Department of Health & Human Services

Centers for Medicare & Medicaid Services
Center for Consumer Information & Insurance Oversight
200 Independence Avenue SW
Washington, DC 20201

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

Centers for Medicare & Medicaid Services (CMS)

Title: 2017 Letter to Issuers in the Federally-facilitated Marketplaces

The Centers for Medicare & Medicaid Services (CMS) is releasing this final 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 any such Marketplace℠[1] 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 provided additional standards in the final rule titled, "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017; Final Rule" (2017 Payment Notice), CMS 9937-F, which went on public display on February 29, 2016.[3] CMS expects issuers to consult all applicable regulations, in conjunction with the final version of

[1] Health Insurance Marketplace℠ and Marketplace℠ 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; Final Rule; CMS-9937-F (February 29, 2016).

this Letter, to ensure full compliance with the requirements of the Affordable Care Act. 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).

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CHAPTER 1: CERTIFICATION PROCESS FOR QUALIFIED HEALTH PLANS

The Affordable Care Act and applicable regulations establish that health plans, including 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 Affordable Care Act (but the State continues to enforce State law requirements with which issuers must be in compliance).[4] 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 that States review for compliance with Federal laws and regulations and complete the reviews in a manner consistent with FFM operational timelines.[5] States that have Effective Rate Review[6] programs should also consult forthcoming guidance from CMS regarding timelines for rate filing for 2017 plan year coverage. CMS must receive confirmation that, in addition to complying with Affordable Care Act requirements, all QHP issuers, including

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

[5] 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.

[6] See 45 CFR 154.301 for a list of criteria that CMS considers when evaluating whether a State has an Effective Rate Review Program.

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 reasonable 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 on May 11, 2016, and make necessary updates to the QHP application prior to the last deadline for issuer submission on August 23, 2016. 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 deadline for issuer submission of changes to the QHP application or that have consistently submitted inaccurate data in past certification years may have their QHP application denied.[7] Table 1.1. Key Dates for QHP Certification in the FFMs, Including in States Performing Plan Management Functions.[8]

[7] 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 afford 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 Final 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.

[8] 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 SBM-FPs.

Note: All dates are subject to change.

Activity		Dates (Approximate)
QHP Application Submission and Review Process	Initial QHP Application Submission Window[9]	4/11/2016 – 5/11/2016
	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
	Deadline for Issuer Submission of Changes to QHP Applications; Deadline for All Risk Pools with QHPs to be in "Final" Status in the Unified Rate Review (URR) System[10]	8/23/2016
	CMS Reviews Final QHP Data Received as of 8/23/16	8/24/2016 – 9/09/2016
	States Send CMS Final Plan Recommendations	9/08/2016[11]

[9] 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 the timeline for URRT submissions in States that have an Effective Rate Review Program.

[10] 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/cciio/Resources/Forms-Reports-and-Other-Resources/index.html#Review_of_Insurance_Rates.

[11] Separate from Correction Notices, CMS will send plan lists for confirmation to States with an FFM, including in States performing plan management functions, or SBM-FP. CMS requires responses to that State outreach by September 8, 2016, including if plans were transferred in error or a State otherwise recommends against certification

Activity		Dates (Approximate)
QHP Agreement, Plan Confirmation, and Final Certification	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[12]
	CMS Sends Validation Notice 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.[13] Issuers must obtain HIOS product and plan IDs.

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.

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of a plan. States must communicate that information to CMS in order for the information to be incorporated into certification decisions and Certification Notices.

[12] This is the final opportunity for issuers to withdraw QHPs from the certification process for the 2017 plan year.

[13] Additional information on HIOS registration is available in the HIOS Portal User Manual, available at: https://www.cms.gov/cciio/Resources/Forms-Reports-and-Other-Resources/index.html#Content_Requirements_for_Plan_Finder.

CMS will use the QHP application to collect both issuer-level information and plan-level benefit and rate data,[14] 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. Issuers in a State with an Effective Rate Review program[15] must submit proposed rate filings for single risk pool coverage (for both QHPs and non-QHPs) on a date set by the State, so as long as the date is no later than July 15, 2016. Issuers should 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

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[14] Issuers in FFMs and SBM-FPs are required to submit their QHP Rates Table Template by May 11, 2016 even if their Rate Filing Justification is not due until a later date.

[15] See 45 CFR 154.301 for a list of criteria that CMS considers when evaluating whether a State has an Effective Rate Review Program.

[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.

to that required for QHP certification through the FFMs, if required by a State, and must comply with any requests for resubmissions from the State or from CMS in order to be certified. CMS will coordinate with States to ensure that any State-specific review guidelines and procedures are consistent with applicable Federal law and operational deadlines. In addition, CMS will work with all State regulators near the end of the QHP certification cycle to confirm that all potential QHPs meet applicable State and Federal standards, and are approved for sale in the 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 compliance review. Issuers in those States must submit proposed rate filings for single risk pool coverage (for both QHPs and non-QHPs) on a date set by the State, so long as the date is no later than May 11, 2016. 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.

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

[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.

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 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.

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, those 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 application data submitted by August 23, 2016, CMS will make final certification decisions. CMS will send certification notices to issuers and States by 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

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

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.

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, including 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	No new plans may be submitted. Issuers may not change plan type. Child-only value cannot be changed for QHPs. Petition to CMS required for changes to service area. Issuers must submit petitions by August 9, 2016. Issuers may submit plan withdrawal requests. For all other changes, issuers are not required to submit petitions or document State authorization to CMS.	5/12/16-08/23/16

	CMS will monitor all data changes and contact issuers if there are concerns about changes made.	
After Final Application Submission	No further data changes allowed prior to certification. Issuers will have a final opportunity to withdraw plans during the plan confirmation process. CMS may allow issuers to make critical post-certification data corrections in order to: • Correct data display errors on HealthCare.gov, and • Align QHP plan display with products and plans approved by the State. Post-certification data corrections require data change petitions and State and CMS approval. Allowed changes will occur during periodic, scheduled limited data correction windows.	8/24/16 - onward

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 May 11, 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 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. Issuers are required to submit evidence of State approval for service area changes. For QHPs in direct enforcement States, the CMS Form Filing team, instead of the State, must authorize data changes. 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.

An issuer may submit a plan withdrawal request to withdraw one or more plans from its QHP application during this period. SADP issuers seeking to change on-Marketplace to off-Marketplace plan certification must submit a plan withdrawal request. CMS expects to allow issuers to withdraw plans as needed prior to QHP Certification Agreement signing

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's QHP data as of the specific due dates as listed in Table 1.1.

