

Under the Uniform Timeline for Submitting the URRT for on and off-Marketplace coverage, issuers will enter their submissions into the HIOS Rate Review Module for both their QHPs and their non-QHPs at the same time. In addition to the initial submission period, issuers will be able to make corrections to their URRT and upload supplemental materials needed to complete the review in direct enforcement States. In enforcing States when the State requires an issuer to make changes and the rate filing is altered, causing a change to the URRT, the issuer must revise its URRT in HIOS, ensuring that both the State and CCIIO have matching URRTs.

⁸ Additional information related to HPID requirements is available at: [http://www.cms.gov/ccio/Resources/forms-reports-and-other-resources/index.html#Health Insurance Market Reforms](http://www.cms.gov/ccio/Resources/forms-reports-and-other-resources/index.html#Health%20Insurance%20Market%20Reforms).

Consistent with the approach for plan years beginning in 2015, issuers do not need to submit URRTs for SADPs.

ii. Issuer Data Collection and Coordination with States

CMS expects States to review plans seeking QHP certification for compliance with all applicable requirements under State law, as well as market-wide standards established by the Affordable Care Act. Specifically, CMS expects States to review these plans for compliance with essential health benefits (EHB) requirements and actuarial value (AV) standards, among others.⁹ State regulators may request access to QHP data templates to facilitate review of these plans.

Issuers in direct enforcement States will also be required to comply with any CMS requirements related 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.¹⁰

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 May 15, 2015. CMS will not consider plans for which QHP Applications are received after this date. CMS will not conduct certification reviews of plans that

⁹ 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 only for compliance with applicable Affordable Care Act standards.

¹⁰ Additional information on the CMS requirements for rate and form filings in direct enforcement States is available at: [http://www.cms.gov/ccio/Resources/forms-reports-and-other-resources/index.html#Health Insurance Market Reforms](http://www.cms.gov/ccio/Resources/forms-reports-and-other-resources/index.html#Health%20Insurance%20Market%20Reforms).

are submitted for offering only outside of the FFM. Additionally, if an issuer changes its application to indicate that plans will only be offered outside of the FFMs, such plans will no longer be eligible for certification. CMS reviews all prospective SADPs, whether offered on or off an FFM.

CMS expects to review FFM QHP Applications in two rounds: the first review period occurring between May 18 and June 26, 2015 and the second review period occurring between July 13 and August 12, 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 August 25, 2015. Issuers must submit all final QHP data by August 25, 2015.

Issuers may withdraw plans prior to August 25, 2015 by removing the plan from their QHP Application and submitting a plan withdrawal notification form.¹¹ Issuers will be given a final opportunity to withdraw plans during the agreement signing process.

After August 25, 2015, CMS will conduct a final round of review and make final certification decisions. CMS will notify issuers of its certification decisions between September 17 and September 18, 2015 followed by the QHP Agreement signing process. Issuers will not have an opportunity to make any further corrections to their QHP Application data after receiving CMS certification notices and prior to QHP 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 final 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 below. These changes are in addition to any corrections that CMS has identified during its review of QHP Applications. Table 1.2 presents a high-level overview of key dates during the QHP data change process for FFMs. Each phase of the process is described in greater detail in the subsections that follow Table 1.2.

¹¹ The plan withdrawal notification form discussed here is not the same as HIPAA product discontinuation or market withdrawal. CMS intends to provide more details on the form for withdrawal from QHP certification in future guidance.

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	<p>Issuers will submit QHP Applications including recertification for 2015 plans and new 2016 plans.</p> <p>Issuers may make any changes to their data without State or CMS authorization.</p>	4/15/2015 – 5/15/2015
QHP Review and Modification	<p>No new plans may be submitted.</p> <p>Petition to CMS required for changes to service area.</p> <p>Petitions must be submitted by 8/11/2015.</p> <p>For all other changes, issuers are not required to submit petitions or document State authorization to CMS.</p> <p>CMS will monitor all data changes and contact issuers if there are concerns about changes made.</p>	5/16/2015 – 8/25/2015
After Final Data Submission	<p>No further data changes allowed prior to Certification.</p> <p>CMS may allow issuers to make critical post-certification data corrections in order to:</p> <ul style="list-style-type: none"> • Correct data display errors on HealthCare.gov, and • Align QHP plan display with products and plans approved by the State. <p>Post-certification data corrections require data change petitions and State and CMS</p>	8/26/2015 – onward

	approval. Allowed changes will occur during periodic, scheduled limited data correction windows.	
--	--	--

Initial Application Submission

As described in Section 1 of Chapter 1, issuers will submit their initial QHP Applications between April 15 and May 15, 2015, including applications for SADPs to be offered on and off the FFM. ¹² 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 August 25, 2015. Issuers will be able to upload revised QHP data templates and make other necessary changes to QHP Applications in response to State or CMS feedback until the final data submission deadline. An issuer may also submit a petition to make service area changes during this period, as further described below. All changes must be authorized by the State, but issuers are only required to submit evidence of State approval for service area changes. For QHPs in direct enforcement States, the CMS Form Filing team, instead of the State, must authorize data changes. CMS reviews will be based on the issuer QHP data as of the specific due dates as listed in Table 1.1.

After the initial submission deadline of May 15, 2015, issuers cannot add new plans to a QHP Application or change an off-Marketplace plan to both on- and off-Marketplace.

CMS intends to implement a petition process to receive and review requests for service area changes after the initial application deadline of May 15, 2015, but before the final data submission deadline on August 25, 2015. The petition process will require a signed data change

¹² 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. This submission deadline applies to URRT and Form Filing submissions for QHPs and non-QHPs. The deadline for a State with an Effective Rate Review Program to post on the State’s website (if the State elects to post on its website) at least the information contained in Parts I, II, and III of the Rate Filing Justification that CMS makes available on its website is the 10th business day after receipt of all rate filings in the relevant market segment.

request form, justification for the change, and evidence of State approval. Requests for service area changes must be submitted with evidence of State approval at least two weeks prior to the final data submission deadline in order to allow CMS sufficient time for review. Issuers must submit approved service area changes to QHP Applications prior to the final data submission deadline of August 25, 2015.

