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**From: Center for Consumer Information and Insurance Oversight (CCIIO),
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Title: Draft 2017 Letter to Issuers in the Federally-facilitated Marketplaces

The Centers for Medicare & Medicaid Services (CMS) is releasing this draft 2017 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^{SM1} in 2017. 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 also describes how parts of this Letter apply to issuers in State-based Marketplaces on the Federal Platform (SBM-FPs). CMS notes that the policies articulated in this Letter apply to the certification process for plan years beginning in 2017.²

Previously published rules concerning market-wide and QHP certification standards, eligibility and enrollment procedures, and other Marketplace-related topics are set out in 45 CFR Subtitle A, Subchapter B. CMS proposed additional standards in a proposed rule titled, "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017" (2017 Payment Notice Proposed Rule), CMS 9937-P, which published in the Federal Register on December 2, 2015.³ CMS expects issuers to consult all applicable regulations, in conjunction

¹ Health Insurance MarketplaceSM and MarketplaceSM are service marks of the U.S. Department of Health & Human Services.

² Plan years in the FF-SHOPs will not always align with calendar year 2017.

³ Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017; Proposed Rule; 80 Federal Register 75488 (December 2, 2015).

with the final version of this Letter, to ensure full compliance with the requirements of the Affordable Care Act.⁴ Throughout the plan year, QHP issuers may be required to correct deficiencies identified in CMS's post-certification activities, as a result of the investigation of consumer cases, oversight by State regulators or by CMS, or an issuer's own industry-standard internal compliance and risk management program. QHP issuers in the FFMs may also be subject to other requirements for plan years beginning in 2017, as indicated in future rulemaking.

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

Comments

CMS welcomes comments on this proposed guidance. To the extent that this guidance summarizes policies proposed through other rulemaking processes that have not yet been finalized, such as the rulemaking process for the 2017 Payment Notice Proposed Rule, stakeholders should comment on those underlying policies through the ongoing rulemaking processes, and not through the comment process for this Letter. Please send comments on other aspects of this Letter to FFEcomments@cms.hhs.gov by January 17, 2016. Comments will be most helpful if organized by subsections of this Letter.

⁴ We remind issuers that certain other Federal civil rights laws impose non-discrimination requirements. Issuers that receive Federal financial assistance, including in connection with offering a QHP on a Marketplace, are subject to Title VI of the Civil Rights Act of 1964, the Age Discrimination Act of 1975, section 504 of the Rehabilitation Act of 1973, and section 1557 of the Affordable Care Act. The Office for Civil Rights (OCR), which enforces these provisions, published a notice of proposed rulemaking on September 9, 2015 entitled "Nondiscrimination in Health Programs and Activities" (80 Federal Register 54172) on the requirements of section 1557. Issuers that intend to seek certification of one or more QHPs are directed to that proposed rule and to <http://www.hhs.gov/ocr/civilrights> for additional information.

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CHAPTER 1: CERTIFICATION PROCESS FOR QUALIFIED HEALTH PLANS

The Affordable Care Act and applicable regulations establish that health plans, including stand-alone dental plans (SADPs), must meet a number of standards in order to be certified as QHPs. Several of these are market-wide standards that apply to plans offered in the individual and small group markets both inside and outside of the Marketplaces established by the Affordable Care Act. The remaining standards are specific to health plans seeking QHP certification from the Marketplaces.

This chapter provides an overview of the QHP certification process in all FFM States. This includes 1) a State performing plan management functions and making QHP certification recommendations to CMS, 2) a State where CMS is performing all plan management functions and certifying QHPs while the State is enforcing the market-wide standards under the Affordable Care Act, and 3) a direct enforcement State where CMS is performing plan management functions and enforcing market-wide standards under the ACA (but the State continues to enforce State law requirements with which issuers must be in compliance).⁵ The QHP certification process CMS will conduct in calendar year 2016 for plan year 2017 maintains many aspects of the process that CMS conducted in calendar year 2015 for plan year 2016. CMS intends to incorporate some modified review standards as well as operational changes for the QHP certification process for plan year 2017, as noted in this Letter.

As was the case for prior benefit years, CMS expects to rely on States' reviews of policy forms and rate filings submitted by issuers for market-wide standards as part of its QHP certification process provided such States review for compliance with standards that are consistent with Federal laws and regulations and complete such reviews in a manner consistent with FFM operational timelines.⁶ States that have Effective Rate Review⁷ programs should also consult the proposed draft timelines for review of rates for 2017 plan year coverage that are being released

⁵ SBM-FPs should transfer plan data to CMS in accordance with the QHP application submission deadlines as specified in this Letter.

⁶ 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 CFR 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," but should be aware that they will still generally continue to have some obligations under State law.

⁷ See 45 CFR 154.301 for a list of criteria that CMS considers when evaluating whether a State has an effective rate review program.

in conjunction with this letter. CMS must receive confirmation that, in addition to complying with Affordable Care Act requirements, all QHP issuers, including SADP issuers, are licensed and in good standing to offer health insurance coverage in each State in which the issuer offers health insurance coverage, and confirmation that they are in compliance with all applicable State laws that are conditions of offering health insurance in the State. Therefore, to certify QHPs in the FFMs, CMS must receive confirmation that issuers receive 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 performing plan management functions 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 QHPs, or deny certification to QHPs, including SADPs. States are encouraged to provide CMS with feedback regarding certification of QHPs, as well as the status of issuers and plans in relation to State guidelines separate from Affordable Care Act certification requirements, as early in the certification process as practicable. For CMS to ensure this information is taken into account for certification, States must provide all of their recommendations and relevant information to CMS in a timely manner and no later than the State final plan recommendation deadline in Table 1.1. CMS will provide States with detailed guidance regarding the process for submitting plan approval recommendations to CMS prior to the start of and throughout the QHP certification cycle.

Similar to the QHP certification process for plan years beginning in 2016, States can opt to conduct reviews of QHP applications and provide QHP certification recommendations to CMS for plan years beginning in 2017. CMS will review the State's recommendations or findings to confirm that they are consistent with Federal regulatory standards.

Each of the following sections describes CMS's planned approach for evaluating QHPs against the certification standards when CMS is performing plan management functions for plan years beginning in 2017. 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.

Section 1. QHP Application and Certification Process

This section describes how CMS will conduct QHP certification for plan years beginning in 2017.

In accordance with 45 CFR 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 2017, issuers must submit a complete QHP application for all plans they intend to offer on an FFM. QHP certification must be completed annually. In the case of an FF-SHOP QHP certification, the QHP retains its certification through the end of any plan year beginning in the calendar year for which the QHP was certified, even if the plan year ends after the calendar year for which the QHP was certified.

CMS will review all QHP applications for all current and new issuers applying for QHP certification in an FFM. CMS expects States performing plan management functions in an FFM also to review QHP applications from all issuers applying for certification of a QHP for plan years beginning in 2017.

Issuers are expected to adhere to the QHP certification timeline. CMS requires issuers, including SADP issuers, to submit complete QHP applications by the initial submission deadline, and make necessary updates prior to the final deadline for submission of QHP data. Issuers that fail to meet these deadlines or have consistently failed to meet these deadlines in past certification years may have their QHP application denied. Issuers whose applications are not accurate after the final deadline for submission of QHP data or that have consistently submitted inaccurate data in past certification years may have their QHP application denied.⁸

⁸ Regulations at 45 CFR 155.1000 provide Marketplaces with broad discretion to certify QHPs that otherwise meet the QHP certification standards specified in Part 156, and affords Marketplaces the discretion to deny certification of QHPs that meet minimum QHP certification standards, but are not ultimately in the “interest” of qualified individuals and qualified employers. The preamble to the 2017 Payment Notice Proposed Rule clarifies that HHS will continue to focus denials of certification in the FFMs based on the “interest of the qualified individuals and qualified employers” standard which may include cases involving the integrity of the FFMs and the plans offered through them. We sought comment on what factors HHS should consider when determining if QHPs meet the interests of consumers, such as financial insolvency and inaccurate data issues.

Table 1.1. Key Dates for QHP Certification in the FFMs, Including in States Performing Plan Management Functions.⁹

Note: All dates are subject to change.

Activity		Dates (Approximate)
QHP Application Submission and Review Process	Initial QHP Application Submission Window ¹⁰	4/11/2016 – 5/11/2016 ¹¹
	CMS Reviews Initial QHP Applications as of 5/11/16	5/12/2016 – 6/10/2016
	CMS Sends First Correction Notice	6/15/2016 – 6/16/2016
	Deadline for Submission of Revised QHP Data	6/30/2016
	CMS Reviews Revised QHP Data as of 6/30/16	7/01/2016 – 8/02/2016
	CMS Sends Second Correction Notice	8/08/2016 – 8/09/2016
	Final Deadline for Submission of QHP Data; Deadline for All Risk Pools with QHPs to be in “Final” Status in the Unified Rate Review (URR) System ¹²	8/23/2016

⁹ The submission deadlines apply to all QHP application submissions, including those submitted by issuers directly to CMS via HIOS, those transferred to CMS via SERFF by States performing plan management functions, and those transferred to CMS via SERFF by State-based Marketplaces on the Federal Platform.

¹⁰ Unified Rate Review Template (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 Initial FFM QHP Application Submission Window. This submission deadline applies to URRT and Form Filing submissions for QHPs and non-QHPs. CMS is separately issuing guidance describing a proposed timeline for URRT submissions.

¹¹ The deadline for a health insurance issuer to submit all QHP and non-QHP URR rate filing justifications for 2017 plan year coverage to CMS and the applicable State is May 11, 2016, as described in guidance CMS is separately issuing for comment. The proposed deadline for a State with an Effective Rate Review Program to post 2017 plan year proposed rate increases subject to review on the State’s website, including at least the information contained in Parts I, II, and III of the Rate Filing Justification that CMS makes available on its website for single risk pool coverage is the 10th business day after receipt of all rate filings in the relevant market segment (May 25, 2016).

¹² There are three final submission statuses in HIOS. See Unified Rate Review Instructions for more information regarding HIOS submission statuses, available at: https://www.cms.gov/ccio/Resources/Forms-Reports-and-Other-Resources/index.html#Review_of_Insurance_Rates.

Activity		Dates (Approximate)
	CMS Reviews Final QHP Data Received as of 8/23/16	8/24/2016 – 9/09/2016
QHP Agreement, Plan Confirmation, and Final Certification	States Send CMS Final Plan Recommendations	9/08/2016
	CMS Sends Certification Notices to Issuers	9/15/2016 – 9/16/2016
	Issuers Send Agreements and Plan List to CMS	9/19/2016 – 9/23/2016
	CMS Sends Validation Notice ¹³ to Issuers	10/03/2016 – 10/04/2016
Open Enrollment		11/01/2016 – 1/31/2017

i. Registration and QHP Application

To offer QHPs in the FFMs for plan years beginning in 2017, issuers must register in the CMS Enterprise Identity Management System (EIDM) to gain access to the Health Insurance Oversight System (HIOS) where they request user roles (QHP Issuer Submitter or Validator) and obtain HIOS user IDs.¹⁴ 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 CFR 162.103. In addition, each health plan that an issuer intends to offer on a Marketplace is required to obtain an HPID if it is a controlling health plan.¹⁵

CMS expects that between April 11, 2016, and May 11, 2016, issuers applying to offer QHPs in FFMs will access the QHP Application in HIOS to submit all information necessary for certification of health plans and SADPs as QHPs. Issuers in States performing plan management functions in the FFMs are to submit QHP Applications in the National Association of Insurance Commissioners' (NAIC) System for Electronic Rate and Form Filing (SERFF) in accordance with State and CMS review deadlines. Each State will define the relevant submission window for State-level reviews as well as dates and processes for corrections and resubmissions.

¹³ This is the final opportunity for issuers to withdraw QHPs for display on HealthCare.gov for the 2017 plan year.

¹⁴ Additional information on HIOS registration is available in the HIOS Portal User Manual, available at: <https://www.cms.gov/ccio/Resources/Forms-Reports-and-Other-Resources/index.html#Content Requirements for Plan Finder>.

¹⁵ 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>.

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 CFR Parts 155 and 156, and provide requested supporting documentation. Based on the requirement set forth in 45 CFR 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. Under the proposed Uniform Timeline for Submitting the URRT for on and off-Marketplace single risk pool coverage for the 2017 plan year, issuers will enter their submissions into the HIOS Rate Review Module for both their single risk pool QHPs and 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. If a State requires an issuer to make changes and the single risk pool 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. 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 such as essential health benefits (EHB) and actuarial value (AV) standards, among others.¹⁶ State regulators may request access to QHP data templates to facilitate review of these plans.

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 review 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

¹⁶ 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 reviews SADPs for compliance with applicable Affordable Care Act standards.

QHPs meet applicable State and Federal standards, and are approved for sale in the State. Issuers must meet all applicable obligations under State law to be certified for sale on the FFMs.

Direct Enforcement States

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.¹⁷ Issuers will also have obligations under State law, and should consult with their State for details on any state-specific guidelines or requirements.

FFMs (Excluding States Performing Plan Management Functions)

Issuers applying for QHP certification in FFMs, excluding those in States performing plan management functions, will submit their QHP applications in HIOS. Issuers may also be required to submit data to their State. Some States in which there are FFMs use SERFF to collect plan data, which may include copies of the QHP templates, but any data submitted by issuers applying for QHP certification in FFMs into SERFF will not be transferred to CMS. Issuers should ensure that changes to plan data are submitted to both CMS (in HIOS) and their State.

States Performing Plan Management Functions

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.¹⁸ States performing review of QHP applications use SERFF to collect QHP applications from issuers.

In States performing plan management functions, 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 the State's QHP certification recommendations, make final QHP certification decisions, and load certified QHP plans on the Marketplace website. CMS will work closely with States that are performing plan management functions to coordinate this process.

¹⁷ 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).

¹⁸ CMS will work with States performing plan management functions in an FFM to ensure that such guidance is consistent with Federal regulatory standards and operational timelines.

CMS proposes that the SERFF data transfer deadlines will align with the HIOS submission deadlines, as was the case for plan year 2016 submissions. These State transfers should include all plans submitted to the State for certification, including SADPs for off-Marketplace sale.¹⁹ CMS understands that all State reviews might not be complete by the submission deadlines, but, as stated above, requires State confirmation of approval of QHPs for sale prior to CMS certification.

iii. FFM Review of QHP Applications

Issuers applying for QHP certification in the FFMs, including issuers in States performing plan management functions, will submit complete and accurate QHP applications through HIOS or SERFF by May 11, 2016. CMS will not consider plans for which QHP applications are received after this date. CMS will not conduct QHP certification reviews of plans that are submitted for offering only outside of the FFMs except for SADPs seeking off-Marketplace certification. 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 expects to review QHP applications in two rounds. 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 23, 2016.

After reviewing final plan data submitted by August 23, 2016, CMS will make final certification decisions. CMS will send certification notices to issuers and States around September 16, 2016.

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. Issuers should use the Plan Preview environment to verify that their plan display reflects their State-approved filings. Discrepancies between the issuer's QHP application 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 in States performing plan management functions in the FFMs will be able to view their plan data 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.

¹⁹ SBM-FPs should not transfer off-Marketplace SADPs.

During the certification process for plan years beginning in 2017, 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.

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

Note: All dates are subject to change.