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

After Final Application 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 Subsection V, "Plan Confirmation and QHP/SADP Certification, Privacy and Security Agreement, and Senior Officer Acknowledgement."

After this occurs, CMS may offer 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 their 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 of the final plan confirmation list to CMS 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.

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, which 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

[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.

reenrollment of current enrollees into the same plan, pursuant to §155.335(j). A QHP, including an SADP, recertified for plan year 2017 is expected to 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 2016 – 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 choices 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 Final Rule, we finalized standardized options at each of the bronze, silver (including the three silver cost-sharing reduction plan variation levels), and gold metal levels—a total of 6 standardized options (see Table 9 in the 2017 Payment Notice Final Rule), which issuers will have the option to offer starting in the 2017 plan year. This does not apply to SADPs. We made minor changes to the standardized options proposed in the 2017 Payment Notice Proposed Rule.[21] In making these changes, we ensured that the QHPs more closely reflect the average copayment rates in the most popular QHPs in the 2015 FFMs (weighted by enrollment).

Issuers have the option of offering a standardized option at one level of coverage without offering a standardized option at the other levels of coverage, except that if an issuer offers a silver standardized option, the issuer must also offer the standardized silver cost-sharing reduction plan variation levels. For instance, an issuer may offer a silver standardized option (including the cost-sharing reduction plan variations) without offering a bronze or gold standardized option. We encourage issuers to offer at least one standardized option in 2017, particularly at the silver level of coverage (including the silver cost-sharing reduction plan variation levels). We believe that standardized options will allow consumers to more easily

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

compare plans offered by different issuers. 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 EHB that comprise a large percentage of the average enrollee's total spending. Each standardized options has the four drug tiers currently utilized in our consumer-facing applications—generic, preferred brand, non-preferred brand, and specialty drug tiers—with the option for issuers to offer an additional lower-cost generics drugs tier. The standardized options do not have more than one in-network provider tier.

Issuers may also offer more than one standardized option at each level of coverage. For instance, an issuer could offer more than one standardized option at each metal level by varying network, additional benefits covered, or other features. The meaningful difference requirements discussed in Section 12 of Chapter 2 of this Letter apply uniformly across all QHPs, including standardized options.

Finally, we are conducting consumer testing to determine appropriate modifications in display in our consumer-facing plan comparison features in order to readily allow consumers to identify standardized options and distinguish them from non-standardized plans. 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 not considered to 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 for certification for the 2016 plan year 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.

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. 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. 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.

i. Network Adequacy Standard

This section describes how CMS will conduct its network adequacy review for plan year 2017 QHP certification, including for SADPs. 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 process. The 2017 Payment Notice Final Rule did not finalize policies concerning network adequacy time and distance standards as proposed; therefore, we are not finalizing all of the policies proposed in the Draft 2017 Letter to Issuers in the Federally-facilitated Marketplaces. We are continuing to use the reasonable access standard so that States have time to adopt the NAIC Network Adequacy Model Act provisions.

As was done during the 2015 and 2016 certification processes, for 2017 plan year certification, CMS will assess provider networks using a "reasonable access" standard in order to identify networks that fail to provide access without unreasonable delay, consistent with requirements specified at 45 CFR 156.230(a)(2). We are also providing more transparency and detail for QHP issuers in an FFM regarding how CMS will review QHP network data collected as part of the certification process to determine if plans provide reasonable access.

ii. CMS 2017 Certification Review Criteria

While CMS is not finalizing network adequacy time and distance standards, this section provides clarity on the criteria that CMS has previously used and will use as part of the certification process to review network provider data to determine if plans provide reasonable access to covered services. For 2017, as in 2016, CMS will review provider data with a focus on the following specialties, which have historically raised network adequacy concerns: Hospital systems, Dental providers (if applicable), Endocrinology, Infectious Disease, Mental Health, Oncology, Outpatient Dialysis, Primary Care, and Rheumatology. CMS will not review SADPs for non-dental provider types.

Specifically, in order to determine whether plans provide reasonable access for these specialties, we will review the provider data using the maximum time and distance standards detailed in the table below.

Table 2.1. Specialties and Standards for Marketplace PY17 Certification.[22]

Specialty Area	Maximum Time and Distance Standards (Minutes/Miles)				
	Large	Metro	Micro	Rural	Counties with Extreme Access Considerations (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
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 (Including Substance Use Disorder Treatment)	20/10	45/30	60/45	75/60	110/100
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

For each specialty and standard listed in the table, we will review the issuer-submitted data to make sure that the plan provides access to at least one provider in each of the above-listed provider types for at least 90 percent of enrollees. For example, for Endocrinology in a Large

[22] The full definitions for each of the county types listed can be found on page 12 of the following document - https://www.cms.gov/Medicare/Medicare-Advantage/MedicareAdvantageApps/Downloads/CY2016_MA_HSD_Network_Criteria_Guidance.pdf.

county type, at least 90 percent of enrollees must have at least one provider within 15 miles or 30 minutes.

As in past years, in addition to permitting issuers to add additional providers, we will use a justification process when CMS determines that an issuer's network is inadequate under the reasonable access review standard. The justification process requires that QHP issuers detail patterns of care and other relevant information that explain why the issuer provides reasonable access to enrollees in the identified area(s). The justification must specifically address how issuers meet the reasonable access standard, despite not meeting the time and distance standards.

We have analyzed QHP issuer network data submitted as part of the 2016 certification cycle against the metrics set forth above, and, based on that analysis, over 90 percent of issuers passed for each of these metrics. We anticipate that the vast majority of QHPs today would pass these time and distance standards, either numerically or based upon justifications.

CMS will use any updated provider data and written justification submitted as part of the certification process in assessing whether the issuer meets the regulatory requirement, prior to making the certification decision. CMS will share information about its analysis and coordinate with States that are conducting network adequacy reviews. CMS will continue to monitor network adequacy throughout the year and will coordinate with State Departments of Insurance should it be necessary to remedy potential deficiencies.

iii. Provider Transitions

This section discusses the provider transitions policy established in the 2017 Payment Notice Final Rule. To align with the policy finalized in the 2017 Payment Notice Final Rule, the provisions under §156.230(d) are not intended to, and do not, preempt State provider transition notices or continuity of care requirements and we defer to a State's enforcement of substantially similar or more stringent requirements.