CMS will monitor all data changes made by issuers during this period. If there are concerns about changes made, CMS will contact the issuer to determine next steps.

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

After Final Data Submission

After August 25, 2015, HIOS will close 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 limited data correction windows, during which issuers will not be allowed to make further changes to QHP data unless changes are pre-approved by CMS and the State. For QHPs in direct enforcement States, the CMS Form Filing team instead of the State must authorize data changes, so, for issuers in direct enforcement States, references here to the “State” mean the CMS Form Filing team. During a data correction window, issuers may request to make changes necessary to correct data display errors or align QHP data 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. 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 set forth 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 a plan not being certified or a compliance action if CMS has already certified a plan as a QHP. Issuers that request to make changes that affect consumers may be suppressed until the data are refreshed for consumer display. Additional requirements may apply, and CMS intends to release further instructions about 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 FFMs

This section describes how States performing plan management functions in the FFMs 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 FFMs 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.¹³ 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

¹³ 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.

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. 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 Applications denied. 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 ¹⁴
	First SERFF Data Transfer Deadline for States ¹⁵	5/15/2015
QHP Application Submission and Review Process	FFMs Review Plan Data	5/18/2015 – 6/26/2015
	FFMs Notify States and Issuers of any Needed Corrections to QHP Data	6/29/2015 – 6/30/2015
	Issuers Resubmit Plan Data into SERFF	Varied ¹⁶
	Second SERFF Data Transfer Deadline for States	7/10/2015
	FFMs Conduct Re-review of Plan Data	7/13/2015 –

¹⁴ Date varies as determined by each respective State application submission deadline.

¹⁵ The deadline for a health insurance issuer to submit (and validate in HIOS) all QHP and non-QHP URR rate filing justifications to CMS and the applicable State is May 15th.

¹⁶ Date varies as determined by each respective State application submission deadline.

Activity		Dates (Approximate)
		8/12/2015
	FFMs Notify States and Issuers of any Needed Corrections to QHP Data	8/13/2015 – 8/14/2015
	Issuers Resubmit Plan Data into SERFF	Varied ¹⁷
	Final SERFF Transfer 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	8/25/2015 ¹⁸
	FFMs Conduct Final Review of QHP Application Data	8/26/2015 - 9/16/2015
QHP Agreement/Final Certification	Certification Notices and QHP Agreements Sent to Issuers	9/17/2015 – 9/18/2015
	Agreements Signed by Issuers and Returned to CMS with Final Plan List	9/21/2015 – 9/25/2015
	Validation Notice Confirming Final Plan List and Countersigned Agreements Sent to Issuers	10/8/2015 – 10/9/2015
Open Enrollment		11/1/2015 – 1/31/2016

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 submitting an application 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

¹⁷ Date varies as determined by each respective State application submission deadline.

¹⁸ All risk pools with no QHPs must be in “final” status in the URR system by October 9, 2015.

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 Final Rule, CMS requires 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 deadlines 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 May 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 May 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 and issuers 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 July 10, 2015. CMS will review the data transferred by July 10, 2015 and will notify States and issuers of any needed corrections. States will again be able to work with issuers to revise their submissions according to CMS and State feedback.

A State must transfer all final plan data from SERFF to HIOS by August 25, 2015 and CMS will use the data transferred by August 25, 2015 to make final QHP certification decisions based on State recommendations. CMS will notify issuers of its certification decisions between September 17 and September 18, 2015 followed by the QHP Agreement signing process. Issuers will not have an opportunity to make any further corrections to their QHP Application data after receiving CMS certification notices and prior to QHP Agreement signing.

ii. Data Changes

Issuers in States performing plan management functions in the FFMs will be able to view their plan data once Plan Preview is available and after the State transfers QHP data from SERFF to HIOS. 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.

After August 25, 2015, SERFF data submissions will close, 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 August 25, 2015. After QHP 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 2014 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 will use the amended definition of "plan" from §144.103 of the 2016 Payment Notice Final Rule. 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

For the individual market 2015 plan 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 facilitated 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 of employees and dependents 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, should 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).¹⁹ 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 FFM 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, 2014.²⁰ 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 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.

¹⁹ 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.

²⁰ 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.

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.

The 2016 MSP Program Call Letter was released on January 22, 2014 and is available at <http://www.opm.gov/healthcare-insurance/multi-state-plan-program/program-guidance/#url=2015>. This letter serves as OPM's annual call for applications and recertification submissions from prospective and current MSP issuers. It also highlights program priorities and re-emphasizes MSP issuers' obligations around the Program's External Review Process and coverage of abortion services.

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 “good standing” to mean that an issuer faces no outstanding sanctions imposed by a State’s department of insurance. Therefore, the specific violations or infractions that would jeopardize standing may vary by State. Issuers must be 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 offering health insurance in the State provided that the applicable laws are in accordance with Federal law.
- 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 requirements for an issuer's service area(s) 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 application 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 in considering future additional rulemaking.

ii. *Provider Directory Links*

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 stated in the 2016 Payment Notice Final Rule, CMS is strengthening the provider directory requirement. Specifically, a QHP issuer must publish an up-to-date, accurate, and complete provider directory, including information on which providers are accepting new patients, the provider's location, contact information, specialty, medical group, and any institutional affiliations, in a manner that is easily accessible to plan enrollees, prospective enrollees, the State, the FFM, HHS, and OPM. A provider directory will be considered up-to-date 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 in the provider directory on the issuer'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, including the tier in which the provider is included, should be clearly identified on the website and in the provider directory.

CMS is also 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. The purpose of establishing machine-readable files with this data is to provide the opportunity for third parties to create resources that aggregate information on different plans. We believe this will increase transparency by allowing software developers to access this information and create innovative and informative tools to help enrollees better understand the availability of providers in a specific plan. CMS established these provider directory requirements to enhance the transparency of QHP provider directories and to help consumers make more informed decisions about their health care coverage.