Activity	Allowed Changes	Dates (Approximate)
Initial Application Submission	Issuers will submit QHP applications including recertification for 2016 QHPs and SADPs and new 2017 QHPs and SADPs. Issuers may make any changes to their data without State or CMS authorization.	4/11/16-5/11/16
QHP Review and Modification	<p>No new plans may be submitted.</p> <p>Issuers may not change plan type. Child-only value cannot be changed for QHPs.</p> <p>Petition to CMS required for changes to service area or plan withdrawals.</p> <p>Petitions must be submitted by August 9, 2016.</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>	5/12/16-08/23/16
After Final Data Submission	<p>No further data changes allowed prior to certification.</p> <p>Issuers will have a final opportunity to withdraw plans during the plan confirmation process.</p>	

Activity	Allowed Changes	Dates (Approximate)
	<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 approval. Allowed changes will occur during periodic, scheduled limited data correction windows.</p>	

Initial Application Submission

As described in Section 1 of Chapter 1, issuers will submit their initial QHP applications between April 11, 2016, and May 11, 2016. This includes applications for SADPs to be offered on and off the FFMs. Issuers that intend to include new QHPs must submit their 2017 QHP application data during this submission window. Issuers that are requesting recertification of 2016 QHPs must follow the guidelines in Chapter 1, Section 3 for recertification for 2017. Issuers may make changes to their QHP application until the deadline for initial application submission without State or CMS authorization. Applications must be cross-validated and complete by May 11, 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 23, 2016.

After August 23, 2016, issuers cannot add new plans to a QHP application or change an off-Marketplace plan to both on- and off-Marketplace. Issuers also may not change plan type(s). QHPs (excluding SADPs) may not be changed from a child-only plan or to a child-only plan.

An issuer may submit a petition to make service area changes or withdraw plans from its QHP application during this period. For further information about what constitutes a change to an issuer’s service area, please review Chapter 2, Section 2 “Service Area.” Issuers must submit

petitions for all changes to service area, including responding to a correction CMS identified during CMS application reviews. CMS expects to allow issuers to withdraw plans as needed prior to data lockdown. Issuers are required to submit evidence of State approval for service area changes or plan withdrawals. For QHPs in direct enforcement States, the CMS Form Filing team, instead of the State, must authorize data changes. The petition process will require a signed data change request form, justification for the change, and evidence of State approval. Requests must be submitted with evidence of State approval by August 9, 2016 in order to allow CMS sufficient time for review. Issuers must submit approved changes to QHP applications prior to the final data submission deadline of August 23, 2016.

For all other changes, 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. The issuer's State must authorize all data changes, though evidence of State approval is only required for petitions. 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. CMS reviews will be based on the issuer QHP data as of the specific due dates as listed in Table 1.1.

Data changes to plans that are being recertified must ensure the plan will still be considered the same plan, as outlined in 45 CFR 144.103, and further discussed in Chapter 1, section 2, "Recertification for 2017."

After Final Data Submission

After August 23, 2016, 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. Issuers will have a final opportunity to withdraw plans during the plan confirmation process, as described in Section IV, "Plan Confirmation." 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.

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.

A request for a data change after August 23, 2016, excluding administrative changes, may indicate the presence of inaccuracies or the incompleteness of a QHP application, and may result

in compliance action. Discrepancies between the issuer's QHP application 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 have plans removed from display on HealthCare.gov until the data are refreshed for consumer display. Additional requirements may apply, and CMS intends to release further instructions about this process.

v. *Plan Confirmation and QHP/SADP Certification, Privacy and Security Agreement, and Senior Officer Acknowledgement*

As with the certification process for plan years beginning in 2016, issuers intending to offer QHPs or SADPs in the FFMs, including issuers in States performing plan management functions, will be required to validate their final plan list and sign and submit to CMS a QHP Certification Agreement and Privacy and Security Agreement (the QHP Certification 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 Certification 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 QHP Certification 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.

With the certification notice, CMS sends to each issuer a list of plans received during the QHP application process which is preliminarily approved for certification. The list includes on and off-Marketplace SADPs and on-Marketplace QHPs.²⁰ QHP issuers are asked to review the list and must respond to CMS with a final plan confirmation list that will confirm whether or not CMS's list is accurate. Submission to CMS of the final plan confirmation list is the last opportunity a QHP issuer has to withdraw a plan from the Marketplace for the upcoming plan year.

CMS will review the QHP Certification Agreement, the Senior Officer Acknowledgment, and the final plan confirmation list and, if they are accurate and complete, sign and return the QHP Certification Agreement to issuers. QHP issuers' receipt of a QHP Certification Agreement with CMS signature and final plan list validated by CMS completes the certification process for the upcoming plan year. CMS will not sign or return the Senior Officer Acknowledgement.

²⁰ Plan confirmation tables in SBM-FPs will not include off-Marketplace SADPs. Plan confirmation tables in States where CMS certifies SADPs will include both on and off-Marketplace SADPs.

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

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

FFMs will not display ancillary insurance products and health plans that are not QHPs (e.g., stand-alone vision plans, disability, or life insurance products). The FFMs will only offer QHPs, including SADPs.

Section 2. Recertification for 2017

i. Policy and Process for Recertification

For plan years beginning in 2017, CMS's process for recertifying a QHP, including an SADP, that was certified for the 2016 benefit year will mirror the process for certification of a plan. Issuers seeking recertification will submit all information required under the 2017 QHP application for plans that were QHPs, including SADPs, in 2016.

To be eligible for recertification for plan years beginning in 2017, a QHP, including an SADP, certified by an FFM must be the same "plan," as defined in 45 CFR 144.103, as the plan that was certified for plan years beginning in 2016. The same definition of "plan" also will apply to reenrollment of current enrollees into the same plan, pursuant to §155.335(j). A QHP, including an SADP, recertified for plan year 2017 must use the same HIOS plan identification numbers that it used for its certification for plan year 2016.

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

ii. Plan ID Crosswalk

Previously, CMS developed and released a Plan ID Crosswalk Template for issuers to complete and submit to CMS for the individual market. The submission process applies to all issuers that offered individual market QHPs through an FFM in 2015 – including issuers in States performing plan management functions in an FFM and issuers in SBM-FPs. For the FFMs, this template cross-walked prior year QHP plan ID and service area combinations (e.g., Plan ID and county combinations) to a current QHP plan ID. This data facilitated enrollment transactions from CMS to the issuer 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 2016 to 2017 QHPs in the FFMs. As a result, issuers that offered plans on the individual market FFMs in plan years beginning in 2016, 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 CFR 147.106. However, as CMS has indicated in previous guidance, it again aims to apply the hierarchy set forth at 45 CFR 155.335(j) and the business rules established for the 2017 Plan ID Crosswalk Template to SADPs in order to support automatic re-enrollment for re-enrollment plan years beginning in 2017.

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 2016.

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 CFR 155.335(j). This will also include a review for consistency with submitted Service Area and Plans and Benefits Template data for both 2016 and 2017.

Section 3. OPM Certification of Multi-State Plan (MSP) Options

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

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

OPM anticipates that the process for MSP issuers to participate in a Marketplace for the 2017 benefit year will largely mirror that used for 2016. 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.

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 2017 application when available.

Section 4. Standardized Options

In the 2017 Payment Notice Proposed Rule, we proposed a “standardized option” at each of the bronze, silver (including silver level cost-sharing reduction variations), and gold metal levels—a total of 6 standardized options (see Table 9 in the 2017 Payment Notice Proposed Rule), which issuers would have the option to offer in 2017. We designed the standardized options to be as similar as possible to the 2015 FFM QHPs that were most popular (based on enrollment).

We believe that standardized options would allow consumers to more easily compare plans offered by different issuers within each metal level and thereby simplify the consumer shopping experience by allowing consumers to focus their health plan selection on networks, premiums, and quality, rather than on complex cost-sharing differences that often exist across a large number of plan choices. Each standardized option is standardized in terms of in-network cost-sharing: deductible, annual limitation on cost-sharing, and copayment or coinsurance for a key set of EHBs that comprise a large percentage of the average enrollee’s total spending. In the 2017 Payment Notice Proposed Rule, we proposed that standardized options have the four drug tiers currently utilized in our consumer-facing applications—generic, preferred brand, non-preferred brand, and specialty drug tiers—with the option to offer additional lower-cost tiers. We also proposed that standardized options should not have more than one in-network provider tier. This is because varying cost sharing by provider tier affects the actuarial value of a plan, making it difficult to standardize a cost-sharing structure.

Should this proposal be finalized, we would strongly encourage issuers to offer at least one standardized option in 2017, particularly at the silver level of coverage (including the silver level cost-sharing reduction variations). As explained in the 2017 Payment Notice Proposed Rule, issuers would have the option of offering a standardized option at one level of coverage without offering a standardized option at the other levels of coverage. For instance, an issuer would be able to offer a silver standardized option without offering a bronze or gold standardized option. However, if an issuer offers a silver standardized option, the issuer must also offer the standardized silver level cost-sharing reduction variations.

We also proposed to give issuers the option to offer more than one standardized option at each level of coverage. For instance, the issuer could offer more than one standardized option at each metal level by varying network, additional benefits covered, or other features, subject to the meaningful difference requirements discussed in Section 12 of Chapter 2 of this Letter.

Finally, should this proposal be finalized, we are considering making modifications to our consumer-facing plan comparison features to readily allow consumers to identify standardized options and distinguish them from non-standardized plans. We intend to conduct consumer testing to help us make this determination, and we also anticipate providing information to explain the standardized option concept to consumers.

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 the same approach used in 2016.

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 CFR 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 (DOI). 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. In addition, an issuer is considered to not be in good standing if it is not licensed.
- 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 2016 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 CFR 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 PHS Act, or other factors that exclude specific high utilizing, high cost or medically-underserved populations (see 45 CFR 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. Issuers should note that a change in service area is not always directly related to changes made to the Service Area Template. That is, a change to the Plans and Benefits Template may also potentially impact service area. For example, changing the service area ID associated with a plan from S001 to S002 constitutes a change to service area.

QHP issuers will not be allowed to change their plans' service area after their initial data submission except via petition to CMS. This includes any changes to the Service Area Template (including changing the name of the service area) as well as changing the service area ID associated with a plan on the Plans and Benefits Template. 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, including SADPs.

i. Network Adequacy Standard

This section describes how CMS will conduct its network adequacy review for plan year 2017 QHP certification. Pursuant to 45 CFR 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.

For the 2017 plan year, we also proposed new policies that are detailed in the 2017 Payment Notice Proposed Rule, for which we are currently reviewing comments. As with all proposed

policies, we will carefully review comments received in developing a final rule. If CMS does finalize one or more of these policies as proposed, this Letter outlines the approach CMS would take to operationalize them.

As was done during the 2015 and 2016 plan year certification process, for 2017 plan year certification, CMS proposes to 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 CFR 156.230(a)(2). We propose these new policies to provide more transparency and detail for QHP issuers in an FFM regarding how to fulfill the requirement to provide reasonable access. If finalized as proposed, we intend to work closely with States to operationalize them. These new policies are described below.

ii. State Review of Quantitative Network Adequacy Standard

This section discusses the proposed quantitative network adequacy policy that would apply for 2017 certification.

Some States with an FFM, including States performing plan management functions, currently review QHPs for specific quantitative network adequacy standards. In recognition of the roles States have historically played in reviewing and enforcing network adequacy, CMS proposed to amend 45 CFR 156.230 such that FFMs would rely on State reviews for network adequacy in States in which an FFM is operating, provided that HHS determines that the State uses an acceptable quantifiable network adequacy metric commonly used in the health insurance industry to measure network adequacy. We note below two metrics that a State could adopt as a framework for an acceptable quantifiable metric, which are proposed through the rulemaking process for the 2017 Payment Notice Proposed Rule. The two metrics are:

- The State prospectively enforces time and distance standards at least as stringent as the FFM standard, as articulated in part iii, below.
- The State prospectively verifies a minimum provider to covered person ratio for the specialties with the highest utilization rate for its State.

Should the 2017 Payment Notice Proposed Rule be finalized as proposed, CMS will work closely with State DOIs or the appropriate State agencies to confirm whether States plan to use a recognized metric to perform network adequacy reviews of QHPs for the 2017 plan year. CMS would discuss the selection of and use of the metric with States in advance of the start of the certification cycle. Specifically, an FFM would rely on the State review if the State uses a recognized metric as a foundation for a network adequacy review, in conjunction with an exceptions process for rural areas or other areas with a shortage of available providers, similar to the review CMS performs and describes in section ii. We acknowledge that the NAIC recently

finalized its Health Benefit Plan Network Access and Adequacy Model Act²¹ (Model Act) and that States may need additional time to enact it in whole or in part, if they choose to do so. The proposal in the 2017 Payment Notice Proposed Rule for State review of a quantitative standard is designed to dovetail with the Model Act, and to allow States flexibility to apply a standard that takes into consideration their specific needs.

In States that will review prospective QHPs under such a State metric, the FFM in that State would rely on the State's review for purposes of determining whether a QHP meets the requirements under §156.230(a)(2). CMS will not undertake network adequacy review of these QHPs to meet the requirements under §156.230(a)(2) for certification. CMS would still require issuers in these States to submit provider data — including information on its physicians, facilities, and pharmacies — to CMS, attest to the network adequacy certification requirements, and meet the network adequacy qualitative standards for certification, as described in part iv, v, vi and any other standards that apply.

CMS will provide a list of States in which CMS will conduct a review of prospective QHPs for quantitative network adequacy standards. States performing the review of prospective QHPs will report to CMS whether the plans met the standards, and other QHP certification standards for which the States review, through the State plan confirmation process.

iii. Federal Default Standard - Time and Distance

This section discusses the Federal default time and distance standard that would apply in States that do not elect to review for network adequacy under a quantifiable metric, as proposed in the 2017 Payment Notice Proposed Rule and discussed in part ii above. CMS proposes that this default would involve evaluating a QHP issuer's network based on the numbers, types, and geographic location of providers in its network. If finalized, these default standards would be similar to the time and distance standards applied today to Medicare Advantage plans, and would focus on the providers and facility types identified in Table 2.1. In general, under this default standard, a QHP issuer in a State would be required to ensure that a certain percentage of the potential enrollees residing in a county have access to a minimum number of providers or facilities of each type within the established time and distance standards, and that they meet specific minimum numbers of providers and facilities within specified geographic parameters. As described further below, CMS would couple the time and distance standards with a justification process for issuers that do not meet the quantitative standard. At this time, CMS is proposing the maximum time and distance standards detailed in the table below.

²¹ Available at: <http://www.naic.org/store/free/MDL-74.pdf>.

Table 2.1. Proposed Specialties and Standards for Marketplace PY17.

Specialty Area	Maximum Time and Distance Standards (Minutes/Miles)				
	Large	Metro	Micro	Rural	CEAC
Primary Care	10/5	15/10	30/20	40/30	70/60
Dental	30/15	45/30	80/60	90/75	125/110
Endocrinology	30/15	60/40	100/75	110/90	145/130
Gynecology (OB/GYN)	30/15	45/30	80/60	90/75	125/110
Infectious Diseases	30/15	60/40	100/75	110/90	145/130
Oncology - Medical/Surgical	20/10	45/30	60/45	75/60	110/100
Oncology - Radiation/Radiology	30/15	60/40	100/75	110/90	145/130
Mental Health	20/10	45/30	60/45	75/60	110/100
Pediatrics	30/15	45/30	80/60	90/75	125/110
Cardiology	20/10	30/20	50/35	75/60	95/85
Rheumatology	30/15	60/40	100/75	110/90	145/130
Hospitals	20/10	45/30	80/60	75/60	110/100
Outpatient Dialysis	30/15	45/30	80/60	90/75	125/110
Inpatient Psychiatric Facility Services	30/15	70/45	100/75	90/75	155/140

For each specialty and standard listed in the table, the issuer would need to provide access to at least one provider for at least 90 percent of enrollees. For example, for Endocrinology in a Large Metro county type, 90 percent of enrollees must have at least one provider within 15 miles or 30 minutes.

A file that issuers can use to determine if they meet these standards, in addition to definitions for each of the specialties and facilities, will be available to issuers as part of the certification process. We welcome comments on both the selected types of specialties and facilities and the proposed time and distance standards.