First, we finalized a standard 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 who 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 identify enrollees who see a provider who is terminating, we expect the issuer to work with the provider to obtain the list of affected patients, use its claims data system to identify enrollees who see the affected providers, or use another reasonable method. The issuer does not need to use more than one method. We understand that there are certain situations that cannot be anticipated, and in those cases, we would expect the issuer to send the notice to the enrollee as soon as practically possible. For the written notice, we encourage issuers to notify enrollees of other comparable in-network providers in the enrollee's service area, provide information on how the enrollee could access the

plan's continuity of care coverage, and encourage the enrollee to contact the plan with any questions.

Second, we finalized at 45 CFR 156.230(d)(2) a provision to ensure continuity of care for enrollees in cases where a provider is terminated without cause. Specifically, we require the issuer, in cases where the provider is terminated without cause, to allow an enrollee in active course of treatment to continue treatment until the treatment is complete or for 90 days, whichever is shorter, at in-network cost-sharing rates. Additionally, we defined active course of treatment as meaning:

(1) An ongoing course of treatment for a life-threatening condition, defined as a disease or condition for which likelihood of death is probable unless the course of the disease or condition is interrupted;

(2) An ongoing course of treatment for a serious acute condition, defined as a disease or condition requiring complex ongoing care which the covered person is currently receiving, such as chemotherapy, radiation therapy, or post-operative visits;

(3) The second or third trimester of pregnancy, through the postpartum period; 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 the purposes of the active course of treatment definition, an ongoing course of treatment includes treatments for mental health and substance use disorders that fall within the definition of active course of treatment. If the enrollee has successfully transitioned to a participating provider, if the enrollee has met or exceeded benefit limitations of the plan, or if care is not medically necessary, §156.230(d)(2) would no longer apply to the enrollee. Any QHP issuer decision made for a request for continuity of care must 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.

While we expect issuers to negotiate with a provider for payment of services under §156.230(d)(2), issuers would only be responsible for paying to a provider what was previously being paid under the same terms and conditions of the provider contract, including any protections against balance billing, if the provider agrees to provide care under §156.230(d)(2). We cannot require non-contracted provider to accept a particular payment rate under §156.230(d)(2). Therefore, nothing under §156.230(d)(2) would prohibit balance billing for non-contracted providers in accordance with Section 1302(c)(3)(B) of the Affordable Care Act and §155.20.

QHP issuers in the FFMs are required to update internal processes and procedures to implement these requirements for plan years beginning on and after January 1, 2017.

iv. 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. We intend to further consider how we will display this breadth information as we continue consumer testing. The purpose of the labeling is to provide increased transparency to enrollees about the type of provider network in the coverage they are selecting.

Each network's breadth will be compared to the network breadth of other QHPs available in the same geographic area. CMS will identify network breadth based on analysis of QHP provider and facility data submitted as part of the 2017 certification process. This analysis will compare an issuer's contracted providers to the number of specific providers and facilities included across all QHP networks available in a county. The rating will focus on hospitals, adult primary care, and pediatric primary care with either 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. CMS will make a final determination to use a separate or composite rating based on the results of consumer testing, and intends to provide this information as part of the 2017 QHP certification instructions. These specialty 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 for each plan at the county level. These classifications will be determined by calculating the percentage of providers in a plan's network, compared to the total number of providers in QHP networks available in a county. We will 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, including Essential Community Providers (ECPs). This number is the Provider Participation Rate (PPR). As a baseline standard, networks that are within one standard deviation of the mean PPR will be classified as Standard. Those with a PPR that is more than one standard deviation above the mean PPR will be classified as Broad. Those with a PPR that is more than one standard deviation below the mean PPR will be classified as Basic. Applying this methodology to 2016 QHP issuer provider data, we found that approximately 68 percent of the plans 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 will conduct an analysis of QHP 2017 provider data using the same methodology to determine each plan's classification. These calculations will be based on the network provider data that each QHP issuer submits as part of QHP certification and would be updated annually.

In future years, we may expand these classifications to additional specialties and facility types.

Section 4. Essential Community Providers

This section describes how CMS plans to conduct reviews of the ECP standard for QHP and SADP certification 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 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 will use 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;

[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).

- 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 Addendum[24] 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 2.2) 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, except for terms that would not be applicable to an ECP, such as by virtue of the type of services that an ECP providers. 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 has published an updated list of available ECPs based on data maintained by CMS and other Federal agencies, as well as provider data that CMS received directly from providers through the ECP petition process for the 2017 plan year.[25] CMS has included on the HHS ECP list for the 2017 plan year those providers that submitted an ECP petition during the ECP petition window that closed on January 15, 2016 and met 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).[26] The provider could also have been included in one of the verified datasets from HRSA, the Indian Health Service (IHS), or

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[24] The model QHP Addendum for Indian health care providers is available at: http://www.cms.gov/cciio/programs-and-initiatives/health-insurance-marketplaces/qhp.html.

[25] The Final Non-exhaustive HHS List of ECPs for Plan Year 2017 is available at: http://cciio.cms.gov/programs/exchanges/qhp.html"Other Qualified Health Plan Application Resources under "Other Qualified Health Plan Application Resources."

[26] 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.

the Office of the Assistant Secretary for Health/Office of Population Affairs (OASH/OPA), and appears on the Draft 2017 ECP List, or the provider is a not-for-profit or governmental family planning service site that does not receive Federal funding under Title X of the PHS Act or other 340B-qualifying funding (see 45 CFR 156.235(c)).

- 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, or the provider is a not-for-profit or governmental family planning service site that does not receive Federal funding under Title X of the PHS Act or other 340B-qualifying funding (see 45 CFR 156.235(c)).

- 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.

- 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 will 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.

On December 9, 2015, HHS launched its ECP petition initiative to give providers an opportunity to request to be added to our ECP list, update their provider data on our ECP list, and provide missing provider data. The web-based ECP petition link is available at https://data.healthcare.gov/cciio/ecp_petition. 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 will 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 intends to maintain 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 acknowledges that an issuer cannot force a provider to submit an ECP petition.

For plan year 2017, CMS will determine issuer satisfaction of the 30 percent ECP standard using the following calculation methodology:

- The denominator of available ECPs consists of any ECPs on the non-exhaustive final plan year 2017 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 final plan year 2017 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, Federally Qualified Health Centers (FQHCs), Indian health care providers, Ryan White providers, family planning providers, and providers in the other ECP categories listed in Table 2.2 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 FFMs.

Major ECP Category	ECP Provider Types
Family Planning Providers	Title X Family Planning Clinics and Title X "Look-Alike" Family Planning Clinics
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).