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

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. In the 2016 Payment Notice Final Rule, we clarified that ECPs may also include not-for-profit or State-owned providers that are entities described in section 340B of the PHS Act but do not participate in the 340B Program, as these providers satisfy the same 340B eligibility requirements and therefore meet the definition of ECPs by virtue of the following description in section 1311(c)(1)(C) of the Affordable Care Act – “health care providers defined in section 340B(a)(4) of the PHS Act and providers in section 1927(c)(1)(D)(i)(IV) of the Act.” For the same reasons described above, not-for-profit or governmental family planning service sites that do not receive a grant under Title X of the PHS Act also qualify as ECPs. Furthermore, Indian health care providers are included among other ECPs, as reflected in Table 2.1. 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.

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 care 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 Addendum²¹ for Indian health care providers developed by CMS; and

²¹ The model QHP Addendum for Indian health care providers is available at: <http://www.cms.gov/ccio/programs-and-initiatives/health-insurance-marketplaces/qhp.html>.

- 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 requests to verify 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>.

In the 2016 Payment Notice Final Rule, we clarified that for purposes of inclusion on the non-exhaustive ECP list, those Medicare-certified rural health clinics (RHCs) that meet the following two requirements will be included: 1) based on attestation, the clinic accepts patients regardless of ability to pay and offers a sliding fee schedule; or is located in a primary care Health Professional Shortage Area (geographic, population, or automatic²²); and 2) Accepts patients regardless of coverage source (i.e., Medicare, Medicaid, CHIP, private health insurance, etc.). CMS has determined that all RHCs included on the non-exhaustive ECP list meet these standards.

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

²² As of January 1, 2014, more than 1,000 Rural Health Clinics (RHCs) were designated as an automatic Health Professional Shortage Area (HPSA), the criteria for which include accepting patients regardless of ability to pay; offering a sliding fee schedule based on ability to pay (income); and accepting Medicare, Medicaid, CHIP, and private health insurance patients. To receive the automatic HPSA designation, each RHC is required to complete an attestation form, which is available at: <http://bhpr.hrsa.gov/shortage/hpsas/certifeligibility.pdf>. CMS intends to include RHCs that are not listed on the current non-exhaustive ECP list and complete the attestation form to receive an automatic HPSA designation through the Health Resources and Services Administration in future non-exhaustive ECP lists. More information about the HPSA designation requirements and process is also available at: <http://bhpr.hrsa.gov/shortage/hpsas/ruralhealthhpsa.html>.

in section 340B of the PHS Act, but do not participate in the Program. 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., Medicare, Medicaid, CHIP, private health insurance, etc.).

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”²³;
- 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.
- 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 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 care providers in the service area,

²³ “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>

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 care 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 FQHCs, Indian health care providers, Ryan White HIV/AIDS Program providers, or family planning providers are missing from the network(s), the Application must explain how its target populations will be served.

Table 2.1: 2016 ECP Categories and Provider Types in the FFM

Major ECP Category	ECP Provider Types
Family Planning Providers	Title X Family Planning Clinics and Title X “Look-Alike” Family Planning Clinics
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
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

Major ECP Category	ECP Provider Types
Indian Health Care Providers	Indian Health Service (IHS providers), Indian Tribes, Tribal organizations, and urban Indian Organizations
Ryan White Providers	Ryan White HIV/AIDS Program Providers
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)²⁴ 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 line (FPL).

To ensure that consumers experience equal access to covered benefits, regardless of whether they are enrolled in plans offered by issuers that qualify for the general or the alternate ECP standard, issuers that qualify for the alternate ECP standard must provide access to the same categories of services provided by entities in each of the ECP categories in each county in the plan’s service area as issuers that qualify for the general ECP standard. Therefore, in the 2016 Payment Notice Final Rule at §156.235(b)(2)(ii), issuers that qualify for the alternate ECP standard must provide within the issuer’s integrated delivery system all of the categories of services provided by entities in each of the ECP categories in each county in the plan’s service area as outlined in the general ECP standard; or otherwise offer a contract to at least one ECP outside of the issuer’s integrated delivery system per ECP category in each county in the plan’s service area that can provide those services to low-income, medically underserved individuals. Issuers that qualify for the alternate

²⁴ 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.

ECP standard are not reviewed for compliance with the additional general ECP standard requirement of offering contracts in good faith to all available Indian health care providers.

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 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, on the condition that they do not limit their practice on the basis of a particular source of coverage (e.g., Medicare, Medicaid, CHIP, private health insurance, etc.).

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 care 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 care 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 (AAHHC) 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 AAHHC with "Accredited," status; by NCQA with "Excellent," "Commendable," "Accredited," "Provisional," 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 more 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,”²⁵ 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 collect and report validated data annually, 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.²⁶ 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 this data are those with more than 500 enrollees in the previous year that have been offered in an FFM for at least one year.²⁷ 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.²⁸

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

²⁵ 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.

²⁶ 45 C.F.R. 156.1120

²⁷ 45 C.F.R. 156.1125

²⁸ Additional information on the Marketplace Quality Initiatives is available at:

<http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Health-Insurance-Marketplace-Quality-Initiatives.html>.

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 marketing materials in a manner specified by HHS.²⁹ 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.

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 Marketplaces 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 2014.³⁰ 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 and publish updated technical guidance based on the beta test.

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 Marketplaces. 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 the 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

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

³⁰ 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>.

Survey, as calculated by HHS and in a form and manner specified by HHS.³¹ Guidance related to the Marketplace display requirements is forthcoming.

The FFM 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 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; and
- 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 all rate

³¹ 45 C.F.R. 155.1400 and 155.1405

increases subject to review, the issuer will enter justifications in Part II of the URR rate filing justification in the rate review module of HIOS.

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.