Additionally, as with Medicare Advantage, CMS anticipates the need to include variations in the time and distance standards applicable to issuers in different service areas based on local circumstances, including the availability of particular provider types and local patterns of care. CMS also anticipates working closely with States that elect not to establish their own quantifiable metrics and for which the Federal default standard would apply, so that the standard sufficiently addresses State-specific variations. To address these variations, CMS proposes to use a justification process similar to the justification process used for the 2015 and 2016 plan year network adequacy QHP certification process. The justification process would require that QHP issuers detail patterns of care and other relevant information that explain why the issuer does not meet the time and distance requirements. We have analyzed current QHP issuer network data submitted as part of the 2016 certification cycle against the proposed metrics, and, based on those results, there would generally be an overall passage rate above 90 percent for each of these metrics with the less than 10 percent remaining being addressed via the justifications process or by adding additional providers. It is not our intent that these default standards disqualify narrow network plans. Rather, we anticipate that the vast majority of QHPs today would pass these time and distance standards, either numerically or based upon justifications submitted and accepted.

CMS intends to detail the requirements for the justification process, including instructions on how to submit justifications, in the QHP certification instructions. CMS will continue to monitor network adequacy throughout the year.

iv. Provider Transitions

This section discusses the proposed provider transitions policy outlined in the 2017 Payment Notice Proposed Rule. In the 2017 Payment Notice Proposed Rule, we proposed two new requirements for QHP issuers in the FFM regarding cases when a provider is leaving the network. First, we proposed to require QHP issuers in all States within an FFM to notify enrollees about their network coverage in cases of discontinuation, whether through termination or non-renewal, of a contracted provider. Specifically, we proposed that a QHP in an FFM be required to make a good faith effort to provide written notice of termination of a discontinued provider, 30 days prior to the effective date of the change or otherwise as soon as practicable, to all enrollees who are patients seen on a regular basis by the provider or receive primary care from the provider whose contract is being discontinued, irrespective of whether the contract is being discontinued due to a termination for cause or without cause, or due to a non-renewal. To satisfy this standard, we expect the issuer to try to work with the provider to obtain the list of affected patients or to use their claims data system to identify enrollees who see the affected providers.

We also proposed in §156.230(e)(2) another provision to ensure continuity of care for enrollees in cases where a provider is terminated without cause. Specifically, we proposed to require the issuer, in cases where the provider is terminated without cause, to allow an enrollee in active

treatment to continue treatment until the treatment is complete or for 90 days, whichever is shorter, at in-network cost-sharing rates. Additionally, we proposed a definition of active treatment as meaning:²²

- (1) An ongoing course of treatment for a life-threatening condition;
- (2) An ongoing course of treatment for a serious acute condition;
- (3) The second or third trimester of pregnancy; or
- (4) An ongoing course of treatment for a health condition for which a treating physician or health care provider attests that discontinuing care by that physician or health care provider would worsen the condition or interfere with anticipated outcomes.

For purposes of the active treatment definition, we proposed to interpret a life-threatening condition as a disease or condition for which likelihood of death is probable unless the course of the disease or condition is interrupted and a serious acute condition as a disease or condition requiring complex on-going care which the covered person is currently receiving, such as chemotherapy, post-operative visits or radiation therapy. Finally, we proposed that any decisions made with respect to a request for continuity of care be subject to the health benefit plan's internal and external grievance and appeal processes in accordance with applicable State or Federal law or regulations.

If these provisions are finalized, all QHP issuers in the FFM would be required to update internal processes and procedures to implement these requirements for plan years beginning on and after January 1, 2017. For both of these provisions, issuers would be expected to attest to meeting these requirements during QHP certification.

v. *Network Transparency*

This section discusses how CMS intends to label each QHP network's breadth as compared to other QHP networks on HealthCare.gov. This information will be available to consumers when they are considering which plan to enroll in, and would include a designation that indicates the network's relative breadth. The purpose of the labeling is to provide transparency to enrollees about the type of coverage they are selecting.

We anticipate that each network's breadth would be compared to the network breadth of other QHPs available in the same geographic area. CMS would identify network breadth based on analysis of QHP provider and facility data submitted as part of the 2017 certification process.

²² The proposed definitions are similar to the definitions used in the Model Act.

This analysis would include determining breadth of the network based on the number of specific providers and facilities that are highly utilized by QHP enrollees. CMS is considering a focus on hospitals, adult primary care, and pediatric primary care with a separate classification for each of the three categories or a composite overall classification that reflects the overall network for all three of the indicated specialties. These areas were chosen based on consumer feedback that access to specific hospitals and preferred primary care physicians is important to potential enrollees when comparing plans.

We plan to provide the classifications of network breadth as compared to other available plans in that county for each plan at the county level. We anticipate that these classifications will be determined by calculating the percentage of providers contained in a plan's network, compared to the total number of providers contained in QHP networks available in a county. We would divide the number of each QHP's servicing providers at the issuer, network, county, and specialty combination level by the total number of all available QHP servicing providers for that county. This number is the Provider Participation Rate (PPR). As a baseline standard, networks that are within one standard deviation of the mean PPR would be classified as Standard. Those with a PPR that is more than one standard deviation above the mean PPR would be classified as Broad. Those with a PPR that is more than one standard deviation below the mean PPR would be classified as Basic. Applying this methodology to 2016 QHP issuer provider data, we found that approximately 68 percent of the plan would have been categorized as Standard, about 16 percent would have been classified as basic and about 16 percent would have been classified as Broad. We propose conducting an analysis of QHP 2017 provider data using the same methodology to determine each plan's classification. These calculations would be based on the network provider data information that each QHP issuer submits as part of QHP certification and would be updated annually based on the certification data.

In future years, we may expand these classifications to provide this information for additional specialties and facilities. We welcome comments on this proposed methodology and the designated specialties, including suggestions about what other types of specialties we should consider including now or in the future.

vi. Out-of-Network Cost Sharing

This section discusses the proposed policy for QHP out-of-network cost sharing. The 2017 Payment Notice Proposed Rule would require issuers to count out-of-network services towards the in-network annual limitation on cost sharing in certain circumstances. Specifically, we proposed that for a network to be deemed adequate for purposes of QHP certification, a QHP must count cost sharing paid by an enrollee for an EHB provided by an out-of-network provider in an in-network setting under certain circumstances towards the enrollee's annual limitation on cost sharing. That is, if an enrollee received an EHB in an in-network setting, such as an in-network hospital, but as part of the provision of the EHB the enrollee was charged out-of-network cost-sharing for an EHB provided by an out-of-network provider (such as

anesthesiology or pathology services, for example), that cost sharing would apply towards the annual limitation on cost sharing. The enrollee could still be responsible for out-of-network cost sharing and balance billing (if applicable), for benefits received from an out-of-network provider at any time, but not for cost sharing for a covered EHB provided in-network or out-of-network in a circumstance described in this paragraph received after the annual limitation is met.

Alternatively, the plan could provide a written notice to the enrollee at least 10 business days before the provision of the benefit that additional costs may be incurred for the EHB provided by an out-of-network provider in an in-network setting, including balance billing charges, unless such costs are prohibited under State law, and that any additional charges and cost sharing may not count toward the in-network annual limitation on cost sharing. The notice could be provided during preauthorization. If the plan provides such a notice, this rule would not require the plan to apply the out-of-network cost sharing towards the enrollee's annual limit on cost sharing or to be responsible for covering out-of-network cost sharing above the annual limit. This alternative would not be available if less than 10 business days' notice is provided, including in cases where that amount of time is not available (for example, in urgent but non-emergency care situations).

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 for plan years beginning in 2017. 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,²³ 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 CFR 156.235, CMS established requirements for inclusion of ECPs in QHP provider networks and provided an alternate standard for issuers that provide a

²³ Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016; Final Rule, 80 Federal Register 10750 (February 27, 2015).

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 2017 against the ECP inclusion standard described below.

General ECP Standard

Similar to 2016, for plan years beginning in 2017, CMS proposes to 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 Addendum²⁴ for Indian health care providers developed by CMS; and
- Offers contracts in good faith to at least one ECP in each ECP category (see Table 2.1) in each county in the service area, where an ECP in that category is available and provides medical or dental services that are covered by the issuer plan type.

To be offered in good faith, an issuer should offer contract terms comparable to terms that it offers to a similarly-situated non-ECP provider. CMS expects 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 will publish during the winter of the 2016 calendar year an updated list of available ECPs based on data maintained by CMS and other Federal agencies, as well as provider data that CMS receives directly from providers through the

²⁴ 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>.

2015 ECP petition process. CMS proposes to include on the HHS ECP list for the 2017 plan year those providers that submit an ECP petition during the 2015 ECP petition window and meet the definition of an ECP under 45 CFR 156.235 through satisfaction of the following criteria:

- Provider consents to be added to or remain on the HHS ECP list for the 2017 plan year.
- Provider is either A) eligible for or participating in the 340B program or is a Rural Health Clinic or is an Indian Health Care Provider; or B) located in a low-income ZIP code or Health Professional Shortage Areas (HPSA),²⁵ unless the provider has been included in one of the verified datasets from HRSA, the Indian Health Service (IHS), or the Office of the Assistant Secretary for Health/Office of Population Affairs (OASH/OPA), and appears on the Draft 2017 ECP List.
- Provider accepts patients regardless of ability to pay and offers a sliding fee schedule, unless the provider has been included in one of the verified datasets from HRSA, IHS, or OASH/OPA and appears on the Draft 2017 ECP List.
- Provider accepts patients regardless of coverage source (i.e., Medicare, Medicaid, CHIP, private health insurance, etc.).
- Provider agrees to be listed in a consumer-facing directory of ECPs.
- Provider consists of one or more MDs, DOs, PAs, NPs, DMDs, or DDSs authorized by the State to independently treat and prescribe within the listed facility and must attest to the following Statements within the petition.
- Provider lists the number of executed contracts and good faith contract offers rejected.
- Provider completes any missing data from critical data fields on the HHS ECP list, such as the National Provider Identifiers (NPIs), points of contact (POCs), ECP category, provider site and organization addresses, and the number of full-time equivalent MDs, DOs, PAs, NPs, DMDs, and DDSs authorized by the State to independently treat and prescribe within the listed facility.

For plan year 2017 QHP certification, CMS proposes to credit issuers for providers that the issuer selects from the final HHS ECP list and includes on the issuer's ECP template toward satisfaction of the 30 percent ECP threshold requirement. CMS will make the final 2017 HHS ECP list available during the winter of the 2016 calendar year at the following link:

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

²⁵ Based on the HHS Low-Income and Health Professional Shortage Area (HPSA) ZIP Code Listing, available at: <http://www.cms.gov/cciio/programs-and-initiatives/health-insurance-marketplaces/qhp.html>.

Given the ECP petition process designed to add qualified ECPs to the 2017 HHS ECP list, including providers that issuers may have included as ECP write-ins in previous years, CMS proposes to offer a conditional ECP write-in process for plan year 2017. In previous years, an issuer's ECP write-ins counted toward satisfaction of the ECP standard for only the issuer that wrote in the ECP on its ECP template, resulting in a variation of the available identified ECPs for a given service area based on the number of ECP write-ins a specific issuer included on its ECP template. To ensure that the HHS ECP list more accurately reflects the universe of qualified available ECPs in a given service area, CMS proposes an ongoing initiative to collect more complete provider data directly from providers through the ECP petition process so that all issuers are held to a more uniform ECP standard in future years. CMS will allow issuers to count their qualified ECP write-ins toward satisfaction of the 30 percent ECP standard for plan year 2017 as long as the issuer arranges that the written-in provider has submitted an ECP petition to CMS by no later than August 22, 2016.

CMS proposes for plan year 2017 to 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 ECP list located within the plan's service area and any qualified ECP write-ins that the issuer has chosen to list on its ECP template, on the condition that the issuer arranges that such written-in providers have submitted an ECP petition by no later than August 22, 2016.
- The numerator of the issuer's contracted ECPs consists of any ECPs that the issuer has listed from the non-exhaustive HHS ECP list located within the plan's service area and any qualified ECP write-ins that the issuer has chosen to list on its ECP template, on the condition that the issuer arranges that such written-in providers have submitted an ECP petition by no later than August 22, 2016.
- 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 CFR 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, 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 2017;
- The number of additional contracts that an issuer expects to offer for plan years beginning in 2017 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 2.2. 2017 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
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 CFR 156.235(a)(2) and (b) 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).

CMS proposes for plan year 2017 to determine issuer satisfaction of the 30 percent ECP standard for issuers that qualify for the alternate ECP standard using the following calculation methodology:

- The denominator of available ECPs consists of any ECPs on the non-exhaustive HHS ECP list located within the plan's service area and any qualified ECP write-ins that the issuer has chosen to list on its ECP template (i.e., including providers employed by the issuer or providers of its contracted medical group), on the condition that the issuer arranges that such written-in providers have submitted an ECP petition by no later than August 22, 2016.
- The numerator of the issuer's employed or contracted ECPs consists of any ECPs that the issuer has listed from the non-exhaustive HHS ECP list located within the plan's service area and any qualified ECP write-ins that the issuer has chosen to list on its ECP template (i.e., including providers employed by the issuer or providers of its contracted medical group), on the condition that the issuer arranges that such written-in providers have submitted an ECP petition by no later than August 22, 2016.
- 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 CFR 156.235.

CMS proposes to count allowable ECP write-ins toward satisfaction of the ECP standard for issuers that qualify for the alternate ECP standard for only those providers that are employed by the issuer or providers of its single contracted medical group that are located in a low-income ZIP code or Health Professional Shortage Area (HPSA), given that such providers generally would not appear on the HHS ECP list. In addition, such providers that the issuer writes in must not limit their practice on the basis of a particular source of coverage (e.g., Medicare, Medicaid, CHIP, private health insurance, etc.), unless limited to only the employed or contracted issuer's coverage.

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. In accordance with §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 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 and mental 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 provides 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.

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*

For plan years beginning in 2017, CMS proposes to utilize a general ECP enforcement standard for SADPs whereby it will consider the issuer to have satisfied the regulatory standard if an application demonstrates satisfaction of the following criteria:

- Offers a contract in good faith to at least 30 percent of available ECPs in each plan's service area to participate in the plan's provider network; and
- Offers a contract 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 Addendum²⁶ for Indian health care providers developed by CMS.

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 expects 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.

For the same reasons described above for medical QHPs, CMS proposes for SADPs an ongoing initiative to collect more complete dental provider data directly from dental providers through the ECP petition process so that all issuers are held to a more uniform ECP standard. CMS proposes to launch this initiative by offering a conditional ECP write-in process that will allow issuers to count their qualified ECP write-ins toward satisfaction of the 30 percent ECP standard for plan year 2017 on the condition that the issuer has arranged that the written-in dental provider has submitted an ECP petition to CMS by no later than August 22, 2016.

CMS proposes for plan year 2017 to determine SADP issuer satisfaction of the 30 percent ECP standard using the following calculation methodology:

- The denominator of available dental ECPs consists of any ECPs on the non-exhaustive HHS ECP list located within the plan's service area and any qualified ECP write-ins that the issuer has chosen to list on its ECP template, on the condition that the issuer has arranged that such written-in providers have submitted an ECP petition by no later than August 22, 2016.

²⁶ 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>.

- The numerator of the issuer’s contracted dental ECPs consists of:
 - Any ECPs that the issuer has listed from the non-exhaustive HHS ECP list located within the plan’s service area;
 - Any qualified ECP write-ins that the issuer has chosen to list on its ECP template, on the condition that the issuer has arranged that such written-in providers have submitted an ECP petition by no later than August 22, 2016; and
 - The number of good faith contract offers extended to dental ECPs on the HHS ECP list located in the plan’s service area that were rejected by the provider and identified by the issuer within its narrative justification.
- Applicable to both the numerator and denominator, multiple dental 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 CFR 156.235.