For plan year 2017, CMS will 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 final plan year 2017 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 final plan year 2017 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 will 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/cciio/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 will 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 Addendum[27] 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 intends to maintain 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 will offer 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.

For plan year 2017, CMS will 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 final plan year 2017 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.

- The numerator of the issuer's contracted dental ECPs consists of:

    - Any ECPs that the issuer has listed from the non-exhaustive final plan year 2017 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.

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[27] The model QHP Addendum for Indian health care providers is available at: http://www.cms.gov/cciio/programs-and-initiatives/health-insurance-marketplaces/qhp.html.

- 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 will require the issuer 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.

iii. Requirements for Payment to FQHCs

We reiterate the importance of issuers complying with 45 CFR 156.235(e) regarding payment to FQHCs. For covered services provided by an FQHC, QHP issuers must pay an amount that is not less than the amount of payment that would have been paid to the center under section 1902(bb) of the Social Security Act for such item or service, as specified in section 1302(g) of the Affordable Care Act. Section 156.235(e) does allow the QHP issuer and FQHC to agree upon payment rates other than those that would have been paid to the FQHC under section 1902(bb) of the Social Security Act, as long as such agreed upon rates are at least equal to the generally applicable payment rates of the issuer. We note that State law may define covered services for closed-panel HMO plans to be limited to those services provided by in-network providers. In such cases, this requirement would not apply to non-covered services, which would include non-

emergent out-of-network services if provided by FQHCs if such services are not treated under State law as covered services. Otherwise, we would expect issuers to pay FQHCs for covered services in accordance with section 1902(bb) of the Social Security Act. We encourage issuers and FQHCs, as well as other ECPs, to develop mutually beneficial business relationships that promote effective care for medically underserved and vulnerable populations. We intend to assess available data to understand the degree to which such patients are cared for effectively and to inform our future regulatory approach.

Section 5. Accreditation

This section describes how CMS will conduct a review of the accreditation standards necessary for QHP certification. States performing plan management functions in the FFMs 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 FFMs 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 provided under 45 CFR 155.1045(b)(2) and are described further in the 2016 Letter to Issuers. The accreditation requirements for QHP issuers entering their second year of certification are provided under 45 CFR 155.1045(b)(2) and 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), but 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 that are required to be accredited 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 must 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 following 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. 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 finalized proposals to strengthen the patient safety standards for QHP issuers, which are detailed in the 2017 Payment Notice Final Rule.

As outlined 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 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 3.20[28] 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, or other information demonstrating a partnership with a Patient Safety Organization (PSO), based on the reasonable exceptions provision that CMS finalized in 45 CFR 156.1110(a)(2)(ii), a QHP issuer may verify that the hospital has implemented an evidence-based initiative to improve health care quality through the collection, management and analysis of patient safety events that reduces all cause preventable harm, prevents hospital readmission, or improves care coordination. In this case if a contracted hospital is implementing an evidence-based initiative other than working with a PSO,

[28] 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)."

a QHP issuer is required to collect and maintain documentation such as hospital attestations or current agreements to partner 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 Formats[29] 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).

As part of the certification for plan years beginning in 2017, QHP issuers are required to demonstrate compliance with the patient safety standards that are finalized in the 2017 Payment Notice along with the QHP application affirming 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. 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.[30] 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 child-only and SADP 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.[31] Consistent with 45 CFR 156.200(b)(5), QHP issuers will be

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[29] See https://www.pso.ahrq.gov/common.

[30] A limited number of child-only QHPs and enrollees may prohibit reliable child-only QRS calculations and QHP Enrollee Survey results. CMS will continue to monitor child-only and SADP plan types in Marketplaces and will consider developing a quality rating system and a QHP Enrollee Survey for them in the future.

[31] See Patient Protection and Affordable Care Act; Exchange and Insurance Market Standards for 2015 and Beyond, 79 Federal Register 30240 (May 27, 2014); codified at 45 CFR Parts 144, 146, 147, et al.

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.[32] 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 at least annually 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 fall of 2016.

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.[33] 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. In addition, CMS intends to work with QHP issuers to provide appropriate technical assistance and will issue further information on the timelines for release of QRS ratings.

QHP issuers may reference their respective QRS scores and ratings, as well as QHP Enrollee Survey results, in a manner specified by CMS.[34,35] A QHP issuer that elects to include QRS

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[32] 45 CFR 156.1120 and 45 CFR 156.1125

[33] 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," 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.

[34] 45 CFR 156.1120(c) and 156.1125(c).

[35] 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.

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.[36] Guidance related to the Marketplace display requirements for 2016 QRS and QHP Enrollee Survey results during the individual market open enrollment 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 will display QRS rating information in a clear, understandable manner that has been consumer-tested. In addition, appropriate language (e.g., Not Rated) will be displayed if there is insufficient data for public reporting. CMS will display the 2016 QRS global rating and is considering displaying additional QRS rating information (i.e. summary indicator ratings) for each QHP offered through HealthCare.gov. This includes SBM-FPs. 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. 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 issuer must implement a QIS, as described in section 1311(g)(1) of the Affordable Care Act. The 2016 Payment Notice Final Rule established

[36] 45 CFR 155.1400 and 155.1405.

standards and requirements related to issuer implementation and reporting of a QIS for eligible QHPs 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. In addition, QHP issuers must submit a QIS to the Marketplace for the 2017 plan year if they meet participation criteria. 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 directs 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 2016 Payment Notice Final Rule, 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.[37] 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 self-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. All eligible QHPs within eligible product types (e.g., HMO, PPO) must be included in a QIS.

The QIS requirements apply to all issuers offering QHPs and MSP options through Marketplaces, whether through the individual Marketplace or through the SHOP Marketplace. At

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[37] Available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/QIS-Technical-Guidance-and-User-Guide.pdf and http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Health-Insurance-Marketplace-Quality-Initiatives.html.

this time, the QIS reporting requirements do not extend 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 that meet the QIS participation criteria 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.

- 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 FFM with final determination being made by the FFM.

- SBMs, including SBM-FPs, 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.

As finalized in the 2017 Payment Notice Final Rule, for 2017 plans, a health insurance issuer must submit the Unified Rate Review Template (Part I of the Rate Filing Justification) for all single risk pool plans, including plans with rate increases, rate decreases, no rate change, and new plans. The 2017 Payment Notice also amends 45 CFR 154.200(c)(2) such that a rate increase is subject to review if the average increase, 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.