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. We also remind issuers that individuals under age 65 with end stage renal disease (ESRD) are not required to sign up for or enroll in Medicare. Further, individuals who do not have Medicare Part A or Part B are eligible to enroll in individual market coverage, including a QHP, if the individual meets the eligibility requirements for enrollment (i.e., criteria related to citizenship, lawful presence, incarceration, and residency).³²

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.

In the 2016 Payment Notice Final Rule, CMS addressed 45 CFR §156.125, which implements a prohibition on discrimination by issuers providing EHB. Also in the 2016 Payment notice Final Rule, CMS discussed three examples of potentially discriminatory practices. CMS cautions both

³² For more information, see Frequently Asked Questions Regarding Medicare and the Marketplace, August 1, 2014, available at: http://www.cms.gov/Medicare/Eligibility-and-Enrollment/Medicare-and-the-Marketplace/Downloads/Medicare-Marketplace_Master_FAQ_8-28-14_v2.pdf.

issuers and States that age limits may potentially be discriminatory when applied to services that have been found clinically effective at all ages. For example, it might 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 might effectively discriminate against, or discourage 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 might effectively discriminate against, or discourages enrollment by, individuals who have those chronic 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.

Section 1302(b) of the Affordable Care requires that the definition of EHB be based on the scope of benefits provided under a typical employer plan, subject to requirements under the joint interpretive jurisdiction of the Departments of HHS, Labor, and the Treasury.³³ Because the nondiscrimination provisions are related to many other such requirements, HHS will consult with relevant Federal agencies, such as the Departments of Labor and the Treasury, as necessary in developing new guidance related to discriminatory benefit designs.

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,

³³ To inform the determination as to the scope of a typical employer plan, section 1302(b)(2)(A) of the Affordable Care Act requires the Secretary of Labor to conduct a survey of employer sponsored coverage to determine the benefits typically covered by employers, and to provide a report to the Secretary of HHS. These provisions suggest that, while detailed requirements for EHB in the individual and small group health insurance markets were deemed necessary, the benefits covered by typical employer plans providing primary coverage at the time the Affordable Care Act was enacted were seen as sufficient to satisfy the Act’s objectives for the breadth of benefits needed for health plan coverage and, in fact, to serve as the basis for determining EHB.

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 identified above, 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 documents 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 as part of the QHP Application. Similar to 2015, CMS will collect QHPs' formulary drug list URLs as part of the QHP Application and will make formulary drug list links provided by issuers available to consumers on HealthCare.gov. This formulary drug list URL link should be the same direct formulary drug list link for obtaining

information on prescription drug coverage in the Summary of Benefits and Coverage, in accordance with 45 C.F.R. 147.200(a)(2)(i)(K).

In the 2016 Payment Notice Final Rule, CMS finalized a number of changes to the EHB prescription drug benefit. While some of these changes are not applicable until 2017, some of these changes apply starting with the 2016 plan year. These changes include a requirement that issuers' formulary drug lists be up-to-date, accurate, and include a complete list of all covered drugs. The formulary drug list must include any tiering structure that the plan has adopted and any restrictions on the manner in which a drug can be obtained. The Final Rule clarifies that for the purpose of 45 C.F.R. 156.122(d), for a formulary drug list to be considered complete, the formulary drug list must list all drugs that are EHB, and list all drug names that are currently covered by the plan at that time. The formulary drug list does not have to list every covered formulation for each covered drug, but the issuer should be prepared to provide information on the specific formulations upon request. Issuers must also include accurate information on any restrictions on the manner in which an enrollee can obtain the drug, including prior authorization, step therapy, quantity limits, and any access restrictions related to obtaining the drug from a brick and mortar retail pharmacy. The formulary drug list must be up-to-date, which means that the formulary drug list must accurately list all of the health plan's covered drugs at that time.

The formulary drug list must be published 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 is 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 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. The purpose of establishing machine-readable files with this data is to provide the opportunity for third parties to create resources that aggregate information on different plans. We believe this will increase transparency by allowing software developers to access this information and create innovative and informative tools to help enrollees better understand the drug coverage in a specific plan. CMS established these requirements to enhance the transparency of QHP formulary drug lists and to help consumers make more informed decisions about their health care coverage.

The 2016 Payment Notice Final Rule also includes new 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 provisions include a requirement that starting with the 2016 plan year, an issuer must 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 must have a process for the enrollee or the enrollee's designee or the prescribing physician (or other

prescriber) to request that the denied exception request be reviewed by an independent review organization. As part of these requirements, we also finalized in the 2016 Payment Notice Final Rule that in the event that an exception request is granted, the plan must treat the excepted drug(s) as an EHB, including by counting any cost-sharing towards the plan's annual limitation on cost-sharing under 45 C.F.R. 156.130, and that a health plan that grants a standard exception request must provide coverage of the excepted non-formulary drug for the duration of the prescription, including refills (or in the case of an expedited request, a health plan that grants an exception must provide coverage of the excepted non-formulary drug for the duration of the exigency). Issuers must update their policies and procedures to reflect the new requirements for plan years beginning in 2016. In addition to the above standards, CMS continues to encourage issuers to temporarily cover non-formulary drugs, as well as 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.

Finally, as discussed in the 2016 Payment Notice Final Rule, CMS is concerned about issuers making mid-year formulary changes, and especially changes that negatively affect enrollees. In particular, for QHPs, we have concerns about these changes to the plan design when the plan design was certified under the assumption that it was going to cover specific benefits. For these reasons, we are monitoring this issue and whether further standards are needed on the updating of formulary drug lists. We note that under guaranteed renewability requirements and the definitions of "product" and "plan," issuers generally may not make plan design changes, including changes to drug formularies, other than at the time of plan renewal. However, we recognize that certain mid-year changes to drug formularies related to the availability of drugs in the market may be necessary and appropriate. Such changes generally would not affect a QHP's certification.