If an issuer’s application does not satisfy the 30 percent ECP standard based on its contracted providers listed on its ECP template as well as the requirement to offer contracts in good faith to all available Indian health care providers in the service area, CMS proposes that the issuer be required to include as part of its application a satisfactory narrative justification that consists of a listing of good faith contract offers extended to dental ECPs on the HHS ECP list located in the plan’s service area that were rejected by the provider. The issuer’s justification should describe 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.

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

- The number of contracts offered to ECPs for plan years beginning in 2017;
- The number of additional contracts that an issuer expects to offer for plan years beginning in 2017 and the timeframe of those planned negotiations;
- The names of the dental ECPs to whom 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.

An SADP issuer that submits a narrative justification would do so as part of the issuer’s application for QHP certification.

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.

45 CFR 155.1045(b) establishes the timeline by which QHP issuers offering coverage in the FFM must be accredited. In 2017, CMS is continuing its phased approach to accreditation for QHP issuers in an FFM. The accreditation requirements for QHP issuers entering their fourth year of certification are described in 45 CFR 156.275(a), which State that QHP issuers must be accredited on the basis of local performance of its plans based on clinical quality measures, patient experience ratings, consumer access, utilization management, quality assurance, provider credentialing, complaints and appeals, network adequacy and access, and patient information programs.

As previously stated, QHP issuers in their second or third year of certification must be accredited. The accreditation requirements for QHP issuers entering their third year of certification are described further in the 2016 Letter to Issuers. The accreditation requirements for QHP issuers entering their second year of certification are described further in the 2015 Letter to Issuers. Issuers entering their initial year of QHP certification for plan years beginning in 2017 (i.e., issuers that did not offer a QHP a previous year) must meet the requirement at 45 CFR 155.1045(b)(1), and may submit accreditation information for display if they have existing accreditation. CMS reviews issuers that crosswalk enrollees to a new HIOS ID for accreditation based on their cumulative years of certification.

As CMS required in 2016, QHP issuers must attest that they meet the standards under 45 CFR 155.1045 (b)(2) and authorize the release of their accreditation information as stated in 45 CFR 156.275 (a)(2). CMS will apply the timeline in 45 CFR 155.1045(b) by looking at the issuer's accreditation status 90 days prior to open enrollment. CMS will not consider an issuer accredited if the accreditation review is scheduled or in process.

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

CMS will consider issuers in their first, second or third year of QHP certification accredited if the QHP issuer is accredited with the following status: by AAAHC with "Accredited" status; by

NCQA with “Excellent,” “Commendable,” “Accredited,” “Provisional,” or “Interim” status; or by URAC with “Full,” “Provisional,” or “Conditional” status.

CMS will consider issuers in their fourth year of QHP certification accredited if the QHP issuer is accredited with the follow status: by AAAHC with “Accredited status; by NCQA with Marketplace accreditation and “Excellent,” “Commendable,” “Accredited,” or “Provisional,” status; or by URAC with Marketplace accreditation and “Full” 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 2017. For 2017, we proposed to strengthen the patient safety standards for QHP issuers, which are detailed in the 2017 Payment Notice Proposed Rule.

As proposed in 45 CFR 156.1110(a)(2), there are new standards for QHP issuers to demonstrate compliance with the patient safety standards for coverage beginning on or after January 1, 2017. Specifically, the proposed regulatory amendments direct QHP issuers that contract with a hospital with more than 50 beds to verify that the hospital utilizes a patient safety evaluation system as defined in 42 CFR 3.20²⁷ and has implemented a comprehensive person-centered discharge program to improve care coordination and health care quality for each patient.

If the applicable network hospital does not have a current agreement with a Patient Safety Organization (PSO), based on the reasonable exceptions provision that CMS proposes in 45 CFR 156.1110(a)(2)(ii), a QHP issuer may verify that the hospital has implemented evidence-based initiatives to reduce all cause preventable harm, prevent hospital readmission, improve care coordination and improve health care quality through the collection, management and analysis of patient safety events. As proposed in this case, a QHP issuer would be required to collect and maintain documentation such as a participation agreement with a Hospital Engagement Network (HEN) or a Quality Improvement Organization (QIO). In addition, CMS strongly supports hospital tracking of patient safety events using the Agency for Healthcare Research and Quality (AHRQ) Common Formats²⁸ whether a hospital chooses to work with a PSO as described in proposed 45 CFR 156.1110(a)(2)(i)(A) or implements the alternative approach proposed in 45 CFR 156.1110(a)(2)(ii).

²⁷ A patient safety evaluation system is defined as “the collection, management, or analysis of information for reporting to or by a Patient Safety Organization (PSO).”

²⁸ More information on Common Formats is available at: <https://www.pso.ahrq.gov/common>.

As part of the certification for plan years beginning in 2017, QHP issuers would be required to demonstrate compliance with the patient safety standards proposed as part of the 2017 Payment Notice Proposed Rule 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 QHP issuer compliance with the quality reporting standards related to the Quality Rating System (QRS) and the QHP Enrollee Experience Survey (QHP Enrollee Survey) for purposes of QHP certification and recertification. For the QRS and QHP Enrollee Survey requirements, States performing plan management functions in State Partnership States may use a similar approach. Child-only plans and SADPs are not subject to these quality reporting standards at this time. (CMS will continue to monitor the number of child-only QHPs in Marketplaces. A limited number of child-only QHPs and enrollees may prohibit reliable child-only QRS rating calculations and QHP Enrollee Survey results. CMS will continue to monitor both of these plan types and will consider developing a quality rating system and QHP Enrollee Survey for these in the future.)

i. QHP Issuer Data Collection and Reporting Requirements

QHP issuers that meet participation criteria are required to comply with standards and requirements related to quality reporting for QHPs offered on Marketplaces through implementation of the QRS pursuant to 45 CFR 156.1120, and the QHP Enrollee Survey pursuant to 45 CFR 156.1125. Consistent with 45 CFR 156.200(b)(5), 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 as part of certification process for the 2017 plan year. QHP issuers offering coverage through the Marketplaces must collect and submit validated clinical quality measure data and QHP Enrollee Survey response data, on a timeline and in a standardized form and manner specified by CMS, to support the calculation of QRS ratings.²⁹ QHP issuers are also required to contract with and authorize an HHS-approved QHP Enrollee Survey vendor to collect and submit QHP Enrollee Survey response data on their behalf. CMS anticipates issuing technical guidance on an annual basis that will detail requirements for the QRS and QHP Enrollee Survey including the standards related to data collection, validation and submission, as well as the minimum enrollment and other participation criteria. CMS anticipates issuing technical guidance for 2017 data submissions in the 2016 calendar year.

²⁹ 45 CFR 156.1120 and 45 CFR 156.1125.

Using the QHP issuer's validated QRS clinical measure data and QHP Enrollee Survey response data submitted in the 2016 calendar year, CMS will use the QRS rating methodology to calculate 2016 QRS ratings (on a 5-star scale) and 2016 QHP Enrollee Survey results for each reporting unit.³⁰ CMS will assign these 2016 ratings to each QHP issuer's product type offered through a Marketplace during the individual market open enrollment period for 2017. QHP issuers will have an opportunity to review their QRS and QHP Enrollee Survey results and submit inquiries during an established preview period each year prior to public display of results.

QHP issuers may reference their respective QRS scores and ratings, as well as QHP Enrollee Survey results, in a manner specified by HHS.^{31,32} A QHP issuer that elects to include QRS and/or QHP Enrollee Survey results in its 2017 plan year marketing materials must do so in a manner that does not mislead consumers and in accordance with all applicable Federal and State requirements. Additional CMS guidelines related to the use of the 2016 QRS and/or QHP Enrollee Survey results in 2017 plan year marketing materials are included in the Quality Rating System and Qualified Health Plan Enrollee Experience Survey: Technical Guidance for 2016.

ii. Marketplace Oversight & Display Requirements

Consistent with 45 CFR 155.200(d), Marketplaces are required to oversee the implementation of the QRS and QHP Enrollee Survey. Beginning in the 2016 calendar year, and on an annual basis thereafter, all Marketplaces must prominently display QHP quality rating information (e.g., QRS and QHP Enrollee Survey results) on their respective websites, as calculated by CMS and in a form and manner specified by CMS.³³ Guidance related to the Marketplace display requirements for 2016 QRS and QHP Enrollee Survey results during the individual market open enrollment

³⁰ For 2016 reporting, QHP issuers were required to collect and submit validated QRS clinical measure data and QHP Enrollee Survey response data by product type (i.e., EPO, HMO, POS, PPO, indemnity), with separate submissions by State, for each product type offered through a Marketplace in 2016 that was also offered in 2015 and that had more than 500 enrollees as of July 1, 2015. Therefore, the reporting unit for the 2016 QRS and QHP Enrollee Survey data submissions is defined by the unique State-product type for each QHP issuer. For further details on the 2016 QRS and QHP Enrollee Survey requirements, please see the "Quality Rating System and Qualified Health Plan Enrollee Experience Survey: Technical Guidance for 2016" (September 2015), available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/QRS-and-QHP-Enrollee-Experience-Survey-Technical-Guidance-for-2016.pdf>.

³¹ 45 CFR 156.1120(c) and 156.1125(c).

³² QHP issuers may not use QRS and QHP Enrollee Survey 2015 beta test results in marketing materials. QHP issuers may begin including 2016 QRS and QHP Enrollee Survey results in marketing materials for 2017 plan year coverage.

³³ 45 CFR 155.1400 and 155.1405.

period for 2017 is included in the *Quality Rating System and Qualified Health Plan Enrollee Experience Survey: Technical Guidance for 2016*.

Beginning in the 2016 calendar year, CMS will publicly display QHP quality rating information on HealthCare.gov to help consumers compare QHPs in time for the individual market open enrollment period for 2017. CMS anticipates displaying the 2016 QRS global rating and the rating for the Enrollee Experience summary indicator for each QHP offered through the FFMs and through the SBMs that rely on the Federal eligibility and enrollment platform (i.e., use HealthCare.gov for enrollment). SBMs that do not rely on the Federal platform are also required to display QHP quality rating information calculated by CMS, and in a form and manner specified by CMS, on their respective websites in the 2016 calendar year to facilitate consumer shopping for the 2017 plan year.

Section 8. Quality Improvement Strategy Requirements

This section describes how CMS will review QHP issuer compliance with the quality reporting standards related to the Quality Improvement Strategy (QIS) for purposes of QHP certification and recertification. For the QIS requirements, States performing plan management functions in State Partnership States must evaluate the QIS submissions of the QHP issuers offering coverage through their States using the Federal QIS evaluation methodology; however, issuers should contact their States for additional details.

Section 1311(c)(1)(E) of the Affordable Care Act specifies that, to be certified as a QHP for participation through a Marketplace, each QHP must implement a QIS, as described in section 1311(g)(1) of the Affordable Care Act. The 2016 Payment Notice Final Rule established standards and requirements related to issuer implementation and reporting of a QIS for each eligible QHP in every Marketplace at 45 CFR 156.1130. All issuers offering QHPs through the Marketplaces that meet participation criteria must comply with the QIS requirements as a condition of certification and participation in the Marketplaces. 45 CFR 156.200(b) directs issuers to implement and report on a quality improvement strategy or strategies consistent with the standards in section 1311(g). Consistent with 45 CFR 156.200(b)(5), issuers will attest that they comply with the specific requirements related to the implementation of quality improvement strategies to demonstrate compliance with QIS requirements as part of the certification process for the 2017 plan year. This aligns with the standards in section 1311(g)(3), which requires periodic reporting to the applicable Marketplace, and 45 CFR 155.200(d), which direct Marketplaces to evaluate quality improvement strategies.

Section 1311(g)(2) of the Affordable Care Act directs the Secretary, in consultation with experts in health care quality and stakeholders, to develop guidelines concerning the implementation and oversight of quality improvement strategies. Based on that authority and building on the regulations outlined in the Payment Notice, CMS published the Quality Improvement Strategy: Technical Guidance and User Guide for the 2017 Coverage Year (QIS Technical Guidance) and

the QIS Implementation Plan and Progress Report form on the CMS Marketplace Quality Initiatives website in November 2015.³⁴ The QIS Technical Guidance provides details about the QIS, including a policy overview, Marketplace oversight responsibilities, issuer participation criteria, reporting requirements and data collection (via the QIS Implementation Plan and Progress Report form), evaluation process and methodology, and a step-by-step guide for issuers on how to complete the data collection form.

As detailed in the QIS Technical Guidance, issuers must submit a QIS to the Marketplace for the 2017 plan year if they offered coverage through the Marketplace in 2014 and 2015, provide family and/or adult-only medical coverage, and meet the QIS minimum enrollment threshold. An issuer meets the QIS minimum enrollment threshold if it had more than 500 enrollees within a product type as of July 1, 2015. Additionally, each eligible QHP within a product type (e.g., HMO, PPO) that has more than 500 enrollees as of July 1, 2015, must be included in a QIS.

The QIS requirements apply to all issuers offering QHPs and MSP options through Marketplaces, whether through the individual market or through the SHOP. At this time, QIS requirements do not apply to child-only plans, SADPs, or QHPs that are compatible with HSAs.

To meet the QHP certification standard related to QIS requirements, issuers may choose to either implement one QIS that applies to all of their eligible QHPs in a given Marketplace, or implement more than one QIS to cover all of their eligible QHPs in a given Marketplace. A QIS does not have to address the needs of all enrollees in a given QHP offered through a Marketplace. Depending on the rationale an issuer provides in its QIS submission, a QIS may address a sub-population of a QHP's enrollee population, based on the subpopulation's identified needs.

Issuers applying for QHP certification in the FFMs for the 2017 plan year are expected to submit the QIS Implementation Plan portion of the QIS Implementation Plan and Progress Report form to the relevant Marketplace during the 2017 QHP Certification process, which occurs in calendar year 2016, and then implement the QIS beginning no later than January 2017. An issuer must submit a Progress Report to the FFMs through which it offers QHPs during the QHP Certification process in the year after the issuer submitted its QIS Implementation Plan. The QIS evaluation process for the FFMs will take place annually as part of the QHP Certification process.

All Marketplaces are required to evaluate an issuer's QIS, and issuers must submit separate QIS submissions by State.

³⁴ Available at: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Health-Insurance-Marketplace-Quality-Initiatives.html>.

- CMS will evaluate the QIS submissions for issuers applying to offer QHPs in FFM States.
- In States performing plan management functions, issuers applying to offer QHPs will undergo a joint review of their QIS submissions by the State and the FFMs with final determination being made by the FFM.
- SBMs will evaluate the strategies of the issuers applying to offer QHPs in their respective Marketplaces. SBMs must comply with the Federal minimum reporting requirements. They may establish their own reporting forms and evaluation methodologies that exceed the Federal minimum, as well as their own reporting manner and frequency requirements; or they may choose to use those established by CMS for the FFMs.
- OPM will evaluate QIS submissions for MSP products for all Marketplaces and will issue technical guidance to issuers. For more information on requirements for MSP issuers, issuers should visit: <http://www.opm.gov/healthcare-insurance/multi-state-plan-program/issuer/>. OPM will post specific instructions regarding the 2017 application when available.

Issuers applying to offer QHPs in SBM states should contact the states to confirm timing and whether there are any state-mandated QIS requirements beyond the Federal minimum requirements.

Section 9. Review of Rates

This section pertains to QHP rate filings. Additional information is available in 45 CFR Part 154.

As required by 45 CFR 155.1020(a), a Marketplace must ensure that a QHP issuer submits a justification for a rate increase and prominently posts the justification on its website as required under 45 CFR 156.210. In addition, 45 CFR 155.1020(b) requires a Marketplace to consider all rates increases when certifying plans as QHPs. CMS works with States to review rate increases for QHPs seeking certification to participate 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.