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, II, and III of each Rate Filing Justification that is not a

trade secret or confidential commercial or financial information, as defined by HHS Freedom of Information Act regulations.[38]

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.

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,[39] which are based on 2014 plans, when designing their plans. 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 does not cover a single-tablet drug regimen or extended-release product that is customarily prescribed for HIV patients and is just as effective as a multi-tablet regimen, absent an appropriate reason for the exclusion (such as a substantial difference in the cost of the two regimens), such a plan design might effectively discriminate against, or discourage enrollment by, such HIV patients 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 discourage enrollment by, individuals who have those conditions.

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[38] 45 CFR 5.65.

[39] More information on the benchmark plans is available at: https://www.cms.gov/cciio/resources/data-resources/ehb.html.

The enforcement of this standard is largely conducted by States. CMS encourages States that are enforcing the Affordable Care Act to consider a number of strategies for assessing compliance with this standard including, but not limited, to analysis of information entered in the "explanations" and "exclusions" sections of the QHP Plans and Benefits Template.

Because the nondiscrimination provisions are related to many requirements under the joint interpretive jurisdiction of the Departments of HHS, Labor, and the Treasury (the Departments), 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 proposed rule on the requirements of section 1557.[40] 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.

In reviewing a plan's cost-sharing structure, CMS will analyze information contained in the Plans and Benefits Template, including the "explanations" and "exclusions" sections, with the

[40] Nondiscrimination in Health Programs and Activities, 80 Federal Register 54172 (Sept. 8, 2015) (regarding categorical exclusions of coverage for all health services related to gender transition and denials or limitations of coverage for specific health services related to gender transition that result in discrimination against a transgender individual).

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 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.

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 45 CFR 156.125 and 45 CFR 156.225, CMS will conduct the following reviews as part of the 2017 QHP certification process. If CMS identifies a QHP for follow-up based on these reviews, CMS will offer the issuer the opportunity to resolve the identified deficiency as part of the certification process. CMS will offer the issuer the opportunity to submit a justification with supporting documentation or to make a change to its application to address the concern.

i. Formulary Outlier Review

CMS will perform an outlier analysis of each QHP issuer's formulary drug list 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 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, based on data submitted by issuers in the prescription drug template, CMS 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. 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

CMS is 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 in 2017. States performing plan management functions in the FFMs 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 Final Rule, CMS removed 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. For review purposes, CMS will organize an issuer's proposed QHPs from a given State into subgroups based on plan type, metal level, and 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 differences 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) $500 or more difference in MOOP; or 5) $250 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.

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, 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 Final Rule, we finalized amendments to 45 CFR 156.1250, governing requirements related to QHP and SADP issuers' acceptance of third party payments of premiums on behalf of enrollees. First, we finalized an amendment to 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 will be required to accept third party payments from Federal, State, and Local government programs.

We also finalized an amendment to 45 CFR 156.1250. Under a new provision at 45 CFR 156.1250(a)(3), we require that if a Federal, State, and Local government program administers premium and/or cost-sharing assistance through grantees or sub-grantees, then QHP and SADP issuers are required to accept these third party payments from the grantees or sub-grantees on behalf of plan enrollees. 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 directed by the government program, the requirement for issuers to accept the payments falls under 45 CFR 156.1250.

The same grantee/sub-grantee payment structure is utilized by the Ryan White HIV/AIDS programs, which 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.

In the Final Rule, we clarified that that while issuers offering individual market QHPs, including SADPs, generally do not collect cost-sharing payments, their downstream entities, or agents of the issuer, are required to accept third party cost-sharing payments made by the entities listed at §156.1250(a) on behalf of QHP enrollees if the downstream entities or agent routinely accept cost-sharing payments from enrollees. We clarified in response to comments, that an agent of the QHP issuer with a mail order pharmacy, such as a PBM with a mail order pharmacy, must accept the third party cost-sharing payments directly from the entities listed at §156.1250(a). With respect to third party payments from entities other than those listed at 45 CFR 156.1250, we refer issuers to our February 7, 2014 FAQ guidance document.

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 finalized in the 2017 Payment Notice Final Rule. For 2017, the reduced maximum annual limitation for self-only coverage is $2,350 for 94% and 87% plan variations, and $5,700 for the 73% plan variation.
- 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)[41]) 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, 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.[42]
- 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

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[41] 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.

[42] 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.

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.

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 no 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, and CMS will continue to consider options for improvements to these tools. 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),[43] 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

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

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 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 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 and CMS will continue to consider options for improvements to these tools. 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 bulletin[44] 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/.

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," will seek additional feedback on these proposed elements for

[44] Available at: https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/OOP-Tool-Bulletin-10-29-15.pdf.

transparency reporting upon publication of a notice that will provide the public with a 30-day comment period. 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. We intend to finalize this package soon, so that issuers may provide data for 2017.

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*
Non-discrimination	Service Area
Acceptance of Third Party Premium and Cost-sharing Payments	Data Integrity Tool
Rates submission*	Machine Readable* (SADPs must comply with provider directory standards but not drug formulary standards)
Transparency in Coverage Reporting	

Table 4.2: Standards and Tools Not Applicable to SADPs

Standard or Tool Does Not Apply	
Accreditation	Patient Safety
Quality Reporting and Quality Improvement Strategy	Meaningful Difference
Prescription Drugs	Standardized Options
Cost-sharing Reductions	Out-of-Pocket Cost Comparison Tool

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. For the 2014, 2015, and 2016 plan years, 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 Final Rule, we finalized 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 2017. Any increase would be based upon the percentage increase in the Consumer Price Index (CPI) for dental services and be made in $25 increments for coverage of one child. We intend to publish any 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 Guide[45] 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

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

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.

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 ended at the close of 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 2016 and 2017, issuers will have gained more experience operating in the FFMs environment, 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 standard[46] compliance reviews. CMS may also select a QHP/SADP or issuer for a compliance review based on a specific issue of potential non-compliance. If CMS selects a QHP/SADP or issuer due to a specific issue of potential non-compliance, CMS may perform a targeted[47] review specific to the area(s) of potential non-compliance and/or conduct the compliance review on an expedited basis.[48] 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.

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[46] Standard reviews include all review areas.

[47] Targeted reviews can include all review areas or just select review areas.

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

CMS may conduct either a desk review or an on-site review[49] 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 documentation[50] 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 otherwise noted, references to agents and brokers include web-brokers.[51]

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 registration and training requirements[52] 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

[49] On-site reviews will take place at the issuer's place of business.

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

[51] 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).