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 QHP for follow-up based on this review, CMS will offer the issuer the opportunity to resolve the identified issue as part of the certification process. CMS anticipates that it will 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 FFMs to implement this type of review.

ii. Review of Prescription Drugs

CMS will review each QHP's prescription drug coverage to ensure that it meets applicable standards in 45 C.F.R. 156.225 and 45 C.F.R. 156.125. Based on data submitted by issuers in the prescription drug template, this 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. Other conditions, including HIV, may be considered as part of future reviews.

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.³⁴

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 Final Rule.
- 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)³⁵) 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.

³⁴ 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.

³⁵ 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.

- 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.³⁶
- 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 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

³⁶ 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.

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),³⁷ and their limited scope of benefits. The charts below (Tables 3.1 and 3.2) are intended to assist issuers in understanding those standards that are applicable or not applicable to SADPs seeking certification in the FFMs for plan years beginning in 2016, and are 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. As previously noted, States that are performing QHP certification reviews have flexibility in their application of QHP certification standards including SADPs, provided that the State’s application of each standard is consistent with CMS regulations and guidance.

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

Standard or Tool Applies (* denotes modified standard)	
Essential Health Benefits*	Actuarial Value*
Annual Limits on Cost-sharing*	Licensure
Network Adequacy	Inclusion of ECPs
Marketing	Service Area
Non-discrimination	Acceptance of Third Party Premium and Cost-sharing Payments
Data Integrity Tool	

³⁷ 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.

Table 3.2: Standards and Tools Not Applicable to Stand-alone to Dental Plans

Standard or Tool Does Not Apply	
Accreditation	Patient Safety
Cost-sharing Reduction Plan Variations	Quality Reporting
Unified Rate Review Template	Prescription Drugs
Meaningful Difference	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 section 1302(b)(4)(F) of the Affordable Care Act, QHP issuers are permitted to offer QHPs that omit coverage of the pediatric dental EHB if a SADP is offered 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 will follow a similar approach for 2016.

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 SBMs that use CMS’s eligibility system and platform (i.e., HealthCare.gov and the FFM Call Center). For issuers offering QHPs through the Marketplace for the first time, CMS will assign an Account Manager prior to the start of open enrollment for the 2016 plan year. The Account Managers will serve as issuers’ primary point of contact with the FFM 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 Rule³⁸ 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. The 2016 Payment Notice Final Rule extended that policy through the 2015 calendar year. Under that policy, for the 2015 calendar year, CMS will not impose civil monetary penalties on issuers or decertify QHPs that are not in compliance with applicable Marketplace requirements 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.

³⁸ Patient Protection and Affordable Care Act: Program Integrity: Exchange, SHOP and Eligibility Appeals; Final Rule, 78 Federal Register 54070 (August 30, 2013); codified at 45 C.F.R. Parts 147, 153, 155, and 156).

Regardless of the good faith compliance policy, issuers are expected to be in compliance with all applicable Marketplace standards at all times.

The good faith compliance policy will end after 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 standard³⁹ 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 targeted⁴⁰ review specific to the area(s) of potential non-compliance and/or conduct the compliance review on an expedited basis.⁴¹ 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 review⁴² and the type and location of the review will be included in the issuer selection notification. CMS will review data at both the

³⁹ Standard reviews include all review areas.

⁴⁰ Targeted reviews can include all review areas or just select review areas.

⁴¹ Issuers selected for expedited compliance reviews will be required to submit documentation with a shorter turnaround time.

⁴² On-site reviews will take place at the issuer's place of business.

issuer and the QHP/SADP level. CMS may request, as part of the compliance review process, policies, procedures, and any other applicable documentation⁴³ 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 FFMs. It also provides an overview of accompanying QHP and SADP 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 FFMs. Unless noted otherwise, references to agents and brokers include web-brokers.⁴⁴

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 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 brokers' FFM registration and training status according to the registration completion list on the CMS agent and broker resources page.⁴⁵ CMS intends to update the list of registered agents and brokers frequently, and QHP issuers will not have to collect training certificates and FFM user IDs from agents and brokers who complete plan year 2016 FFM registration. In addition to verifying registration and training status, QHP issuers are responsible for ensuring that activities related to the FFMs that are conducted on their behalf by affiliated agents and brokers (e.g., enrollment) comply with applicable Federal standards, including those related to privacy and security, conflict(s) of interest, marketing, and continuing education. CMS believes that these steps, at a minimum, would be required for a QHP issuer to

⁴³ Additional documentation could include sample sets of applicable data (i.e., notices, claims, complaints, etc.).

⁴⁴ 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).

⁴⁵ This page is available at: <http://www.cms.gov/CCIIO/programs-and-initiatives/health-insurance-marketplaces/a-b-resources.html>. CMS intends to continue updating the list at least twice monthly.

demonstrate good faith efforts at complying with 45 CFR 156.340 as it relates to oversight of affiliated agents and brokers.

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.⁴⁶ Before assisting consumers in the FFMs, 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 the applicable agreement(s) with CMS as part of the registration process with the FFMs. 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 agreement(s), agents and brokers attest that they will:

- 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;

⁴⁶ These include the eight privacy principles listed at 45 C.F.R. 155.260(a)(3).

- Maintain valid licensure in all States where they wish to enroll qualified individuals and employers/employees into QHPs through the FFMs; and
- Complete the full FFM registration process in advance of assisting consumers, including taking all applicable training.

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 FFMs, and will monitor QHP issuer activities to confirm they are meeting their responsibilities for oversight of affiliated agents and brokers.

CMS 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 (based on what Federal standards have been violated, and factors such as financial impact and number of consumers affected), 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.⁴⁷ 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 FFMs), 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.

CMS will inform States, QHP issuers, and FFM consumers of agents and brokers who have had their registration terminated for cause pursuant to 45 C.F.R. 155.220(g) by posting a list of those agents' and brokers' NPNs on the CMS agent and broker resources webpage.⁴⁸ An agent's or broker's NPN would only be added to this revocation list after the conclusion of the reconsideration process, or the expiration of the time permitted for such activity.⁴⁹ Prior to posting the revocation list, CMS intends to adopt safeguards to ensure the accuracy of the NPN information. We note that termination for cause does not include a natural termination due to a lapse in completion of the annual registration requirements.