As proposed in the 2017 Payment Notice Proposed Rule, for rates filed for 2017 plans, a health insurance issuer would be required to submit the Unified Rate Review Template (Part I of the Rate Filing Justification) for all single risk pool plans, including new or discontinuing plans. As proposed, this would include single risk pool plans that experience no rate changes, rate decreases, as well as rate for new single risk pool plans. The 2017 Payment Notice Proposed Rule also proposes to amend 45 CFR 154.200(c)(2) such that a rate increase is subject to review if the average increases, including premium rating factors described in 45 CFR 147.102 for all

enrollees, weighted by premium volume for any plan within the product is 10 percent or more. As discussed above, CMS is actively reviewing comments to these proposed policies, and will consider and respond to those comments as part of our rulemaking process.

When reviewing rate increases, CMS will consider:

- Issuers' data and actuarial justification provided in the Rate Filing Justification;
- 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. CMS will post the information contained in Parts I and III of each Rate Filing Justification that is not a trade secret or confidential commercial or financial information, as defined HHS Freedom of Information Act regulations,³⁵ and, as proposed in the 2017 Payment Notice Proposed Rule, would do so for all proposed rate increases (regardless of whether they are subject to review) and for all final rates.

Section 10. 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.

We 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

³⁵ 45 CFR 5.65.

individual meets the eligibility requirements for enrollment (i.e., criteria related to citizenship, lawful presence, incarceration, and residency).³⁶

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 for non-grandfathered health insurance plans offered in the individual and small group markets. 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.

Issuers must use the 2017 benchmark plans,³⁷ which are based on 2014 plans, when designing their plans. However, CMS continues to caution both 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 coverage for 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 as a substantial difference in the cost of the two regimens), 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 formulary tiers, that plan design might effectively discriminate against, or discourages enrollment by, individuals who have those 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

³⁶ 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. At the same time, individuals who have Medicare Part A or Part B are generally not eligible to enroll in individual market coverage, and as noted in the 2017 Payment Notice Proposed Rule, CMS seeks to ensure consumers enroll in the correct coverage.

³⁷ More information on the benchmark plans is available at: <https://www.cms.gov/ccio/resources/data-resources/ehb.html>.

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.

Because the nondiscrimination provisions are related to many requirements under the joint interpretive jurisdiction of the Departments of HHS, Labor, and the Treasury, 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.

As noted previously, we remind issuers that certain other Federal civil rights laws impose non-discrimination requirements. Issuers that receive Federal financial assistance, including in connection with offering a QHP on a Marketplace, are subject to Title VI of the Civil Rights Act of 1964, the Age Discrimination Act of 1975, section 504 of the Rehabilitation Act of 1973, and section 1557 of the Affordable Care Act. The Office for Civil Rights (OCR), which enforces these provisions, published a notice of proposed rulemaking on September 9, 2015 entitled “Nondiscrimination in Health Programs and Activities” (80 Federal Register 54172) on the requirements of section 1557. Issuers that intend to seek certification of one or more QHPs are directed to that proposed rule and to <http://www.hhs.gov/ocr/civilrights> for additional information.

ii. QHP Discriminatory Benefit Design

For purposes of QHP certification, CMS will assess compliance with this standard by collecting an attestation that issuers’ QHPs will not discriminate against individuals on the basis of health status, race, color, national origin, disability, age, sex, gender identity or sexual orientation, consistent with 45 CFR 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 marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs pursuant to 45 CFR 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.

CMS will conduct a review of each QHP to identify outliers based on estimated out-of-pocket costs associated with the standard treatment protocols for medical services and drug regimens needed to treat certain chronic and high cost medical conditions. These protocols are based upon nationally-recognized clinical guidelines. The medical conditions included in the 2017 plan year review will include: bipolar disorder, diabetes, HIV, rheumatoid arthritis, and schizophrenia. QHPs with unusually high estimated out-of-pocket costs associated with accessing these required benefits when compared to similar type plans, at the State and national level, will be flagged as outliers. Other medical conditions may be considered as part of future reviews. In addition,

CMS cautions issuers that the mere fact that a benefit design is similar to other benefit designs offered in a market does not establish that the benefit design is non-discriminatory. CMS retains the right to identify a benefit design as discriminatory even if it is not flagged in the outlier analysis.

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 clinical supporting evidence. CMS will review the supporting documentation and determine if the plan design is discriminatory.

Section 11. Prescription Drugs

To help ensure that QHPs are in compliance with applicable regulations, CMS will conduct the following reviews as part of the 2017 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 deficiency 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 CFR 156.225 and 45 CFR 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 where plans are compared to other plans seeking certification to be offered through an FFM and flagged when identified as outliers. The outlier calculation includes both State-level and national lower outlier threshold values. CMS requires that QHPs meet or exceed both threshold values. QHPs that are outliers have an unusually high number of drugs that are subject to prior authorization and/or step therapy requirements in a particular United States Pharmacopeia (USP) category and class. CMS also encourages States performing plan management functions to implement this type of review.

ii. *Clinical Guideline-Based Review of Prescription Drug Coverage*

As we have in prior years, CMS will review each QHP's prescription drug coverage to determine that it meets applicable standards in 45 CFR 156.225 and 45 CFR 156.125. Based on data submitted by issuers in the prescription drug template, this review will analyze the availability of drugs recommended by nationally-recognized clinical guidelines used in the treatment of specific medical conditions. The medical conditions included in the review include the following: bipolar disorder, breast cancer, diabetes, hepatitis C, HIV, multiple sclerosis, prostate cancer, rheumatoid arthritis, and schizophrenia. In addition to analyzing the appropriate coverage of drugs recommended by the clinical guidelines, the review will also analyze cost-sharing requirements associated with these drugs so that they are not used to dissuade consumers with such conditions from enrolling in the QHP. This portion of the review will identify QHPs that are outliers based on the presence of unusually high cost-sharing requirements for specific drugs. Other additional medical conditions may be considered as part of future reviews.

iii. *Review of Tier Placement of Prescription Drugs Recommended for Treatment of Specific Medical Conditions*

As referenced in Section 10.ii on QHP Discriminatory Benefit Design, CMS will conduct a review of each QHP's coverage of standard treatment protocols for the treatment of certain chronic and high-cost medical conditions which includes the associated medical services and drug coverage for first and second line therapies as recommended by nationally-recognized clinical guidelines. CMS is also concerned about adverse tiering, which occurs when a formulary benefit design assigns most or all drugs in the same therapeutic class needed to treat a specific chronic, high cost medical condition to a high cost-sharing tier. Since adverse tiering is potentially discriminatory, this review may examine the tier placement of prescription drugs to determine whether QHPs are also consistently placing drugs used to treat these medical conditions on a high cost-sharing tier.

Section 12. Supporting Informed Consumer Choice/Meaningful Difference

This section describes how CMS plans to conduct reviews of the meaningful difference standard for QHP certification and recertification in 2017. States performing plan management functions in the FFMAs may use a similar approach. This section does not apply to SADPs.

For 2017, CMS intends to apply more standardized criteria than previous years in assessing whether plans proposed to be offered by potential QHP issuers are meaningfully different from other plans the issuer has submitted for certification. In the 2017 Payment Notice Proposed Rule, CMS proposed to remove the following criteria in assessing whether a reasonable consumer would be able to identify one or more material differences between a plan and other plan offerings: Health Savings Account eligibility, self-only plan offering and non-self-only plan offering.

CMS will consider plans within the same metal level and service area to be meaningfully different on the basis of different plan type or different child-only plan offering status, in accordance with requirements in 45 CFR 156.298. As such, CMS will organize an issuer's proposed QHPs from a given State into subgroups based on plan type, metal level, child-only plan offering status, and overlapping counties/service areas.

Second, CMS will review each subgroup to determine whether the potential QHPs in that subgroup differ from each other based on the criteria of one or more material difference in cost sharing, provider networks, and covered benefits.

Cost Sharing

For plans to be considered materially different on the basis of cost sharing, QHPs within the subgroup must differ in at least one of the following ways: 1) having an integrated medical and drug maximum-out-of-pocket limit (MOOP); 2) having an integrated medical and drug deductible; 3) having multiple in-network tiers rather than only one; 4) \$200 or more difference in MOOP; or 5) \$100 or more difference in deductible.

CMS will not consider the following criteria in determining whether plans are meaningfully different: 1) having an in-network deductible rather than only a combined in/out-of-network deductible; and 2) having an in-network maximum-out-of-pocket (MOOP) rather than only a combined in/out-of-network MOOP.

Provider Networks

For plans to be considered materially different on the basis of provider networks, the plans within the subgroup must have different provider network IDs.

Covered Benefits

For plans to be considered materially different on the basis of covered benefits, the plans within the subgroup must differ in the coverage of one or more benefits that display to consumers on the HealthCare.gov website. Plans will be considered meaningfully different if they vary in the coverage of at least one of the following benefits that display on the website: Skilled Nursing Facility; Chiropractic Care; Habilitation Services; Routine Eye Exam (Adult); Routine Dental Services (Adult); Basic Dental Care – Adult; Major Dental Care – Adult; Orthodontia – Adult; Dental Check-Up for Children; Basic Dental Care – Child; Major Dental Care – Child; Orthodontia – Child; Hearing Aids; Infertility Treatment; Private-Duty Nursing; Bariatric Surgery; or Acupuncture. Note that QHPs must cover benefits required to provide EHB based on the applicable benchmark in their State.

CMS will not consider plans to be meaningfully different on the basis of covered benefits if the difference involves only benefits that are not displayed on the HealthCare.gov website. CMS will not consider differences in formulary ID in assessing differences on the basis of covered

benefits, as CMS intends to determine meaningful difference with regard to prescription drugs on the basis of cost-sharing differences.

If CMS finds that two or more plans within a subgroup do not differ based on at least one of the factors of cost sharing, provider networks or covered benefits as specified above, then those QHPs would be flagged as not being meaningfully different. If CMS flags potential QHPs as not meaningfully different, 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.

Section 13. Third Party Payment of Premiums and Cost-sharing

In the 2017 Payment Notice Proposed Rule, we proposed amendments to 45 CFR 156.1250, governing requirements related to QHP and SADP issuers' acceptance of third party payments of premiums and cost-sharing on behalf of enrollees. First, we proposed to amend 45 CFR 156.1250(c) to include under "Federal and State government programs," programs of the political subdivisions of the State, namely counties and municipalities. In other words, QHP and SADP issuers in the individual market would be required to accept third party payments from "Federal, State, and Local government programs." We also proposed that if a Federal, State, and Local government program is authorized by law to administer premium and cost-sharing assistance through grantees or sub-grantees, then the payments made by such grantees or sub-grantees on behalf of plan enrollees are required to be accepted by issuers. In this case, because the source of the premium or cost-sharing assistance is the government program and administration or distribution of that assistance through grantees and/or sub-grantees is authorized under statute and/or regulations, the requirement for issuers to accept the payments fall under 45 CFR 156.1250(c).

We also proposed that the same grantee/sub-grantee payment structure requirement applies under 45 CFR 156.1250(a), for Ryan White HIV/AIDS programs, which are authorized by law to administer funds through sub-grantees that are not government entities. These programs operate by working with cities, States, and local community-based organizations to provide services in line with their statutory authority. Sections 2604(c)(3)(F), 2612(c)(3)(F), and 2651(c)(3)(F) of the PHS Act authorize Ryan White HIV/AIDS program grantees and sub-grantees to use program funds for premium and cost-sharing assistance. These grantees and sub-grantees must provide the assistance through third-party payments as they are prohibited from making payments directly to patients.

We also proposed to add a new requirement that the entities from which third party premium and cost-sharing payments must be accepted under 45 CFR 156.1250 must notify HHS, in a format and timeline specified in guidance, their intent to make payments of premiums under this section

and the number of consumers for whom they expect to make payments. Finally, while cost-sharing payments are generally made to providers, rather than to issuers, there are certain contractual circumstances where an issuer's downstream entity engages in activities on behalf of the issuer, including the collection of cost-sharing payments. For example, an issuer's pharmacy benefits manager may collect cost-sharing payments from the issuer's plan enrollees for prescription drugs. We proposed that in such situations, the rules at 45 CFR 156.1250 regarding third party payments would apply. Issuers would be required to accept third party cost-sharing payments on behalf of enrollees in circumstances where the issuer or the issuer's downstream entity accepts cost-sharing payments from plan enrollees.

Section 14. Cost Sharing Reductions

QHP issuers are required under 45 CFR 156.420 to submit three plan variations with reduced cost sharing for each silver level QHP an issuer offers through the Marketplace, as well as zero and limited cost-sharing plan variations for all metal-level 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 2017 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 2017 AV requirements.
- Do not have an annual limitation on cost-sharing that exceeds the permissible threshold for the specified plan variation, as will be finalized in the 2017 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 CFR 156.420(d)³⁸) does not exceed the corresponding cost sharing in the standard silver plan or any other silver plan variation of the standard silver plan with a lower AV. For example, if an enrollee in a 87 percent plan variation pays a \$40 co-pay for a specialist visit, the specialist visit co-payment for an enrollee in the associated 94 percent plan variation must be less than or equal to \$40.
- Are designed such that no individual member of an enrollment group is charged more cost sharing than the 2017 maximum annual limitation on cost sharing for individuals or,

³⁸ To simplify benefit design, issuers may reduce out-of-pocket spending for non-EHB 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.

as applicable, the 2017 reduced maximum annual limitation on cost sharing for individuals.

- Are designed such that zero cost-sharing plan variations may not have positive cost-sharing for any covered EHB, either in or out-of-network. This includes any copayment, coinsurance, deductible, or application of an annual limitation on cost sharing.³⁹
- 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 15. Data Integrity Tool

This section describes the Data Integrity Tool and the data integrity reviews that CMS will conduct for 2017 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.

CMS expects issuers to use the Data Integrity Tool in 2016 for plan years beginning in 2017 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 risk that their plan information will not display properly on Plan Compare, including that their plans will not be displayed at all due to data errors.

QHP and SADP issuers can use the Data Integrity Tool, which runs checks specific to individual and SHOP market plans. CMS will release an updated version of the Data Integrity Tool that will incorporate validations specific to the 2017 QHP Application templates.

³⁹ 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.

CMS will conduct data integrity reviews on all QHP and SADP applications for plan years beginning in 2017. During each review round, CMS will send issuers notices of data integrity errors that would result in either improper display of plan information to consumers or other irregularities. CMS will send summary data integrity review results to States during each review round. Data integrity notices are different from correction notices, which are generated during the separate process of QHP certification reviews.

CHAPTER 3: DECISION SUPPORT TOOLS

CMS has developed a number of decision support tools to help consumers select plans. Under 45 CFR 156.122(d) and 156.230(b), QHP issuers in the FFMs must submit certain drug formulary and provider directory information to the FFMs in a manner specified by HHS. HHS has required that issuers in the FFMs submit the information in a machine readable format, and update it not less than monthly. With this information, CMS developed a formulary lookup tool and provider lookup tool.

Section 1. Provider Directory Links and Provider Lookup Tool

This section discusses the provider directory links and the provider lookup tool for QHPs. Under 45 CFR 156.230(b), a QHP issuer, including issuers of SADPs, 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 FFMs, CMS, and OPM. CMS will consider a provider directory to be up-to-date if the issuer updates it at least monthly. Additionally, CMS will consider a provider directory to be 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 plans and provider networks. Further, if the health plan issuer maintains multiple provider networks, the plans 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. Similar to previous years, QHP issuers must make their provider directories available to the FFM for publication online by providing the URL link to their network directory. CMS will collect QHPs' provider directory URLs as part of the QHP Application.