[52] Agents and brokers assisting Marketplace consumers in an SBM-FP must complete FFM registration and training requirements.

Private Issuer Community site of CMSzONE.[53] 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.[54] Before assisting consumers in the FFMs, agents and brokers must execute the Individual Market and/or FF-SHOP Privacy/Security Agreement (depending on whether the agent or broker is participating in the FFMs for the Individual Market, the FF-SHOP, or both), which includes further details on the Marketplace privacy and security standards related to the use and disclosure of PII.

Every agent and broker must execute the applicable agreement(s) with CMS as part of the registration process with the FFMs. These agreements include:

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

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[53] 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. 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.

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

- 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.[55] 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 General Agreement, IM Privacy and Security Agreement, SHOP Privacy and Security Agreement, and/or the Web-Broker Agreement, as applicable.[56] A termination would effectively bar the agent or broker from assisting with enrollment through the FFM. Termination can be

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

[56] 45 CFR 155.220(g).

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 the Agent and Broker FFM Registration Completion List, which generally bars the agent or broker from being compensated by QHP issuers for FFM enrollments[57]; 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 into the SHOP agent/broker portal.

We finalized 45 CFR 155.220(g)(5) in the 2017 Payment Notice Final Rule to provide that if CMS reasonably suspects that an agent or broker may have engaged in fraud or abusive conduct that may result in imminent or ongoing consumer harm 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. If there is a finding or determination by a Federal or State entity that an agent or broker engaged in fraud or abusive conduct that may result in imminent or ongoing consumer harm, 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. Agents and brokers who are suspended or terminated may submit evidence to rebut the allegation, according to the instructions provided in the written notice of suspension or termination, in the terms and conditions of the FFM agreements, and as described in §155.2202(g)(5)(i)(B) or §155.220(h), respectively. Such evidence must be submitted within 90 calendar days of the date of the written notice from CMS. In the event of termination, a CMS reconsideration entity will provide the agent or broker with a written notice of the reconsideration decision within 30 calendar days of the date it receives the request for reconsideration; this decision will constitute CMS's final determination. During the suspension period and following termination of the agreements under section, the agent or broker will not be registered with the FFMs, or be permitted to facilitate enrollments through an FFM, or be permitted to assist individuals with applying for advance payments of the premium tax credit (APTC) or cost-sharing reduction (CSRs).

We note that this suspension and termination authority pertains only to agents' and brokers' agreements and registration with the FFMs to assist consumers with enrollments through the

[57] See vi. under this section for information on the one exception to this general rule.

FFMs; this does not preempt any State authority to regulate agents or brokers who are licensed to do business in their jurisdiction. Only States can license or certify agents and brokers; the FFMs enter into agreements with agents and brokers, which include registration and training requirements,[58] only with respect to facilitating enrollments through an FFM. In the 2017 Payment Notice Final Rule, we finalized that CMS will notify the State DOI or equivalent State producer licensing authority in cases of suspensions or terminations of the agent's or broker's agreements and registration with an FFM effectuated under §155.220(g). CMS will also coordinate with impacted QHP issuers to the extent that it will not impede any State or Federal law enforcement investigation and as otherwise permitted under applicable Federal or State law. CMS currently works with States and law enforcement to investigate and resolve suspected incidents of fraud or abusive conduct, and we will continue to coordinate with State and Federal agencies (including law enforcement) if CMS were to take suspension or termination action as appropriate. In order to alert States, QHP issuers, as well as members of the public of the agents and brokers that have been suspended or terminated, CMS will publish on its website a "Registration Termination List" that includes impacted NPNs and effective dates for the termination or suspension action.[59] QHP issuers who suspect that an agent, broker, or web-broker is engaging in fraudulent or abusive conduct related to enrollments through the FFMs should report the incident or activity to the State DOI as well as their CMS Account Managers.

In the 2017 Payment Notice Final Rule, we also finalized in 45 CFR 155.220(j) the requirement that agents and brokers participating in the FFMs comply with 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 Final Rule, we finalized in paragraph (k) of §155.220 that CMS may deny the agent or broker the right to enter into 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 her own website, or that of another agent or broker, to facilitate enrollment in a QHP through the

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[58] Agents and brokers who assist small group employers and employees through the SHOP are strongly encouraged, but not required, to complete annual training.

[59] 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. The list on the CMSzONE Private Issuer Community is updated weekly and posted by Friday morning.

FFMs.[60] 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 QHPs[61] (including SADPs[62]) 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 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

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[60] 45 CFR 155.220(c)(3)-(4).

[61] 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.

[62] 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 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 FFMs to comply with applicable rules and requirements in connection with SADPs, just as they must comply with those rules in connection with medical QHPs.

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 March 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 that CMS may offer at a later date under which an applicant could remain on the web-based entity's (WBE's)[63] 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 financial assistance (as applicable). The intent is to have this information exchange occur through a Marketplace-approved web service, while offering WBEs more operational flexibility to expand front-end, consumer-facing channels for enrollment through a seamless consumer experience. This expanded direct enrollment pathway option for WBEs will not be operational for 2017 coverage. CMS continues to consider this option for the open enrollment period for 2018 coverage. CMS will further consider 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 is also considering how to ensure that consumers understand that they are applying for Marketplace coverage, such as through specific branding or wording requirements if

[63] A WBE maintains an API connection with the Marketplace to support the direct enrollment pathway. WBEs can be web-brokers or QHP issuers.

a non-FFM front-end website is used for the entire application and enrollment process. Until CMS has identified the Marketplace-approved web services under §155.220(c)(1) that can be used to support the enhanced direct enrollment process and created a pre-approval process under §155.220(c)(4)(i)(F), the current direct enrollment approach and all associated guidance must be followed.

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.[64] 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.[65] 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). In cases where an FFM-registered agent or broker receives compensation through a third party entity such as an agency or brokerage that is registered with the FFMs, 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. Those records

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[64] See vi. under this section for information on the one exception to this general rule.

[65] See i. under this section and 45 CFR 156.340.

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 FFMs 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, including any requirements for disclosure of the amount being charged directly to the consumer for providing assistance.