⁴⁷ 45 C.F.R. 155.220(g)

⁴⁸ This page is available at: <http://www.cms.gov/CCIIO/programs-and-initiatives/health-insurance-marketplaces/a-b-resources.html>.

⁴⁹ 45 C.F.R. 155.220(h)

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 Marketplaces, 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 Marketplaces. Whether the agent or broker, or QHP issuer would be responsible for the civil money penalty will depend on an analysis of the particular facts and circumstances of the situation. The good faith compliance policy described in Section 2 above was extended only through the 2015 calendar year.

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 FFMs.⁵⁰ 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).

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 individual market QHPs⁵¹ through the FFMs online, alongside traditional agents and brokers who assist consumers with enrollment through the Marketplaces.

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.

Regulations at 45 C.F.R. 155.220(c)(3)(i) generally require web-brokers to disclose and display all QHP information provided to them by the FFMs or directly by QHP issuers. To the extent that not all information required under 45 C.F.R. 155.205(b)(1) is displayed on the web-broker’s website, the web-broker must prominently display a standardized disclaimer provided by CMS

⁵⁰ 45 C.F.R. 155.220(c)(3),(4)

⁵¹ Pursuant to 45 C.F.R. 155.220(i), as amended by the 2016 Payment Notice Final Rule, 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 enrollees in SHOP QHPs, subject to the requirements of 45 C.F.R. 155.220(c)(3). The FF-SHOPS may elect to implement this functionality for plan years beginning in 2016.

stating that information required under 45 C.F.R. 155.205(b)(1) for the QHP is available on HealthCare.gov, and provide an operational link to HealthCare.gov. This disclaimer is in addition to the requirement that web-brokers must prominently display a standardized disclaimer on its website to inform consumers that the website is not an official FFM website, and provide an operational link to HealthCare.gov.

In the 2016 Payment Notice Final Rule, CMS specified that a web-broker's existing obligation under 45 C.F.R. 155.205(c)(2)(i) to provide oral interpretation services includes making available telephonic interpreter services in at least 150 languages. This standard applies to web-brokers beginning November 1, 2015, or one year after a web-broker registers with the FFM, whichever date is later.

CMS also specified language access requirements for web-brokers pertaining to taglines and translation of website content which will become applicable beginning with the first day of the open enrollment period for the individual market for the 2017 benefit year, or one year after a web-broker registers with the FFM, whichever date is later. First, under 45 C.F.R. 155.205(c)(2)(iii)(B), we specified that a web-broker's existing obligation to include taglines in non-English languages specifically includes providing taglines on website content and any document that is critical for obtaining health insurance coverage or access to health care services through a QHP for qualified individuals, applicants, qualified employers, qualified employees, or enrollees. Such taglines must indicate the availability of language services in at least the top 15 languages spoken by individuals with limited English proficiency in the relevant State, as determined in HHS guidance. A document is deemed to be critical for obtaining health insurance coverage or access to health care services through a QHP if it is required to be provided by State or Federal law or regulation to a qualified individual, applicant, qualified employer, qualified employee, or enrollee. Second, under 45 C.F.R. 155.205(c)(2)(iv)(C), we specified that a web-broker must translate website content that is intended for a qualified individual, applicant, qualified employer, qualified employee, or enrollee on a website maintained by the web-broker into any non-English language that is spoken by an LEP population that reaches 10 percent or more of the population of the relevant State, as determined in HHS guidance.⁵² We intend to publish data identifying the non-English languages that are triggered by these standards for each State as well as sample taglines in future guidance.

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

⁵² We note that based on current data and subject to future changes, this threshold triggers the translation of website content into Spanish in California and Texas.

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 do not set compensation levels or pay commissions to agents or brokers. CMS does not require QHP issuers to offer contracts to agents and brokers, including offering compensation for enrollment in QHPs through the FFMs. QHP issuers should compensate only affiliated agents and brokers that are compliant with applicable Federal requirements, including those for registration with the FFMs.⁵³ CMS believes that withholding compensation from affiliated agents and brokers who fail to comply with FFM registration and other applicable Federal requirements would generally be required for an issuer to demonstrate good faith efforts at complying with 45 CFR 156.340 as it relates to oversight of affiliated agents and brokers.

The FFMs transmit the identifying information of agents and brokers (e.g., national producer number (NPN)) to QHP issuers on the 834s, but the FFMs do not play a role in setting compensation levels or ensuring that compensation is paid to agents and brokers because the FFMs are 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 Marketplaces.⁵⁴ This compensation approach is a required participation standard for QHP issuers offering coverage in the FFMs, including both the Individual Market and SHOP.

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.⁵⁵

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

⁵³ See “i. QHP Issuer Responsibilities” under this section, and 45 C.F.R. 156.340.

⁵⁴ 45 C.F.R. 156.200(f)

⁵⁵ 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>.

enrollment of any individuals or employees in a QHP or non-QHP. All agents and brokers should follow State standards with respect to charging consumers directly for services provided.

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 directly assisting consumers to facilitate the re-enrollment in a QHP through the FFMs, 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 involve agent or broker assistance, agents or brokers must have a current registration with the FFMs at the time they are assisting consumers.

vii. HHS-Approved Vendors of FFM Training and Information Verification

In the 2016 Payment Notice Final Rule, HHS establishes standards at 45 C.F.R. 155.222 for approved vendors to provide training and information verification services by which State licensed agents and brokers could complete the training requirements necessary to assist consumers seeking coverage through the FFMs. This provides an additional avenue by which agents and brokers could satisfy the requirement to receive training in the range of QHP options and the insurance affordability programs; HHS will continue to offer training. An entity that is interested in becoming a vendor would be required to submit an application and, upon approval of the application, execute an agreement with HHS. Vendors will be approved for one-year terms and those seeking to continue their recognition the following year must be re-approved by HHS. Approved vendors are also required to adhere to HHS specifications for content, format, and delivery of training and information verification; and to collect, store, and share with HHS all data from agent and broker users of the vendor's training and information verification in a manner, format, and frequency specified by HHS. HHS will post the list of all approved vendors on its website. HHS also anticipates monitoring and auditing vendors' compliance after launching of their respective training and information verification programs, and HHS may revoke approval if the vendor does not comply with HHS standards. Entities whose applications are not approved or who have their approval revoked may request an appeal.