CMS also requires QHP issuers in the FFMs, including issuers of SADPs, to make this provider directory information publicly available on their websites in a machine-readable file and format specified by CMS, to allow the creation of user-friendly aggregated information sources. These machine-readable files increase transparency by allowing CMS and other software developers to access provider data and create innovative and informative tools to assist consumers in understanding plans' provider networks. With this information, CMS developed a provider

directory lookup tool on HealthCare.gov. This tool allows consumers to determine if a plan includes a specific provider in its network based on issuer-provided data. For this reason, QHP issuers in an FFM must submit data in a manner that complies with the data requirements and specifications in the Information Collection for Machine Readable Data for Provider Network and Prescription Formulary Content for FFM QHPs (CMS-10558),⁴⁰ update this information not less than monthly, and submit the machine readable link at: <https://marketplace.cms.gov/submission/>.

Section 2. Formulary Drug List and Formulary Lookup Tool

This section discusses the issuer formulary drug list and formulary lookup tool. Under 45 CFR 156.122(d), issuers' formulary drug lists are required to 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. For the purpose of 45 CFR 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.

Similar to previous years, CMS will collect FFM 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 CFR 147.200(a)(2)(i)(L). The formulary drug list must be published in a manner that is easily accessible to plan enrollees, prospective enrollees, the State, the Marketplace, CMS, 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.

Under section 156.122(d)(2), CMS requires QHP issuers in the FFMs (including Small Business Health Options Programs [SHOP] issuers but excluding SADP issuers) to make this formulary drug list information publicly available on their websites in a machine-readable file and format

⁴⁰ Information regarding the data requirements and specifications is available at: <http://www.reginfo.gov/public/do/PRAOMBHistory?ombControlNumber=0938-1284>.

specified by CMS, to allow the creation of user-friendly aggregated information sources. These machine-readable files increase transparency by allowing CMS and other software developers to access formulary data and create innovative and informative tools to assist enrollees in understanding plans' formularies. With this information, CMS developed a formulary lookup tool on HealthCare.gov. This tool allows consumers to determine if a plan covers a specific drug (or drugs) based on issuer-provided data. As noted in section 1, QHP issuers in the FFMs must submit the data in a manner that complies with the data requirements and specifications in the Information Collection for Machine Readable Data for Provider Network and Prescription Formulary Content for FFM QHPs (CMS-10558), update this information not less than monthly, and submit the machine readable link at: <https://marketplace.cms.gov/submission/>.

Section 3. Out-of-Pocket Cost Comparison Tool

This section describes the Out-of-Pocket (OOP) Cost Comparison Tool that is available on HealthCare.gov to help consumers make more informed choices about their health insurance coverage and to help them pick a plan that will best meet their needs.

CMS offers an OOP cost comparison tool that can help a potential enrollee evaluate key differences across QHPs available through the FFMs. Using this tool, potential enrollees can see, based on their expected low, medium, or high use of health care services, a total OOP estimate for the costs they could expect to pay throughout the year given the cost sharing design for a particular health insurance plan. The OOP cost comparison tool allows shoppers in the FFMs to see estimates of total spending (including premiums and cost-sharing) across various health insurance plans available through the FFMs. This OOP estimate takes into account key cost sharing design elements in a plan including but not limited to copayments, coinsurance, deductibles, out-of-pocket maximums and uncovered expenses.

CMS published a bulletin⁴¹ explaining the methodology and implementation of the OOP cost estimator tool for the FFMs. The bulletin discusses the following major inputs to the calculator:

- Utilization and Cost Data
- Plan Benefit Data
- User Input

The OOP Cost Comparison Tool can be accessed at <https://www.healthcare.gov/see-plans/>.

⁴¹ Available at: <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/OOP-Tool-Bulletin-10-29-15.pdf>.

Section 4. Transparency in Coverage Reporting

The content of this section outlines proposed transparency reporting requirements for all QHP issuers, including SADP issuers, in the FFMs, including in States that are performing plan management functions. Issuers in SBM-FPs will also use the same approach.

CMS's information collection request, CMS-10572, "Transparency in Coverage Reporting by Qualified Health Plan Issuers," seeks additional feedback on these proposed elements for transparency reporting. Therefore, the proposed data collection elements are subject to change pending approval by the Office of Management and Budget pursuant to the Paperwork Reduction Act of 1995.

We note that an initial notice was posted in the Federal Register at 80 Federal Register 48320, initiating a 60-day comment period from August 12, 2015 that closed on October 13, 2015.

CHAPTER 4: STAND-ALONE DENTAL PLANS: 2017 APPROACH

Issuers submitting applications for certification of SADPs will have several unique standards due to their excepted benefit status, and their limited scope of benefits. The charts below (Tables 4.1 and 4.2), are intended to assist issuers in understanding those standards that are applicable to SADPs seeking certification in the FFMs for the 2017 plan year. 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 4.1: Standards and Tools Applicable to SADPs

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	Data Integrity Tool
Acceptance of Third Party Premium and Cost-sharing Payments	Machine Readable*

Table 4.2: Standards and Tools Not Applicable to SADPs

Standard or Tool Does Not Apply	
Accreditation	Patient Safety
Cost-sharing Reduction Plan Variations	Quality Reporting
Unified Rate Review Template	Meaningful Difference
Cost Sharing Reductions	Prescription Drugs

Section 1. Stand-alone Dental Plans: 2017 Approach

CMS has previously outlined a process for SADPs to complete the rating template portion of the QHP Application. As in previous years, for certification for 2017 plan years, SADP issuers will complete the rating templates in accordance with the associated rating and business rules and to indicate in the 2017 Plan and Benefits Template whether they are committing to charging that rate (“guaranteed” rates) or retaining flexibility to change the rate (“estimated” rates).

Section 2. Intent to Apply

QHP issuers are permitted to offer QHPs that omit coverage of the pediatric dental EHB through a Marketplace if an SADP is offered through the Marketplace in the same service area in which the QHP is offered. In 2014, 2015, and 2016, CMS conducted a voluntary reporting process for SADP issuers to communicate their intent to apply for certification to be offered through the Marketplace and is following a similar approach for 2017.

Section 3. SADP Annual Limitation on Cost Sharing

In the 2017 Payment Notice Proposed Rule, we proposed a new process by which the annual limitation on cost sharing for SADPs would be increased over time. Any increase in the annual limitation would be implemented on plans in years beginning after 2016. Any increase would be based upon the Consumer Price Index (CPI) for dental services and be made in \$25 increments for coverage of one child. If this proposal in the 2017 Payment Notice Proposed Rule is finalized, we intend to publish new annual limitations on cost-sharing annually in the Notice of Benefit Payment Parameters rule.

Section 4: Display of Adult Dental Benefits Icon

CMS's 2016 Plan Preview User Guide⁴² indicates that in order for the "Dental: Child & Adult" icon to display, SADPs must cover three categories of pediatric benefits (i.e., Dental Check-up, Basic, and Major) as well as all three categories of adult benefits (i.e., Routine, Basic, and Major). We believe that a consumer should have the general expectation that an SADP with the "Dental: Child & Adult" icon would cover services typically offered by a dental plan, including preventive care and minor and major dental services. These policies will be carried forward to the 2017 plan year and be replicated in the 2017 Plan Preview User Guide.

CHAPTER 5: QUALIFIED HEALTH PLAN PERFORMANCE AND OVERSIGHT

Section 1. Account Management: 2017 Issues

All issuers participating in the FFMs, 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 SBM-FPs. For issuers offering QHPs through the FFMs for the first time, CMS will assign an Account Manager prior to the start of open enrollment for the 2017 plan year. The Account Managers will serve as issuers' primary point of contact with the FFMs for non-technical QHP and SADP issues and will provide QHP issuers with clarification and other assistance related to issuers' responsibilities and requirements for participating in the FFM. Additionally, the Account Manager will communicate updates to issuers, direct issuers to other resources as appropriate, and coordinate resolution of cross-cutting issues. CMS expects that States, regardless of Marketplace type, will continue to take the lead in addressing market-wide issues, such as complaints related to market conduct.

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

Section 2. QHP Issuer Compliance Monitoring

This section describes how CMS, in its role as operator of the FFMs, will monitor issuer compliance with all applicable Marketplace standards on an ongoing basis throughout plan years beginning in 2017. CMS anticipates adopting the same approach in States that are performing plan management functions.

⁴² Available at: <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/FFM-PM-User-Guide-Plan-Preview-0515015.pdf>.

Pursuant to 45 CFR 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 CFR 155.1000(c). CMS will evaluate an issuer's performance to determine if making the issuer's health plan(s) available is in the interest of qualified individuals and employers enrolling in coverage through the FFMs. 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 2016 Payment Notice Final Rule extended the good faith compliance policy at 45 CFR 156.800(c) through the 2015 calendar year. The good faith compliance policy will end after the 2015 calendar year. As a general principle, CMS intends to continue providing technical assistance to issuers to assist with understanding applicable Marketplace standards and guidance. CMS expects that by 2017, issuers will have gained more experience operating in the FFMs environment and will be more familiar with the Marketplace requirements, and have updated their policies and procedures to reflect the applicable standards, guidelines, and operations.

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 FFMs, will assess QHP and SADP issuer compliance with applicable Marketplace 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 Marketplace standards by choosing to perform selected compliance reviews on issuers in their respective States.

Consistent with CMS's authority under 45 CFR 156.715, CMS will continue to perform these compliance reviews to monitor issuer compliance with applicable Marketplace-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.

Similar to past years, 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 standard⁴³ 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

⁴³ Standard reviews include all review areas.

specific issue of potential non-compliance, CMS may perform a targeted⁴⁴ review specific to the area(s) of potential non-compliance and/or conduct the compliance review on an expedited basis.⁴⁵ 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 review⁴⁶ and the type and location of the review will be included in the issuer selection notification. CMS will review data at both the issuer and the QHP/SADP level. CMS may request, as part of the compliance review process, policies, procedures, and any other applicable documentation⁴⁷ reasonably necessary to evaluate and verify compliance with the applicable 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 a summary of the results of the reviews conducted by CMS with States and the lessons learned with issuers, as well as make this information generally available to the public on a CMS website.

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.⁴⁸

i. QHP Issuer Responsibilities

Pursuant to 45 CFR 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, and verify fulfillment of the applicable FFM

⁴⁴ Targeted reviews can include all review areas or just select review areas.

⁴⁵ Issuers selected for expedited compliance reviews will be required to submit documentation with a shorter turnaround time.

⁴⁶ On-site reviews will take place at the issuer's place of business.

⁴⁷ Additional documentation could include sample sets of applicable data (i.e., notices, claims, complaints, etc.).

⁴⁸ 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 FFMs in accordance with 45 CFR 155.220(c)(3).

registration and training requirements before allowing access to the QHP issuers' 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 by reviewing the registration completion list on the CMS agent and broker resources page, or the on the Private Issuer Community site of CMSzONE.⁴⁹ 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, conflicts of interest, marketing, and continuing education.

ii. Agent and Broker Agreement

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 CFR 155.260, related to the use of personally identifiable information (PII) by non-Marketplace entities.⁵⁰ 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.

⁴⁹ The list on the agent and broker resources page is updated twice monthly and is available at [https://www.cms.gov/CCIIO/programs-and-initiatives/health-insurance-marketplaces/a-b-resources.html#Agent and Broker Federally-Facilitated Marketplace \(FFM\) Registration Completion List](https://www.cms.gov/CCIIO/programs-and-initiatives/health-insurance-marketplaces/a-b-resources.html#Agent and Broker Federally-Facilitated Marketplace (FFM) Registration Completion List). The list on the CMSzONE Private Issuer Community is updated weekly and posted by Friday morning at: <https://zone.cms.gov/document/agent-and-broker-federally-facilitated-marketplace-ffm-registration-completion-list>. More agent and broker guidance is available on the Agent and Broker Resources Page at: <http://www.cms.gov/CCIIO/programs-and-initiatives/health-insurance-marketplaces/a-b-resources.html>.

⁵⁰ These include the eight privacy principles listed at 45 CFR 155.260(a)(3).

- 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;
- 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.

Agents and brokers registered with the FFMs must comply with all applicable privacy and security requirements, including but not limited to the standards established by HHS pursuant to 45 CFR 155.260, related to the use and handling of PII by non-Marketplace entities.⁵¹ Before facilitating enrollments through the FFMs, agents and brokers must execute the IM and/or 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.

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 which 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

⁵¹ These include the eight privacy principles listed at 45 CFR 155.260(a)(3).

General Agreement, IM Privacy and Security Agreement, SHOP Privacy and Security Agreement, and/or the Web-Broker Agreement, as applicable.⁵² 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's 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 CFR 155.260. We note that termination of the agreement results in the following: termination of registration and removal of the agent's or broker's National Provider Number (NPN) from our registration completion list, which generally bars the agent or broker from being compensated by QHP issuers for FFM enrollments⁵³; and removal of the agent/broker role from the FFM User ID, which prevents the agent or broker from logging into the agent/broker landing page on a QHP issuer or web-broker website for direct enrollment, and prevents the agent or broker from logging in to the SHOP agent/broker portal.

We proposed to amend 45 CFR 155.220(g) in the 2017 Payment Notice Proposed Rule to provide that if CMS reasonably suspects that an agent or broker may have engaged in fraud or abusive conduct using PII of FFM applicants or enrollees, or in connection with an FFM enrollment or application, CMS may temporarily suspend the agent's or broker's agreement(s) with the FFMs for up to 90 calendar days, with the suspension effective as of the date of the notice to the agent or broker. We further proposed that if CMS reasonably confirms the credibility of an allegation that an agent or broker engaged in fraud or abusive conduct (or is notified by a State or law enforcement authority of the State or law enforcement authority's finding or determination of fraud or behavior that would constitute abusive conduct) using PII of FFM enrollees or applicants, or in connection with an FFM enrollment or application, CMS will terminate the agent's or broker's agreement(s) with the FFMs for cause with the termination effective as of the date of the notice to the agent or broker. During the suspension period and following termination of the agreements under section, the agent or broker would not be registered with the FFMs, or be permitted to facilitate enrollments through an FFM, or be permitted to assist individuals with applying for the advanced payment of the premium tax credit (APTC) or cost sharing reduction (CSRs). We note that CMS currently works with States and law enforcement to investigate and resolve suspected incidents of fraud or abusive conduct, and we would coordinate with OIG and other State and Federal agencies (including law enforcement) if CMS were to take suspension or termination action. We also proposed in new paragraph (j) the requirement that agents and brokers participating in the FFMs comply with new proposed

⁵² 45 CFR 155.220(g).

⁵³ See vi. under this section for information on the one exception to this general rule.

FFM standards of conduct to protect consumers and ensure the proper administration of the FFMs. These include the requirement to provide the FFMs with correct information under section 1411(b) of the Affordable Care Act; and to obtain the consent of the individual, employer, or employee prior to assisting with or facilitating enrollment through an FFM, or assisting the individual in applying for insurance affordability programs. Finally, as part of the 2017 Payment Notice Proposed Rule, we propose in new paragraph (k) that CMS may deny the agent or broker the right to enter in an agreement(s) with the FFMs in future years and/or impose civil money penalties under 45 CFR 155.285 for non-compliance with requirements under 45 CFR 155.220.

iv. Web-brokers

CMS regulations establish additional requirements that apply when an agent or broker uses his or hers own website, or that of another agent or broker, to facilitate enrollment in a QHP through the FFMs.⁵⁴ 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 CFR 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 QHPs⁵⁵ (including SADPs⁵⁶) through the FFMs online, alongside traditional agents and brokers who assist consumers with enrollment through the Marketplaces. This enrollment pathway through a web-broker is referred to as “direct enrollment.”

Regulations at 45 CFR 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 CFR 155.205(b)(1) is displayed on the web-broker’s website, the web-broker must prominently display a standardized disclaimer provided by CMS stating that information required under 45 CFR 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 each web-broker must prominently display a standardized disclaimer

⁵⁴ 45 CFR 155.220(c)(3)-(4).