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 outside the Marketplaces.[66] This compensation approach is a required participation standard for QHP issuers offering coverage in the FFMs, 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 FFMs, we would consider whether the plan has a similar cost sharing and benefit structure, covers a majority of the same service area, and covers a majority of the same provider network as compared to the QHP.[67] A compensation arrangement in which an issuer pays no commission for sale of a QHP through an FFM, but does pay commission for sale of a similar plan outside of the FFM, would violate this FFM standard for agent and broker compensation.

vi. Registration Requirements for Initial Enrollment and Re-enrollment Transactions

Agents or brokers who are assisting consumers with enrollment in QHPs offered through the FFMs must meet all applicable State and Federal requirements, including those for State licensure and FFM registration, at the time they are providing assistance.[68] When assisting a consumer with initial enrollment in a QHP through the FFMs, the agent or broker must have a current FFM registration. In any future plan year, the requirement for FFM registration depends

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[66] 45 CFR 156.200(f).

[67] In making this determination, 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) of the definition of "QHP" set out at 45 CFR 153.500.

[68] See 45 CFR 155.220(d), (e) and (j).

on whether the agent or broker is providing assistance with updates to the FFM application or enrollment (active re-enrollment), or if the consumer is automatically re-enrolled in the same plan without assistance from the agent or broker in making any changes to the FFM application or the enrollment (passive re-enrollment).[69]

- If the agent or broker is actively assisting the consumer to make changes to the FFM application or to the enrollment, the agent or broker must have a current FFM registration.

- If the consumer is automatically re-enrolled in the same plan without assistance from the agent or broker in making any changes to the FFM application or the enrollment, CMS does not require the agent or broker to have a current FFM registration status at the time of the re-enrollment. Assuming the agent or broker was registered and met all applicable State and Federal requirements at that time of assisting the consumer with the initial enrollment through the FFM, the QHP issuer has the discretion to pay commissions, in accordance with State law and applicable contractual requirements, for the coverage renewal.

The issuer should use the Agent and Broker FFM Registration Completion Lists published by CMS to verify that the NPN of the agent or broker who is credited for the FFM enrollment was registered at the time of the original enrollment or the active re-enrollment.

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

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

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[69] See "Operational Tips for Agents/Brokers in the Federally-facilitated Marketplaces (FFMs)" (January 22, 2016) available at: https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/AB_Operational_Tips_01_22_2016.pdf. For information about the required steps for agent and broker FFM registration, see "Role of Agents, Brokers, and Web-brokers in Health Insurance Marketplaces" (January 8, 2016) available at: https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/Role-of-ABs-in-Marketplace-1_6_16.pdf.

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.

In the 2017 Payment Notice Final Rule, CMS eliminated the requirement from 45 CFR155.222 that approved vendors to perform information verification services, as CMS intends to continue performing the identity proofing function and expects that QHP 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.[70] 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.[71] CMS also reminds issuers that they are subject to section 1557 of the Affordable Care Act, which proposes to prohibit discriminatory marketing practices in its notice of proposed rulemaking.

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

[70] Also see 45 CFR 147.104(e) for the parallel market-wide prohibition.

[71] Also see 45 CFR 147.104(e) for the parallel market-wide prohibition.

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 Final Rule, we finalized a new paragraph (j)(2)(i) at 45 CFR 155.220 that requires agents and brokers assisting consumers with FFM transactions to provide consumers with correct information, without omission of material fact, regarding the FFMs, QHPs (including SADPs[72]) offered through the FFMs, and insurance affordability programs, and to 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 interpret this standard for conduct to require that agents, brokers, and web-brokers avoid the use of "Exchange," "Marketplace," or other words in the name of a business or URL if doing so could reasonably cause confusion with a Federal program or website.

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.[73] 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

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[72] 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 FFMs to comply with applicable rules and requirements in connection with SADPs, just as they must comply with those rules in connection with medical QHPs.

[73] 45 CFR 155.220(c)(3)(ii).

HealthCare.gov must also be provided.[74] 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 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 (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 Group Switch File identifies employer groups that are not renewing their enrollment or coverage with any issuer through an FF-SHOP. The Member Switch File identifies enrollees that are not renewing their enrollment or coverage through an FF-SHOP, 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.[75]

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

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[74] 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).

[75] Available at: http://www.regtap.info/uploads/library/FFSHOPPASEnrollmentReconciliationICDv19_101615_5CR_101615.docx.

Section 2. Premiums Based on Average Enrollee Premium Amounts

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

45 CFR 147.102(c)(3)(iii) and 45 CFR 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 average enrollee premium amounts will be available to consumers for plan years beginning in 2017 and will provide guidance when this functionality becomes available in the FF-SHOPs for future plan years.

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 employers 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.[76] The FF-SHOPs will send notices to employers approximately two months in advance of the date when the group's current coverage through an FF-SHOP will end, so long as rates are available for the quarter in which renewed coverage would take effect. This means, employers will generally receive notices 45-60 days prior to the date when the group's current coverage through an FF-SHOP will end. Qualified employees will receive information about the renewal process when their qualified employer makes a renewed offer of coverage for the new plan year.

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

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[76] Available at: http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Renewal-Notices-9-3-14-final.pdf.

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. The FF-SHOPs will send notices to employers approximately two months in advance of the date when the group's current coverage through an FF-SHOP will end, so long as rates are available for the quarter in which renewed coverage would take effect; this will generally be 45-60 days prior to the date when the group's current coverage through an FF-SHOP will end. 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. A qualified employer could offer qualified employees an annual enrollment period of more than one week, but CMS provides for a one-week minimum to enable qualified employers and qualified employees, especially at very small companies, to finalize their annual renewal process more quickly. 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 an FF-SHOP treat a qualified employer purchasing FF-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 FF-SHOP until the employer otherwise fails to meet FF-SHOP eligibility criteria or no longer purchases coverage for qualified employees through the FF-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 FF-SHOP, until the employer otherwise fails to meet FF-SHOP eligibility criteria or no longer purchases coverage for qualified employees through the FF-SHOP. Generally, once employers have been determined eligible for coverage through an FF-SHOP, they remain eligible unless there are any changes to the FF-SHOP through which they offer coverage, unless they no longer offer coverage to all full-time employees, or unless they otherwise fail to meet FF-SHOP eligibility criteria. Pursuant to CMS regulations, at 45 CFR 157.205(f), a qualified employer participating in an FF-SHOP must provide the FF-SHOP with information about dependents or employees whose eligibility status for coverage purchased through the employer in the FF-SHOP has changed.