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 FFMs, 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. We recommend that as a best practice, a non-FFM website should indicate if it does not offer all available Marketplace plans, and note that web-broker websites must provide consumers the ability to view all QHPs offered through the Exchange.⁵⁶ 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 a Health Insurance Marketplace website, and an active link to HealthCare.gov

⁵⁶ 45 C.F.R. 155.220(c)(3)(ii)

must also be provided.⁵⁷ Although CMS does not require disclosure of affiliations with QHP issuers, consistent with 45 C.F.R. 155.220(e), CMS expects agents, brokers, and web-brokers to comply with applicable State standards for disclosing financial information, including financial relationships with QHP issuers.

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, a qualified employee, as defined at 45 C.F.R. 155.20, would have to enroll in dental coverage before dependents of that qualified employee will be able to enroll in dental coverage, just as is the case for medical coverage.

We received comments about the availability of child-only plans in the FF-SHOP. Because qualified employees must first enroll in FF-SHOP coverage before any of their dependents can enroll in coverage, dependent child-only plans will generally not be available in the FF-SHOPS. If an employer participating in an FF-SHOP is offering qualified employees medical and dental coverage through the FF-SHOP, and a qualified employee under age 21 is eligible to enroll in that coverage consistent with Section 1302(f) of the Affordable Care Act, then the qualified employee may enroll in the dental coverage without also having to enroll in the medical coverage.

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

For example, the following situations might be possible:

- A qualified employee and all dependents are enrolled in the same medical and dental coverage.

⁵⁷ See 45 C.F.R. 155.220(c)(3)(vii). Also see 45 C.F.R. 155.220(i), as amended by the 2016 Payment Notice Final Rule, 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 enrollees in SHOP QHPs, subject to the requirements of 45 C.F.R. 155.220(c)(3).

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

CMS notes that because of operational limitations, estimated premiums for SADPs will not be available in the FF-SHOP for plan years beginning on or after January 1, 2016. As is the case in 2015, consumers in 2016 will be able to obtain premium quotes for SADPs in the same way they do for QHPs, and premiums will always be guaranteed for the employer's plan year.

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 as early as plan years beginning on or after January 1, 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 or SADP issuer participating in an FF-SHOP from offering a qualified employer premiums based on average enrollee premium amounts if the employer elects to offer qualified 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 qualified employees a single plan instead of employee choice. In addition, because of operational limitations, premiums based on average enrollee amounts will only be allowed for groups that have at least one adult age 21 or older enrolled in coverage. Without an adult age 21 or older enrolling at the time of initial enrollment, CMS will not know how much to charge adults enrolling after initial enrollment because a 12-month average was not initially calculated.

When employers choose the single plan option, they will 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.⁵⁸ If an employer selects the option to select QHPs that make available premiums based on average enrollee amounts, then only those plans offered by issuers that have made this option available will be displayed.

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, based on the applicable enrollee's per-member per-month premium.

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 qualified employee (over age 21) would be \$200; the premium charged for a qualified employee and spouse (both over age 21) would be \$400 ($\$200 + \200); and the premium charged for a family consisting of a qualified employee and spouse (both over age 21) and four children (all under age 21) would be \$700 ($\$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 per-month 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 based on the enrollee's per-member per-month premium, not the average enrollee premium amount. 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 \$140 ($\$100 + (0.5 \times 80)$),

⁵⁸ 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.

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 enrollees 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. A new variable will be added to the Plans and Benefits template to identify whether the issuer is offering premiums based on average enrollee premium amounts.

Section 3. Online Renewals

An employer may decide to renew its FF-SHOP participation as well as the coverage it offered in the previous year through the FF-SHOPs. The employer may also decide that it will renew its FF-SHOP participation, but not renew the coverage it offered in the previous year through the FF-SHOPs. 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, as defined for purposes of guaranteed renewability. For plan years beginning on or after January 1, 2016, CMS anticipates that renewals of FF-SHOP participation and renewals of health and dental coverage offered through the FF-SHOPs will continue to be handled by qualified employers and qualified employees online at HealthCare.gov. Employers and qualified employees working with an agent or broker will also need to handle renewals and changes to FF-SHOP participation and coverage at HealthCare.gov.

The FF-SHOP renewal process applies to employer groups that were determined eligible to buy coverage through the FF-SHOPs and had qualified employees enroll in a plan through the FF-SHOP in the previous plan year. The qualified 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 qualified 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.⁵⁹ Qualified employers must provide their qualified 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 was a small employer when it began participating in the FF-SHOP but has ceased to be a small employer solely by reason of an increase in the number of 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 qualified 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 45 C.F.R.147.106.

Pursuant to 45 C.F.R. 155.725(i), a qualified employer's offer of coverage and a qualified employee's coverage may be automatically renewed if certain conditions are met. If no action is taken by the qualified employer or qualified employee, provided that the conditions in 155.725(i) are met, the qualified employee will remain in the QHP selected in the previous year. CMS expects that QHP and SADP renewals will be considered separately so that a qualified employee (and dependents, if applicable) may be automatically renewed in medical coverage alone, dental coverage alone, or both, provided that the qualified employer continues to offer both that medical and that dental coverage through the FF-SHOP. Pursuant to 45 C.F.R. 155.725(i), a qualified employee's coverage will not be automatically renewed if the qualified employee terminates coverage in accordance with 45 C.F.R. 155.430; the qualified employee enrolls in another QHP if such option exists; or the QHP is no longer available to the qualified employee.