⁵⁵ Pursuant to 45 CFR 155.220(i), beginning January 1, 2015, SHOPs may permit agents and brokers, in States that permit such activity under State law, to use a QHP issuer or web-broker website to provide assistance to employers and facilitate enrollment of employees in SHOP QHPs, subject to the requirements of 45 CFR 155.220(c)(3). The FF-SHOPs may elect to implement this functionality for future plan years.

⁵⁶ As detailed in the rule Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers; Final Rule and Interim Final Rule, 77 Federal Register 18310 (March 27, 2012), with some limited exceptions, SADPs are considered a type of QHP. We expect agents, brokers, and web-brokers registered with the FFEs to comply with applicable rules and requirements in connection with SADPs, just as they must comply with those rules in connection with medical QHPs.

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 CFR 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 Marketplace for the 2017 benefit year, or one year after a web-broker registers with the FFMs, whichever date is later. First, under 45 CFR 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 (LEP) 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 CFR 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 a LEP population that reaches 10 percent or more of the population of the relevant State, as determined in HHS guidance. 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 February 2016.

In prior years, CMS has supported 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.

In the 2017 Payment Notice Proposed Rule, we solicited comments on an expanded direct enrollment pathway option under which an applicant could remain on the web-based entity's

(WBE's)⁵⁷ website to complete the application and enroll in coverage, and the WBE website would obtain eligibility information from the Marketplace to support the consumer in selecting and enrolling in a QHP with the APTC and CSRs (as applicable). The intent is to have this information exchange occur through a Marketplace-approved web service, and offering WBEs more operational flexibility to expand front-end, consumer-facing channels for enrollment through a seamless consumer experience. CMS is considering enhancements to privacy and security protections of the information transmitted by WBEs, and we note that is important for WBEs to have robust cyber-security systems. CMS considered how to ensure that consumers understand that they are applying for Marketplace coverage, such as through specific branding or wording requirements if a non-FFM front-end website is used for the entire application and enrollment process.

v. *Compensation*

Agents and brokers are compensated directly by QHP issuers under the terms of their QHP issuer contracts for assisting consumers enrolling in QHPs through an FFM. Compensation includes commissions, fees, or other incentives as established in the relevant contract between a QHP issuer and the agent or broker. An agent or broker must be affiliated or have a contractual relationship with the respective issuer, in accordance with applicable State law, and must complete the applicable FFM registration requirements in order to be paid by an issuer for a Marketplace transaction. The FFMs 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.⁵⁸ CMS believes that withholding compensation from affiliated agents and brokers that fail to comply with FFM registration and other applicable Federal requirements would generally be required for an issuer to demonstrate compliance 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., NPN) to QHP issuers on the 834 enrollment transactions (834), but the FFMs do not play a role in setting compensation levels or making appointments between issuers and agents and brokers, and 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

⁵⁷ A web-based entity (WBE) maintains an Application Portal Interface (API) connection with the Marketplace to support the direct enrollment pathway. WBEs can be web-brokers or QHP issuers.

⁵⁸ See i. under this section and 45 CFR 156.340.

outside the Marketplaces.⁵⁹ This compensation approach is a required participation standard for QHP issuers offering coverage in the FFM, including both the Individual Market and SHOP. We note that in determining whether a health plan offered in the State outside of the Marketplace is similar to a QHP offered through the FFM, we would consider whether the plan had a similar cost-sharing and benefit structure, cover a majority of the same service area, and cover a majority of the same provider network as compared to the QHP.⁶⁰

In cases where an FFM-registered agent or broker receives compensation through a third party entity such as an agency or brokerage, the agent or broker may work with the QHP issuer to appropriately direct compensation based on the NPN included on the 834. The QHP issuer has the discretion to comply with the agent's or broker's request for direction or manner of payment according to the terms of his or her compensation arrangement and applicable State law.

If an FFM-registered agent or broker has a reason to believe that his or her NPN (or agency/brokerage NPN) should have been included on the 834 but was not, the agent or broker may contact the respective QHP issuer directly to discuss the situation. CMS expects that a QHP issuer would issue compensation to an FFM-registered agent or broker with whom the QHP is affiliated if it is determined from the issuer's, agent's, or broker's records that the agent or broker did in fact assist the consumer, but the NPN was erroneously left off of the 834. Such records may include a consent form from the consumer, an issuer's broker of record form, or similar documentation to demonstrate that the consumer was the agent's or broker's client for the enrollment in question.

Agents and brokers who are acting as Navigators, certified application counselors, and/or (in FFM and States performing plan management functions) non-Navigator assistance personnel may not receive any direct or indirect compensation from health insurance or stop loss insurance issuers in connection with the enrollment of any individuals or employees in a QHP or non-QHP. 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 FFM 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 FFM, agents or brokers would not need to

⁵⁹ 45 CFR 156.200(f).

⁶⁰ CMS would use the same criteria outlined in the market-wide definition of "plan" at 45 CFR 144.103, and the discussion of whether a health plan offered outside the Marketplace is "substantially similar" to a QHP in paragraph (3) under the definition of QHP at 45 CFR 153.500, in making this determination.

have a current registration to be listed on the 2016 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 established standards at 45 CFR 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 may satisfy the requirement to receive training in the range of QHP options and the insurance affordability programs; HHS continues to offer training at no cost. An entity that is interested in becoming a vendor must submit an application and, upon approval of the application, execute an agreement with HHS. Vendors are 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 to collect, store, and share with HHS all data from agent and broker users of the vendor's training in a manner, format, and frequency specified by HHS. Entities whose applications are not approved or who have their approval revoked may request an appeal. The list of approved vendors for Plan Year 2016 is posted on the CCIIO website and we intend to also post the list of approved vendors for Plan Year 2017 on the CCIIO website. HHS continues to monitor vendors' compliance after their respective training programs launch, and HHS may revoke approval if a vendor does not comply with HHS standards.

We proposed in the 2017 Payment Notice Proposed Rule amending the requirements on entities interested in becoming an approved vendor under 45 CFR 155.222. Specifically, we proposed eliminating the requirement that approved vendors perform identity verification services, as CMS intends to continue performing the identity proofing function and would expect that issuers are overseeing affiliated agents and brokers to ensure that they have the appropriate licenses required under the applicable State law.

Section 5. Oversight of Marketing Activities

This section describes how CMS will monitor QHP marketing during plan years beginning in 2017 in the FFMs and provides information that supplements what was discussed in the 2015 and 2016 Letters to Issuers. States performing plan management functions in the FFMs are encouraged to take a similar approach.

Regulations at 45 CFR 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 CFR 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 CFR 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 2016 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 CFR 156.225(a). In FFM States, CMS may review QHP marketing materials for compliance with 45 CFR 156.200(e) and 45 CFR 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 CFR 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.

In the 2017 Payment Notice Proposed Rule, we proposed a new paragraph (j)(2)(i) at 45 CFR 155.220 that would require agents and brokers assisting consumers with FFM transactions to provide consumers with correct information, without omission of material fact, regarding the FFMs, QHPs (including SADPs⁶¹) offered through the FFMs, and insurance affordability programs, and refrain from marketing or conduct that is misleading or coercive, or discriminates based on race, color, national origin, disability, age, sex, gender identity, or sexual orientation. We noted that these proposed standards for conduct would extend to naming of businesses and

⁶¹ As detailed in the Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers; Final Rule and Interim Final Rule, 77 Fed. Reg. 18310 (March 27, 2012), with some limited exceptions, SADPs are considered a type of QHP. We expect agents, brokers, and web-brokers registered with the FFEs to comply with applicable rules and requirements in connection with SADPs, just as they must comply with those rules in connection with medical QHPs.

websites associated with agents, brokers or web-brokers, and that use of “Exchange,” “Marketplace,” or other words in a name or URL that would reasonably cause confusion with a Federal program or website may be considered misleading.

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 Marketplace.⁶² 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 must also be provided.⁶³ Although CMS does not require disclosure of affiliations with QHP issuers, consistent with 45 CFR 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 6: FF-SHOPS

Section 1. Termination Transactions/Switch Files for Non-renewals

This section describes how the Federally-facilitated SHOPS (FF-SHOPS) communicate group terminations to issuers when a group does not renew its enrollment or coverage through an FF-SHOP or when enrollees in coverage through an FF-SHOP switch to a new issuer for a new plan year.

FF-SHOP issuers are currently not receiving Health Insurance Exchange Plan Management (HIX) termination transactions when groups do not renew their enrollment or coverage through an FF-SHOP or when enrollees in coverage through an FF-SHOP switch to a new issuer for a new plan year. Instead, FF-SHOP issuers receive a Switch File when these two scenarios occur.

CMS sends two Switch Files via the managed file transfer (MFT) process where files are pushed and pulled from each trading partner’s Outbound 30 and Inbound 30 folders at the exchange data center. The files are sent in a pipe delimited format and are created and sent between the 20th and 25th of every month. The Issuer Group Switch File identifies employer groups that are not renewing their enrollment or coverage with any issuer through an FF-SHOP for a plan year beginning in 2017. The Member Switch File identifies enrollees that are not renewing their

⁶² 45 CFR 155.220(c)(3)(ii).

⁶³ See 45 CFR 155.220(c)(3)(vii). Also see 45 CFR 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 CFR 155.220(c)(3).

enrollment or coverage through an FF-SHOP for a plan year beginning in 2017, and enrollees who select a different issuer from the one that issued their coverage for the previous plan year. Further, if an issuer remains active, but changes its HIOS ID, CMS sends a Member Switch File for all active enrollments with the issuer. Additional information about the FF-SHOP Switch File is available in the Switch File Interface Control Document located on REGTAP.⁶⁴

Issues and questions concerning Switch Files can be resolved through the FF-SHOP Call Center or through the Enrollment Reconciliation Dispute Resolution process.

Section 2. Premiums Based on Average Enrollee Premium Amounts

This section provides clarification that for the 2017 plan year, CMS will not support calculating premiums based on average enrollee premium amounts.

45 CFR 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 does not anticipate that the operational capacity to calculate and display premiums based on an average enrollee premium amounts will be available to consumers for the 2017 plan year and will provide guidance when this functionality becomes available in the FF-SHOP.

Section 3. Renewals

This section describes the renewal process for employers and employees, as the FF-SHOP system currently does not support automated processes for renewals.

Currently, renewal of FF-SHOP participation and/or coverage is not an automated process and requires both qualified employers and qualified employees to access their accounts on 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-SHOPs in the previous plan year. While the FF-SHOPs will be sending notices describing the renewal process to employer groups and employees, this does not relieve issuers of their renewal notice requirements. For information on issuer requirements involving renewal notices, see guidance published by CMS on September 2, 2014.⁶⁵

Medical and dental coverage renewals will continue to be considered separately so that a qualified employee (and dependents, if applicable) may renew in medical coverage alone, dental

⁶⁴Available at:

http://www.regtap.info/uploads/library/FFSHOPPASEnrollmentReconciliationICDv19_101615_5CR_101615.docx.

⁶⁵ Available at: <http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Renewal-Notices-9-3-14-final.pdf>.

coverage alone, or both, provided that the qualified employer continues to offer both medical and dental coverage through the FF-SHOPs.

i. Renewals for Employers

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 when they do not result in an issuer's renewing coverage, as defined for purposes of guaranteed renewability.

CMS regulations at 45 CFR 155.725 require the FF-SHOPs to set a standard annual employer election period for renewing FF-SHOP employers and to set a standardized annual open enrollment period for renewing qualified employees. Qualified employers will be able to renew their offer of coverage through the FF-SHOPs electronically through HealthCare.gov as soon as plan and rate information becomes available for the quarter in which their coverage would end, but generally not more than two months before the date an enrollment must be submitted to avoid a gap in coverage: this is when the annual election period begins for that employer. Most of the information included in the qualified employer's account from the previous plan year will be pre-populated upon renewing participation, including contact information, employer contribution preferences, and employee roster information. Qualified employers renewing an offer of coverage in the FF-SHOPs must provide their qualified employees with an annual open enrollment period of at least one week to decide whether to accept the coverage offer. This one-week minimum period is the qualified employees' annual open enrollment period. Consistent with §155.725(h)(2), both the qualified employer and qualified employee renewal process must be completed by 11:59 p.m. ET on the 15th day of the month preceding the desired renewal date for it to take effect by that date. The employer's election period should therefore end at least one week prior to the deadline for completing enrollment renewal that would take effect at the end of the employer's prior plan year.

CMS regulations, at 45 CFR 155.710(d), require that the FF-SHOPs treat a qualified employer offering SHOP coverage that ceases to be a small employer solely by reason of an increase in the number of employees, as eligible to participate in the SHOP until the employer otherwise fails to meet FF-SHOP eligibility criteria or no longer purchases coverage for qualified employees through the SHOP. Therefore, a qualified employer with qualified employees enrolled in FF-SHOP coverage that increases in size above a State's small group market upper threshold (either 50 or 100 employees), will be able to renew and maintain group coverage through the SHOP, until the employer otherwise fails to meet FF-SHOP eligibility criteria or no longer purchases coverage for qualified employees through the SHOP. Generally, once employers have been determined eligible for coverage through an FF-SHOP, they remain eligible unless there are any changes to the SHOP through which they offer coverage, any changes to whether they offer

coverage to all full-time employees, or they otherwise fail to meet FF-SHOP eligibility criteria. Pursuant to CMS regulations, at 45 CFR 157.205(f), a qualified employer participating in a SHOP must provide the SHOP with information about dependents or employees whose eligibility status for coverage purchased through the employer in the SHOP has changed.

Personalized notices regarding the annual employer election period and the opportunity to renew or change employer participation in the SHOP will be sent automatically to the user's My Account at HealthCare.gov before the election period begins. Depending on the preferred method of contact, a paper notice or electronic notice will be sent to the employer. The FF-SHOP Annual Employer Election Period notice will include information about potential actions employers may want to take to renew previous coverage choices, modify previous coverage choices or contributions to employee premiums, or terminate FF-SHOP participation. The notice includes information about the date the current plan year is ending as well as the first date the employer can opt to renew its coverage offer and the date by which the annual election period will end. Issuers are not responsible for distributing these notices, but are still subject to market-wide requirements regarding notices under 45 CFR 147.106.

Groups whose enrollment and/or coverage through the FF-SHOP has been terminated for non-payment of premium but that are still within their 30 day reinstatement window will not be able to renew FF-SHOP participation through the online system until their prior coverage has been reinstated. If the group's prior coverage is reinstated, CMS does not consider this a gap in SHOP coverage. Groups that are in a grace period for non-payment of premium will be able to renew their coverage through the online system, but will need to pay all premiums owed prior to the start of the new plan year. Groups will also need to pay the first month's premium for their new plan year by the 20th of the month prior to renewal. Payments sent by existing groups during a renewal period will be applied to current year invoices before they are applied to the new plan year. Issuers are expected to effectuate new plan year coverage if they do not receive a cancellation transaction by the 26th of the month prior to the renewal coverage effective date.

ii. Renewals for Qualified Employees

Qualified employees wishing to renew FF-SHOP participation must navigate to HealthCare.gov to respond to a qualified employer's renewed offer of coverage. Some information entered into the system for the previous plan year will be pre-populated in the employee's electronic application. Generally, as long as a qualified employer extends an offer of coverage to an employee or former employee, the employee or former employee is eligible.

Qualified employees should wait until they receive notice of the employer's renewed offer of coverage through the FF-SHOPs to begin the renewal process. Personalized notices regarding the annual employee open enrollment period will be sent automatically to the user's MyAccount at HealthCare.gov within the Employee portal, upon receipt of a renewal offer of coverage. Depending on the preferred method of contact, a paper notice or electronic notice will be sent to

the employee. The notice will contain information about the last day of the current plan year, the qualified employee's enrollment period start and end dates, the date by which the employee needs to make coverage decisions to prevent a gap in coverage, how employees can learn more about the offer of coverage for the next plan year, and how to waive or accept coverage, as well as potential actions qualified employees may want to take to renew previous coverage choices, modify previous coverage choices, or terminate FF-SHOP participation. When renewing coverage, 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. The employer may provide additional time; however, all qualified employee enrollments must be finalized consistent with the time frames under 45 CFR 155.725(h)(2), and the renewal process for the entire group must be completed by the 15th of a month for coverage to start the first day of the next month. For example, for coverage that ends December 31, 2016, the renewal process must be completed by December 15, 2016 to avoid a coverage gap.