Personalized notices regarding the annual employer election period and the opportunity to renew or change employer participation in the FF-SHOP will be sent automatically to the user's My Account at HealthCare.gov approximately two months in advance of the date when the group's current coverage through an FF-SHOP will end, so long as rates are available for the quarter in which renewed coverage would take effect. 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, the first date the employer can opt to renew its coverage offer, and the last day that employers must submit a group renewal to avoid a gap in coverage for the group. 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 FF-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. We note that under §156.285(c)(8)(iii), FF-SHOP issuers are required to effectuate coverage unless an FF-SHOP sends a cancellation notice prior to the coverage effective date. If an employer's full payment is not received in time by an FF-SHOP, the FF-SHOP will issue a cancellation notice. Thus, issuers should not cancel an enrollment transaction unless the FF-SHOP sends a cancellation transaction. Note that after groups initially enroll or renew their coverage, the FF-SHOP will invoice employers for new hires and SEPs on the employer's next monthly invoice

and remit cleared payments received to issuers as part of the FF-SHOP's weekly issuer payment cycle.

ii. Renewals for Qualified Employees

Qualified employees wishing to renew FF-SHOP participation must use 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 an employer's 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 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. These updates will also display to employers when they log-in to the FF-SHOP.

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 APTC 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 send issuer's rejection notices 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 Cases of Suspected Fraud or Ineligibility

This section discusses how cases of suspected 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 suspected 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 suspected 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.

Based on available resources, CMS plans to make several enhancements to the online system functionality available at HealthCare.gov in order to increase FF-SHOP enrollment and reduce its operational costs. 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 certification 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 issues related to cancellations or terminations for any reason (including for non-payment of premiums), reinstatement review, premium or premium payment disputes, proper application of the APTC and 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 FFMs, 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 FFMs 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 March 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.[77]

Finally, QHP issuers operating in the FFMs 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

[77] For instance, CMS intends to continue coordinating with OCR in OCR's implementation of section 1557 of the Affordable Care Act.

Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973,[78] and section 1557 of the Affordable Care Act,[79] 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.

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

On June 16, 2015, the Departments, published final rules regarding the SBC, which amend the final regulations published on February 14, 2012.[80] 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-excepted abortion services as well as excepted abortion services (that is, those abortion services for which public funding is permitted) are covered or excluded, consistent with the

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[78] 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.

[79] Nondiscrimination in Health Programs and Activities, Notice of Proposed Rulemaking, 80 Federal Register 54172 (Sept. 8, 2015) (proposing 45 CFR 92.8 that would establish, among other things, notice requirements on covered entities regarding provision of language assistance services and auxiliary aids and services; and proposing 45 CFR 92.201 that would require, among other things, a covered entity to take reasonable steps to provide meaningful access to each individual with LEP that it serves or encounters in its health programs or activities).

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

manner specified in guidance by the Secretary.[81] These final regulations were generally applicable for SBCs issued in connection with individual market coverage that began on or after January 1, 2016.[82] In the preamble to the June 2015 final rules, the Departments stated that revisions to the SBC template and supporting materials which were proposed on December 30, 2014 would be finalized separately from the final regulations. We note that the guidance for QHP issuers regarding the wording and placement of this disclosure on the SBC will be included in the final SBC template and instruction guides, and are not included in the final regulations. Issuers should continue to use the current SBC template and supporting materials until the proposed revisions to the SBC template and related supporting materials are finalized. The Departments are going through a separate process to finalize the SBC template and associated documents.[83]

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

As noted above, QHP issuers are responsible for complying with the culturally and linguistically appropriate standards set forth in the 2016 Payment Notice Final Rule. Among other things, this final rule sets out amended language access requirements at 45 CFR 155.205(c) with respect to oral interpretation, written translations, taglines, and website translations. QHP issuers must provide an addendum with language taglines in the top 15 languages spoken by the LEP populations of the relevant State within their SBCs for QHPs offered through a Marketplace. Any additional taglines required under Public Health Service Act sections 2715 and 2719 or their implementing regulations may also be included in this addendum. The addendum, which must

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[81] 45 CFR 147.200(a)(2)(i)(N).

[82] 45 CFR 147.200(g).

[83] See Federal Register notice at 81 FR 9860. Proposed templates are available at: https://www.cms.gov/cciio/resources/Regulations-and-Guidance/index.html#Summary of Benefits and Coverage and Uniform Glossary under "February 2016 Proposed Supporting Materials for Public Comment."

only include tagline information is authorized to be provided along with the SBC by 45 CFR 155.205(c) and is not considered a part of the SBC document. Therefore, the addendum will not count towards the four double-sided page limit for the SBC under PHS Act section 2715(b)(1).

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.[84] 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

[84] 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.

between issuers and Indian health care providers, CMS is continuing to require QHPs to offer contracts in good faith to all available Indian health care providers in the QHP's service area, applying the special terms and conditions necessitated by Federal law and regulations as referenced in the Model QHP Addendum (Addendum). [85]

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.

CHAPTER 9: STATE-BASED MARKETPLACES ON THE FEDERAL PLATFORM

In the 2017 Payment Notice Final Rule, we finalized rules related to State-based Marketplaces on the Federal Platform, or SBM-FPs, that leverage existing Federal assets and operations to support their Marketplace functions and rules governing their QHP issuers. Pursuant to approval from HHS through the Blueprint process described under 45 CFR 155.106 and the execution of a Federal platform agreement with HHS, States may agree to rely on HHS for eligibility and enrollment and related functions. These functions include, but are not limited to, the consumer Call Center, casework processes, and the related information technology infrastructure. Under the Federal platform agreement, the SBM-FP will also agree to require its QHP issuers to comply with certain FFM standards for QHPs, as well as user fee collection requirements. SBM-FPs will retain primary responsibility for plan management functions, including QHP certification. In the

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

Federal platform agreement, an SBM-FP will agree to use the Federal infrastructure to perform these functions 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 will retain primary responsibility for overseeing QHPs and issuers, under 45 CFR 155.200(f), an SBM-FP must agree 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 as follows:

- 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 156.298: 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; and
- 45 CFR 156.1010: casework standards.

Note that issuers and plans offered through an SBM-FP must comply with rules, as interpreted and implemented in policy and guidance related to the Federal eligibility and enrollment infrastructure. These will be the same requirements related to eligibility and enrollment that are applicable to QHP issuers and plans on FFMs, 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. SBM-FP issuers must also comply with certain FFM enrollment policies and operations (e.g., premium payment and grace period rules, effective date logic, acceptable transaction codes, and reconciliation rules) for the FFM to successfully process 834 transactions with issuers and minimize any data discrepancies for reconciliation.

Finally, under 45 CFR 155.200(f)(3), HHS will 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, HHS will 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 have used the Federal platform for eligibility and enrollment functions to date has been close and effective with respect to enforcement matters.