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

⁵⁹ Employers renewing SHOP coverage as of the first quarter of calendar year 2016 will be able to view rates and begin the renewal process as early as October 1, 2015. Thus, they will have more than two months to complete the renewal process.

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 qualified 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, in an FF-SHOP, 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 full-time equivalent 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 was permitted to elect to define small employer by substituting “50 employees” for “100 employees.” For plan years beginning on or after January 1, 2016, this discretion 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, the statute and regulations provide that QHPs and SADPs are to be available through the FF-SHOPs to employers with 1 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 FF-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 an exercise of enforcement discretion under which transition relief would apply to employers with between 51 and 100 employees that purchased large employer coverage while still defined as large employers in the State, under which these employers could renew such policies for plan years beginning before October 1, 2016 and be subject to Federal enforcement only of large employer requirements. As of January 1, 2016, however, employers with from 51 to 100 employees purchasing new coverage must comply with small employer requirements, including the rating restrictions and the single risk pool requirement. Similarly, except to the extent that 45 C.F.R. 155.710(d) applies, when an employer increases in size from a small employer to a large employer, the employer’s small group coverage generally is only guaranteed renewable if it meets all of the requirements applicable to the large group market.

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 FFMs 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 FFMs 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 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.

In the 2016 Payment Notice Final Rule, CMS finalized amendments to 45 C.F.R. 155.205(c) pertaining to oral interpretation, the use of taglines indicating the availability of language services, and website translation. CMS also amended 45 C.F.R. 156.250, which extends the requirements in 45 C.F.R. 155.205(c) to QHP issuers, 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). A document is deemed to meet this standard if the issuer is required by State or Federal law or regulation to provide it to a qualified individual, applicant, qualified employer, qualified employee, or enrollee.

Under these amendments to 45 C.F.R. 156.250, QHP issuers must 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;
- Summary of benefits and coverage disclosures;
- Formulary drug lists;
- Provider directories; and
- The policy, insurance contract, evidence of coverage, or similar legally-required document.

In the 2016 Payment Notice Final Rule, under 45 C.F.R. 155.205(c)(2)(i)(A), CMS specified 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 specified other language access requirements pertaining to taglines and translation of website content that apply to QHP issuers. These requirements will become applicable for issuers beginning with the first day of the open enrollment period for the individual market for the 2017 benefit year. First, under 45 C.F.R. 155.205(c)(2)(iii)(A), we specified that a QHP issuer’s existing requirement to include taglines in non-English languages includes providing taglines on website content and any document that is critical for obtaining health insurance coverage or access to health care services through a QHP for qualified individuals, applicants, qualified employers, qualified employees, or enrollees. Such taglines must indicate the availability of language services in at least the top 15 languages spoken by individuals with limited English proficiency in the relevant State, as determined in HHS guidance. For this purpose, a document is deemed to be critical for obtaining health insurance coverage or access to health care services through the QHP if it is required to be provided by State or Federal law or regulation to the qualified individual, applicant, qualified employer, qualified employee, or enrollee.

Under 45 C.F.R. 155.205(c)(2)(iv)(B), we specified that a QHP issuer must translate certain website content that is “critical” within the meaning of 45 C.F.R. 156.250, into any non-English language that is spoken by an LEP population that reaches 10 percent or more of the population of the relevant State, as determined in HHS guidance.⁶⁰ We intend to publish data identifying the non-English languages that are triggered by these standards for each State as well as sample taglines in future guidance.

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

⁶⁰ We note based on current data, this threshold only triggers the translation of website content into Spanish, and only with respect to California and Texas.

Finally, QHP issuers operating in the FFM 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 might 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 1973,⁶¹ 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.

QHP issuers 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.”

In the 2016 Payment Notice Final Rule, CMS amended 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, and provide adequate notice, in the form of a new SBC, to enrollees after receiving notice from the Exchange of the enrollee’s assignment into a new plan variation (or standard QHP without cost-sharing reductions). In accordance with these new regulations, beginning no later than November 1, 2015, QHP issuers must provide separate SBCs for each plan variation and therefore may not combine information about multiple plan variations in one SBC. Issuers offering plan variations should include a separate URL linking to the SBC created for each plan variation as part of the QHP data submission to CMS.

⁶¹ 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 from HHS, 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>.

Additional changes to 45 C.F.R. 147.200 and accompanying guidance, including the SBC template, Uniform Glossary, and instructions, were proposed by HHS, with the Departments of Labor and the Treasury, through a notice of proposed rulemaking published December 30, 2014.⁶² We note that these proposed changes, if finalized as proposed, would apply with respect to policy or plan years beginning on or after September 1, 2015.

We remind issuers that all URL links included on the SBC must be readily obtainable (that is, without requiring logging on to a website, entering a policy number, clicking through several web pages, or creating user accounts, memberships, or registrations) 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 must directly link to the formulary for the benefit package reflected on the SBC, as noted previously. Similarly, pursuant to 45 C.F.R. 147.200(a)(2)(i)(J) (proposed to be recodified from 45 C.F.R. 147.200(a)(2)(i)(I)), the web address where a copy of the actual individual coverage policy or group certificate of coverage can be reviewed and obtained must also link directly from the appropriate space on the SBC and be readily obtainable to shoppers.

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 Final 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 will begin in 2016.

CMS intends to seek additional feedback on these transparency reporting requirements through a collection of information under the Paperwork Reduction Act.

⁶² Summary of Benefits and Coverage and Uniform Glossary; Notice of Proposed Rulemaking; 79 Federal Register 78578 (December 30, 2014).

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 care 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 Addendum⁶³ (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.

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.

⁶³ The model QHP Addendum for Indian health providers is available at <http://www.cms.gov/ccio/programs-and-initiatives/health-insurance-marketplaces/qhp.html>.