Qualified employees will not be able to make changes to the Social Security Number (SSN), date of birth (DOB), gender, and name for themselves or their dependents as part of the renewal process. These changes can be made by qualified employers by contacting the FF-SHOP Call Center. Issuers will receive maintenance transactions for these changes. Changes to enrollee contact information can be made as part of the qualified employee's renewal process. These changes will be sent on renewal transactions.

Section 4. Enrollment Reconciliation

This section describes the monthly enrollment reconciliation process for the FF-SHOPs, including the form and frequency of file submissions.

Pursuant to 45 CFR 155.720(g), SHOPs must reconcile enrollment information and employer participation information with QHPs on no less than a monthly basis. Pursuant to 45 CFR 156.285(c)(5), SHOP issuers must reconcile enrollment files with the SHOPs at least monthly. CMS will continue to leverage the Enrollment Reconciliation fields, file formats, and dispositions used in the individual market FFMs for FF-SHOPs. The FF-SHOP process focuses on only a subset of applicable elements. Some elements from the individual market FFMs, such as APTCs and CSRs, are not applicable. The FF-SHOP reconciliation process will focus on a monthly snapshot of active enrollments for the previous month. Group-level enrollment reconciliation is currently out of scope.

The FF-SHOPs and issuers will send monthly reconciliation files through the MFT process. Files are validated and data is compared between the FF-SHOP and issuer files. The FF-SHOPs will contact issuers if files fail validation. Discrepancy files are generally sent to issuers within 5 business days from the monthly submission deadline. With the exception of issuer-assigned identifiers, the FF-SHOP enrollment system is generally considered the system of truth. Issuers disagreeing with changes sent on monthly discrepancy files may submit a dispute resolution

form as outlined in the Enrollment Reconciliation Interface Control Document located on REGTAP.

Additional details and technical specifications can be found on REGTAP.

Section 5. Reporting Alleged Cases of Fraud or Ineligibility

This section discusses how alleged cases of fraud and ineligibility related to FF-SHOPs can be reported to CMS and the process that CMS has in place to investigate and resolve the cases.

When applying to participate in the FF-SHOPs, employers or employees may provide incorrect or incomplete information. If CMS receives a report that this has happened, it may investigate and implement corrective action as needed. In addition, CMS will work with DOIs, issuers, employers, employees, and other entities to identify and address potential ineligibility and suspected fraud occurring when applying and enrolling in coverage through the FF-SHOPs. To report an incident of potential ineligibility or fraud in the FF-SHOPs, issuers should send an encrypted email to shop@cms.hhs.gov documenting the concern and providing evidence to support the claim. Issuers may also call the FF-SHOP Call Center for more information. At no time should issuers send PII as part of an e-mail communication to CMS. For the individual market in the FFMs, issuers should report any incidents of alleged fraudulent enrollment to their respective Account Manager.

Pursuant to §155.740, employers and employees may appeal a notice of denial of eligibility or a failure of an FF-SHOP to make an eligibility determination in a timely manner.

Section 6. User Interface Changes

This section discusses CMS's plans to make future FF-SHOP system enhancements.

CMS plans to make several enhancements to the online system functionality available at HealthCare.gov in order to reduce costs and increase FF-SHOP enrollment. Some of these enhancements may include providing more detailed descriptions of plan benefits, enhancing the FF-SHOP Call Center's ability to respond to consumer enrollment concerns without requiring a data correction, and adding agent/broker enhancements to encourage their broader participation.

Final information about FF-SHOP IT system enhancements is forthcoming.

CHAPTER 7: 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 FFMs, including in States performing plan management functions.

CMS expects QHP and SADP issuers to thoroughly investigate and resolve consumer issues received directly from members or forwarded to the QHP or SADP issuer by the State through the issuer's internal customer service process and as required by State law. Additionally, QHP and SADP issuers operating in the FFMs and SBM-FPs must investigate and resolve consumer cases, including complaints, forwarded by CMS in accordance with the requirements at 45 CFR 156.1010. Cases are forwarded through the Health Insurance Casework System (HICS). With the exception of anonymized matters recorded in the "Machine Readable Discrepancy" category of the 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 and SADP issuer participation standards as outlined at 45 CFR 156.200. Timeframes for resolving cases forwarded by CMS are specified in 45 CFR 156.1010(d). Issuers are expected to acquire and maintain sufficient access to the HICS, complying with all applicable CMS security and recertification requirements. Additional information on acquiring access can be found in the Health Insurance Casework System Access Guide distributed on May 21, 2015.

HICS will also be used to record anonymized matters brought to CMS' attention through consumer feedback about machine readable data provided by issuers, including plan provider network and formulary information. The definition of a "case" under 45 CFR 156.1010(a) refers to "a communication brought by a complainant." However, in the event of a machine readable data discrepancy, the identity of the complainant is not relevant to identifying and correcting the issue, which potentially could affect all enrollees and potential enrollees in the plan. Accordingly, CMS does not consider these matters to be "cases," and certain requirements under 45 CFR 156.1010 applicable to cases (including timeframes for resolution under 45 CFR 156.1010(d) and complainant notification requirements under 45 CFR 156.1010(f)) will not apply to anonymized machine readable data discrepancies reported in this section of HICS.

CMS expects issuers to monitor these anonymized matters and use the data to identify trends that could indicate that their machine-readable files need to be corrected or updated. CMS may also monitor this data to identify areas for improvement for machine-readable content, and may provide future guidance about handling these matters.

Cases that CMS may forward include, but are not limited to, issues related to cancellations/terminations, reinstatement review, proper application of the APTCs and/or CSRs, and adjustments of effective dates based on special enrollment periods (SEPs), final appeals decisions, delayed enrollment processing, or other enrollment errors. In all cases, CMS expects QHP and SADP issuers operating in the FFMs and SBM-FPs 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 and SADP issuers operating in the FFMs and SBM-FPs 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 staff is available to assist QHP and SADP issuers by providing technical assistance on casework matters, and cases beyond issuers' control to resolve may result in reassignment of the case to CMS.

QHP and SADP issuers operating in the FFM, including in States performing plan management functions, and in SBM-FPs 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 and SBM-FPs. To the greatest degree possible, CMS collaborates with States, sharing information suggestive of issuer performance problems and provides HICS access to State regulators.

CMS will continue to work with QHP and SADP issuers to identify ways to improve the customer service experience for consumers in FFM and SBM-FP states, including promoting best practices, enhancing the HICS, refining casework guidance, and seeking to minimize cases assigned to issuers in HICS for review and handling.

Section 2. Coverage Appeals

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

As in plan years beginning in 2015 and 2016, in 2017 QHPs will be required to meet the same standards for internal claims and appeals and external review established at 45 CFR 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 CFR 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 LEP speakers and by individuals with disabilities.

In the 2016 Payment Notice Final Rule, CMS finalized amendments to 45 CFR 155.205(c) pertaining to oral interpretation, the use of taglines indicating the availability of language services, and website translation. CMS also amended 45 CFR 156.250, which extends the requirements in 45 CFR 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 CFR 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 CFR 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 CFR 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 CFR. 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 CFR 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 CFR 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. HHS expects to issue guidance beginning in February 2016 identifying the non-English languages that are triggered by these standards for each State as well as sample taglines.

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.

Finally, QHP issuers operating in the FFM are reminded that the meaningful access requirements at 45 CFR 155.205(c), 155.230(b), and 156.250, as well as non-discrimination prohibitions at 45 CFR 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 1973,⁶⁶ 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 (including gender identity), 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 CFR 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 CFR 147.200(a)(3), which requires issuers to “provide an SBC in the form,

⁶⁶ Consistent with Section 504 of the Rehabilitation Act and HHS implementing regulations at 45 CFR 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>.

and in accordance with the instructions for completing the SBC, that are specified by the Secretary in guidance.”

On June 16, 2015, HHS, in conjunction with the Departments of Labor and the Treasury (the Departments), published proposed revisions to the SBC template and new final rules regarding the SBC which amend the final regulations published on February 14, 2012.⁶⁷ The June 2015 final regulations include amendments clarifying that, under Section 2715(b)(3)(I) of the Public Health Service Act, as added by the Affordable Care Act, issuers must include a web address where a copy of the individual coverage policy or group certificate of coverage can be reviewed and obtained. The final regulations require these documents to be easily available to individuals, plan sponsors, participants and beneficiaries shopping for coverage and prior to submitting an application for coverage. In addition, the final regulations require a QHP issuer to disclose on the SBC whether non-expected abortion services as well as expected abortion services (that is, those abortion services for which public funding is permitted) are covered or excluded, consistent with the manner specified in guidance by the Secretary.⁶⁸ These final regulations were generally applicable for SBCs issued in connection with individual market coverage that began on or after January 1, 2016.⁶⁹ On March 30, 2015, the Departments clarified in an FAQ, that the proposed revisions to the SBC template and supporting materials would be finalized separately from the final regulations. We note that the guidance for QHP issuers regarding the word and placement of this disclosure on the SBC will be included in the final SBC template and instruction guides, and not in the final regulations. Information on the proposed revisions to the SBC template and related supporting materials are still forthcoming.

In the 2016 Payment Notice Final Rule, CMS amended 45 CFR 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 CFR 147.200, and, after receiving notice from the Marketplace of an enrollee’s assignment into a new plan variation (or standard QHP without cost-sharing reductions), provide the individual an SBC that accurately reflects the new plan variation (or standard QHP without cost-sharing reductions) as soon as practicable following receipt of notice from the Marketplace, but not later than 7 business days following receipt of notice. 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 must

⁶⁷ Summary of Benefits and Coverage and Uniform Glossary, 80 Federal Register 34292 (June 16, 2015).

⁶⁸ 45 CFR 147.200(a)(2)(i)(N).

⁶⁹ 45 CFR 147.200(g).

include a separate URL linking to the SBC created for each plan variation as part of the QHP data submission to CMS.

On September 8, 2015, CMS issued an FAQ that provided a limited enforcement safe harbor with respect to the date by which the individual coverage policy or group certificate of coverage documents were required to be made accessible via a web address. This FAQ stated that HHS would not take enforcement action against an issuer that made the individual coverage policy or group certificate of coverage documents accessible online no later than November 1, 2015.⁷⁰ We remind issuers that this enforcement safe harbor is no longer effective, and issuers must include on the SBC a web address where the actual individual coverage policy or group certificate of coverage documents can be reviewed and obtained, including by individuals and plan sponsors shopping for coverage.

Lastly, 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 CFR 147.200(a)(2)(i)(L), 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 CFR 147.200(a)(2)(i)(J), 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.

CHAPTER 8: TRIBAL RELATIONS AND SUPPORT

The Federal Government, and therefore CMS, has a historic and unique relationship with Federally-recognized tribes, and the health programs operated by the Indian Health Service (IHS), Tribes and Tribal organizations and Urban Indian organizations. These are collectively known as Indian health care providers. In adhering to QHP certification standards, CMS reminds 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

⁷⁰ This relief was limited to the requirement to post the individual coverage policy or group certificate of coverage. Issuers were still required to provide the SBC in accordance with the timeframes set forth in the final rules. Issuers were required to provide on the SBC the web address where the documents would be available by November 1, 2015, and to include language on the web page indicating that the documents would be accessible on November 1, 2015. This relief was only applicable with respect to the requirement to make individual coverage policy and group certificate of coverage documents accessible online, and did not apply to any other requirements of the June 12, 2015 final rules.

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 Addendum⁷¹ (Addendum).

CMS developed the Addendum to facilitate the inclusion of Indian health care providers in QHP provider networks. The Addendum is a model standardized document for QHP issuers to use in contracting with Indian health care providers. To make it easier for QHPs to find Indian health care providers, a list of eligible providers and their address and contact information may be found on the HHS ECP list available on our CCIIO website. We strongly encourage issuers to ensure each offer is sent to the correct address and contacts. Similarly, we encourage all Indian health care providers to ensure their contact information correctly appears on the HHS ECP list and review all offers and respond timely to issuers.

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 <https://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.

⁷¹ The model QHP Addendum for Indian health providers is available at: <http://www.cms.gov/ccio/programs-and-initiatives/health-insurance-marketplaces/qhp.html>.

CHAPTER 9: STATE-BASED MARKETPLACES ON THE FEDERAL PLATFORM

In the 2017 Payment Notice Proposed Rule, we proposed to permit an SBM and its QHPs to leverage existing Federal assets and operations pursuant to a Federal platform agreement with HHS under which the SBM and its QHPs would rely on HHS for certain functions, particularly eligibility and enrollment through HealthCare.gov, consumer call center, casework processes, and the related information technology infrastructure, and comply with certain FFM standards and user fee collection requirements. This type of Marketplace, which would be defined as a State-based Marketplace on the Federal Platform, or SBM-FP, would retain primary responsibility for plan management functions, subject to proposed regulations requiring the SBM-FP to require its QHP issuers to comply with certain FFM standards and user fees. In the Federal platform agreement, an SBM-FP would indicate its decision to use these HHS services for its individual market Marketplace, its SHOP Marketplace, or both its individual and SHOP Marketplaces. We intend to release the Federal platform agreement at a later date.

Although an SBM-FP would retain primary responsibility for overseeing QHPs and issuers, we proposed to require an SBM-FP to enforce certain QHP and QHP issuer requirements that are no less strict than the requirements that HHS applies to QHPs and QHP issuers in the FFMs. We proposed these requirements to include the existing and proposed regulations under the following sections:

- 45 CFR 156.122(d)(2): the standards for QHPs to make available published up-to-date, accurate, and complete formulary drug lists on its website in a format and at times determined by HHS;
- 45 CFR 156.230: network adequacy standards;
- 45 CFR 156.235: ECP standards;
- 45 CFR 156.260: enrollment period standards for qualified individuals;
- 45 CFR 156.265: enrollment process standards for qualified individuals;
- 45 CFR 156.270: termination of coverage or enrollment standards for qualified individuals;
- 45 CFR 156.298: meaningful difference standards;
- 45 CFR 156.330: issuer change of ownership standards;
- 45 CFR 156.340(a)(4): issuer compliance and compliance of delegated and downstream entity standards;
- 45 CFR 156.705: maintenance of records standards;

- 45 CFR 156.715: compliance reviews standards related to the eligibility and enrollment functions; and
- 45 CFR 156.1010: casework standards.

Note that the eligibility and enrollment requirements in the SBM-FPs must mirror the FFM requirements, as the Federal platform will not have the capacity to modify enrollment periods or otherwise provide customization for other eligibility and enrollment processes in SBM-FPs in 2017.

Finally, we proposed under 45 CFR 155.200(f)(3) that HHS would work with SBM-FPs to enforce the above-listed FFM standards directly against SBM-FP issuers and/or QHPs, when the SBM-FP is not substantially enforcing one or more of the requirements. Under such a circumstance, we proposed that HHS would have the authority to suppress a plan under 45 CFR 156.815. This will ensure that consumers shopping for coverage on HealthCare.gov have access to QHPs that are in compliance with the FFM standards with which SBM-FP issuers must comply as a condition of offering QHPs in an SBM-FP. (Pursuant to 45 CFR 156.815(c), OPM will notify the Marketplace if an MSP option needs to be suppressed.) CMS intends to work closely and collaboratively with SBM-FPs, and we believe that our collaboration with SBMs that currently use the Federal platform for eligibility and enrollment functions has been close and effective with respect to enforcement matters.